



## CHALLENGING A DEA ORDER TO SHOW CAUSE BASED ON POOR RECORDKEEPING: A PHYSICIAN'S PRACTICAL PLAYBOOK

### Introduction

A Drug Enforcement Administration (“DEA”) Order to Show Cause (“OSC”) is the federal government’s formal notice that it intends to deny, suspend, or revoke a practitioner’s controlled substances registration. The registrant then has a limited window to contest the proposed action. When the investigation focuses on poor recordkeeping such as inconsistent drug administration logs, the DEA’s primary theory is usually straightforward: if the practice cannot reliably account for controlled substances, then continued registration is inconsistent with the public interest. Therefore, a practitioner’s DEA registration should be revoked, or the practitioner should otherwise be disciplined.

The physician’s challenge, in turn, should be aggressive and proactive: insist on the procedural protections Congress has authorized and required, and force the DEA to tie alleged documentation defects to the statutory “public interest” factors. As part of the defense strategy, it is incumbent on the physician to build a record that demonstrates both: (1) what the evidence actually proves, and (2) why the physician can be trusted with a registration going forward.

### The DEA’s Legal Lens: “Public Interest” and Recordkeeping as a Revocation Theory

Federal law requires practitioners who dispense controlled substances to hold a valid registration, and it authorizes the DEA to revoke that registration if the registrant has committed acts rendering continued registration inconsistent with the public interest. *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011). The “public interest” determination for practitioners is made by considering a number of statutory factors including, the practitioner’s experience in dispensing controlled substances; compliance with applicable controlled substance laws; and any other conduct that may threaten public health and safety. The administrative tribunal adjudicating the matter must consider these factors, but may assign them varying degrees of weight as deemed appropriate. *Id.*

In recordkeeping-driven cases, the DEA often emphasizes the compliance factor and argues that poor records create an unacceptable diversion risk. Prior reported cases have recognized that the DEA has historically treated recordkeeping failures as a basis for revocation in the public interest analysis. *Morall v. DEA*, 412 F.3d 165, 175 (D.C. Cir. 2005). These cases provide context and frame the issues the physician must be prepared to confront: even if the case is “only” about logs and documentation, the agency may treat those deficiencies as serious enough to justify the ultimate sanction unless the physician can persuasively rebut the allegations and/or demonstrate a credible corrective action plan.

### How an Effective Defense Strategy Can Beat the Government’s Case

The defense should begin by separating three questions that an OSC often blurs: what specific recordkeeping duty was allegedly violated, what the evidence actually proves about diversion risk, and what prospective safeguards now make continued registration consistent with the public interest.

### AUTHORS



Matthew J. Eddy  
Attorney at Law

Email: [meddy@lashlybaer.com](mailto:meddy@lashlybaer.com)

Phone: (314) 436-8355

That framing keeps the response from becoming a generalized apology for imperfect records and instead forces the proceeding back to the statutory standard. Here are suggested guidelines to consider in preparing an effective defense strategy.

*Step One: Treat the OSC as Litigation and Protect the Right to a Hearing*

The OSC is not merely a warning; it is the charging document that triggers an administrative adjudication process. Before taking action to deny, revoke, or suspend a registration, the DEA must serve an OSC that gives the registrant an opportunity to contest the proposed action. *Ashraf v. United States DEA*, 153 F.4th 1161, 1165 (11th Cir. 2025). Critically, the OSC must “contain the basis for the DEA action, including specific citations to law and regulations that the registrant allegedly violated,” must provide an opportunity for a hearing before an administrative law judge, and must notify the registrant of the opportunity to submit a corrective action plan. *Id.* The regulations further provide that if the registrant does not request a hearing within 30 days of publication of the OSC, the registrant waives the right to a hearing. *Id.*

From a defense perspective, this procedural framework creates immediate priorities:

1. Calendar and meet the hearing request deadline to avoid waiver.
2. Scrutinize the OSC for specificity; in particular, analyze whether it identifies the recordkeeping duties at issue and provides “specific citations” to the allegedly violated laws or regulations.
3. Use the hearing process to develop a complete evidentiary record, because the administrative record will drive both the agency’s final decision and any later judicial review.

*Step Two: Narrow and Test the Government’s Recordkeeping Case*

In a poor recordkeeping/inconsistent log case, the physician’s challenge often turns on whether the DEA’s allegations are (a) specific and provable and (b) sufficiently serious to justify revocation under the public interest factors. A practical way to frame the defense is to force the agency to answer, with evidence, questions such as:

1. What exact recordkeeping obligations does the DEA contend were violated (with references to specific facts or omissions)?
2. What specific discrepancies does the DEA rely on (dates, drugs, quantities, locations, and personnel)?
3. Do the alleged inconsistencies actually show an inability to account for controlled substances, or do they show documentation defects that can be reconciled through other records or a follow-up audit?

