

Policymaking through Adjudication: DEA's Red Flags

In brief...

DEA implements a “red flags” policy through a patchwork of agency enforcement orders. The unclear standards have made some pharmacies reluctant to fill prescriptions for buprenorphine, a drug that can help tackle the opioid crisis.

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To fill a prescription for a controlled substance, pharmacies must first obtain a registration (i.e., a license) from the Drug Enforcement Administration (DEA). DEA imposes numerous [obligations](#) on pharmacies, and if they fail to comply, DEA can revoke their registrations. Losing the ability to dispense controlled substances is usually enough to cause a pharmacy to go out of [business](#).

Although DEA regularly uses notice-and-comment [rulemaking](#) to impose obligations on DEA registrants, it also imposes obligations on registrants through adjudication. For example, DEA implements its highly consequential “red flags” policy almost exclusively through enforcement actions. Under this policy, DEA regularly [revokes](#) registrations from pharmacies for filling prescriptions when there were red flags suggestive of drug diversion or abuse. However, DEA has never released a comprehensive list of these red flags, making it difficult for pharmacies to locate and comply with DEA’s requirements.

DEA’s Red Flags Enforcement Policy

DEA imposes its highly consequential red flags policy almost exclusively through enforcement orders. DEA’s [regulations](#) at 21 C.F.R. § 1306.04 require pharmacists to ensure prescriptions are issued for a “legitimate medical purpose.” If a pharmacist ignores red flags that are indicative of drug abuse or diversion, DEA can conclude that the pharmacist is filling illegitimate prescriptions in violation of these regulations. Red flags can [include](#) patients paying in cash, patients driving long distances to obtain their prescriptions, or doctors writing prescriptions for certain combinations of drugs. Even in the absence of concrete evidence of diversion, DEA can issue an [order](#) to revoke a pharmacy’s registration by asserting that the pharmacist ignored certain red flags.

However, pharmacists cannot find a list of the red flags that might cause DEA to pull their registration. The red flags are not codified in DEA's regulations, and there is no complete list in a DEA guidance document. Rather, pharmacists must wade through the [discussions](#) of red flags in previous DEA orders where the agency revoked registrations. Pharmacists can also look to a public DEA [presentation](#) for guidance, but the presentation makes it clear that the list is not exhaustive. There are many open questions that DEA has not answered. For example, how many red flags must be present before a pharmacist must refuse to fill a prescription, or what combination of red flags requires a pharmacist to increase scrutiny?

The red flags are constantly changing, making it difficult for pharmacists to keep track of when they will run afoul of DEA regulations. Consider the following [testimony](#) from a DEA investigator:

[A Miami Diversion Group Supervisor] testified that there is no place where pharmacists can find a comprehensive list of “red flags” because the red flags are changing in various parts of the country. [The Supervisor] said ... that DEA cannot publish a definitive list of red flags because “[p]harmacy practice isn’t a checkoff list, and the red flags change.”

If even DEA is unable to keep an updated list of red flags because they are constantly changing, how can pharmacists be expected to comply with this policy?

Agency Action under the Administrative Procedure Act

The Administrative Procedure Act (APA) divides agency actions into rulemaking and adjudication. Agencies have multiple ways to make [rules](#), which are “the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy ...” The notice-and-comment rulemaking process is the most common form of rulemaking, and it [requires](#) the agency to publish a notice of proposed rulemaking and accept and consider public comments before issuing a final rule.

Adjudication, on the other hand, generally involves individualized decisionmaking based on unique contested facts. Adjudications have generally been categorized as formal or informal. Although formal adjudications require a [hearing](#), the APA does not establish any required procedures for informal adjudications. Since informal adjudications are more often conducted under the authority of organic agency statutes than the APA, they may or may not require a hearing. Professor Emily Bremer [pointed](#) out in her recent article on the stages of agency adjudication that “most agency action is adjudication, most adjudication is informal, and informal adjudication is extremely varied.”

Most agency enforcement of regulatory and statutory requirements, such as DEA's orders to revoke registrations, are informal adjudications. In other words, DEA's red flags policy is not considered a rule under the APA, as recently [affirmed](#) by the U.S. Court of Appeals for the Fifth Circuit. The policy does not bind DEA in the future. It is [articulated](#) through a patchwork of enforcement orders, and DEA could stop revoking registrations using this rationale at any time. The policy does not technically bind the public; DEA has never stated that it will generally apply this policy to assess compliance with its regulations. In practice, however, the policy binds registrants. Registrants operate with the [fear](#) that DEA could revoke

their registrations and put them out of business at any time, meaning they must diligently work to catch any red flags.

By not going through the notice-and-comment rulemaking process, DEA has provided few, if any, opportunities for the public to provide input on this significant policy. In fact, DEA has not put forward sufficient evidence that the red flags are empirically linked to diversion or abuse.

Implications for Pharmacies and the Opioid Crisis

This policy has major implications for the opioid overdose crisis. It makes pharmacies [reluctant](#) to fill prescriptions for drugs used to treat opioid use disorder. Buprenorphine is highly [effective](#) at treating opioid use disorder, but it is also a controlled substance, meaning pharmacies must be on the lookout for red flags that suggest there may be buprenorphine diversion.

DEA recently [revoked](#) the registration of a West Virginia pharmacy because some patients were traveling from out of state to visit the pharmacy and paying for their buprenorphine prescriptions with cash. In his [opinion](#) dissolving DEA's order, U.S. District Judge Joseph Goodwin pointed out that the reality of the opioid crisis in West Virginia actually means the so-called red flags are not necessarily indicative of diversion. For example, many patients do not have insurance and pay out-of-pocket for their prescriptions in cash, and it may be difficult to find a pharmacy in West Virginia willing to fill a prescription.

The uncertainty about what constitutes a red flag and whether DEA will pursue an enforcement action puts pharmacies in a difficult position. Even Walmart, for example, recently sought pre-enforcement [review](#) of DEA's red flags policy because it is "untenable" for the largest company in the United States to comply with DEA's policy.

Conclusion

Relying on a patchwork of agency enforcement orders instead of establishing clear and easy-to-locate standards has left pharmacies afraid to prescribe the drug that can help tackle the opioid crisis. DEA is well positioned to draft a guidance document that lists the red flags and answers frequent questions on how to implement the policy. DEA should accept public comments on the guidance, and it should put forward evidence to show there that there is a connection between the red flags and diversion.