This narrowing approach matters because the DEA’s public interest analysis is fact-specific and discretionary. The agency must consider the statutory factors, but it can weigh them as it sees fit. *MacKay*, 664 F.3d at 816. That makes it especially important for the physician to contest overbroad characterizations such as “systemic noncompliance” and to demonstrate, with concrete proof, what the recordkeeping problems do and do not establish.

*Step Three: Use Corrective Action Strategically and Document It*

Congress built corrective action into the OSC process: the OSC must notify the registrant of the opportunity to submit a corrective action plan. *Ashraf*, 153 F.4th at 1165. In a recordkeeping case, corrective action is not merely a mitigation argument; it is often central to the “trustworthiness” narrative that the DEA is implicitly evaluating under the public interest analysis.

A persuasive corrective action plan presentation in a recordkeeping case typically demonstrates:

1. The physician understands the compliance failure and its diversion control implications.
2. The practice has implemented rigorous oversight and control measures that make recurrence unlikely.
3. The practice can produce records that are complete, accurate, and inspection-ready going forward.

Because the DEA has historically treated recordkeeping failures as a basis for revocation, the physician should assume that any assurance that “we fixed it” must be proven, not asserted. *Morall*, 412 F.3d at 182-83. The most effective corrective action submissions are therefore evidence-heavy (policies, training documentation, audit processes, reconciliation procedures, and accountability measures) and tailored to the specific discrepancies alleged in the OSC.

*Step Four: Be Prepared for (or Challenge) Immediate Suspension if the DEA Claims “Imminent Danger”*

Sometimes the DEA proceeds not only with an OSC but also with an immediate suspension of the registration. Federal law authorizes immediate suspension “in cases where [the Attorney General] finds that there is an imminent danger to the public health or safety,” and the suspension continues through the administrative proceedings and appeal process unless withdrawn or dissolved by a court. 21 USCS § 824(d). The reported cases define “imminent danger to the public health or safety” to mean that, due to the registrant’s failure to comply with registrant obligations, there is a “substantial likelihood” that abuse of a controlled substance will occur absent immediate suspension. *Zaidi v. DEA*, 841 F.3d 707, 713 (6th Cir. 2016). Here, the physician’s response should focus on whether the DEA can actually satisfy that imminent danger standard on the facts it has alleged and proven, as opposed to relying on generalized concerns about documentation.

*Step Five: Build the Record for Appeal from Day One*

If the DEA issues an adverse final order, federal law provides for review in the United States Court of Appeals for the District of Columbia Circuit or the circuit where the registrant’s principal place of business is located, and the petition must be filed within 30 days after notice of the decision. 21 USCS § 877. The statute further provides that the Attorney General’s findings of fact, “if supported by substantial evidence, shall be conclusive.” *Id.*

The reported cases emphasize that substantial evidence review is highly deferential and requires only “reasonable, substantial and probative evidence” when the record is considered as a whole. *Yanez v. Bondi*, 140 F.4th 35, 40 (2d Cir. 2025). In addition, courts apply the Administrative Procedure Act review to the agency’s exercise of discretion and will set aside a revocation if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; the record must show a rational connection between the facts found and the choice made. *Volkman v. United States DEA*, 567 F.3d 215, 220 (6th Cir. 2009).

The practical takeaway is that the physician’s best chance to influence the outcome is often at the administrative hearing stage by contesting the factual basis for the alleged recordkeeping failures, forcing the DEA to properly frame and support its legal theory, and introducing a thorough and credible corrective action plan.

**Conclusion**

A physician facing an OSC based on poor recordkeeping and inconsistent drug administration logs should approach the matter as a structured, record-driven federal proceeding. The physician can challenge the OSC by enforcing the government’s statutory requirements, contesting whether the alleged documentation defects truly establish “public interest” inconsistency under the statutory factors, and presenting a documented corrective action plan that directly addresses diversion control and compliance concerns. Because appellate review is deferential to agency fact finding when supported by substantial evidence, the physician’s strategy should be designed to win, or at least materially improve, the case in the administrative record where the decisive facts and credibility determinations are made.

The Healthcare Advisory Team at Lashly & Baer can help practitioners navigate the minefield they face when confronting a DEA Order to Show Cause.

Please do not hesitate to contact one of our Health Care Advisory Team attorneys if your practice has been issued a DEA Order to Show Cause or is otherwise under investigation by state or federal drug agencies.

Prepared by: Matthew J. Eddy

**Matthew J. Eddy** focuses his practice on complex litigation, health care regulatory matters, product liability, toxic torts, and medical malpractice defense. With more than three decades of legal experience, he has represented clients in handling jury and bench trials, appeals, government investigations, and regulatory proceedings. Matt regularly advises health care providers and organizations on Medicare and Medicaid fraud and abuse issues, false claims, anti-kickback compliance, and professional licensure matters.



714 Locust Street  
St. Louis, MO 63101-1699  
tel: 314.621.2939 [www.lashlybaer.com](http://www.lashlybaer.com)