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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

THE CITY AND COUNTY OF SAN FRANCISCO, CALIFORNIA and THE PEOPLE OF THE STATE OF CALIFORNIA, Acting by and Through San Francisco City Attorney DAVID CHIU,

Plaintiffs,

v.

PURDUE PHARMA L.P., et al.
Defendants.

Case No. 3:18-cv-07591-CRB

**AFFIDAVIT OF
RAJAN VAIDYA**

I, RAJAN VAIDYA, declare:

1. I am Vice President, Practice & Professional Development at the California Pharmacists Association (“CPhA”) in Sacramento, California. I have held this position since 2019.

2. I make this affidavit based on my own personal knowledge. If called upon to testify, I could and would testify competently to the truth of the matters stated herein.

3. On February 2, 2018, CPhA issued a document titled *Corresponding Responsibility Checklist*. The document sets forth four steps each California pharmacy and pharmacist should take when dispensing controlled substances in order to meet their corresponding responsibility.

4. The CPhA issued the *Corresponding Responsibility Checklist* for pharmacist as a pharmacy practice resource to decrease the risk of regulatory violations and comply with the general rules of dispensing controlled substances.

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5. Attached to this affidavit as **Exhibit A** is a true and correct copy of the *Corresponding Responsibility Checklist* issued by the CPhA on February 2, 2018.

6. I declare under penalty of perjury that the foregoing is true and correct.
Executed this 12th day of May, 2022, in Sacramento, California.



RAJAN VAIDYA

Exhibit A

corresponding responsibility

checklist

Corresponding responsibility is perhaps one of the most commonly misunderstood and unknown concepts found in the Drug Enforcement Administration's (DEA) regulations. We have provided this resource as a refresher to help clarify the pharmacist's responsibility as a member of the healthcare team.

The following represents a summary checklist of how to decrease the risk of regulatory violations and comply with the general rules of dispensing controlled substances - in other words, how a pharmacist can ensure that they have met their corresponding responsibility, which is to dispense controlled substances pursuant to a legitimate medical purpose, and none other.

STEP 1

- a. Personally know and be able to recognize the controlled substance red flag indicators, as presented by both the Board of Pharmacy and DEA.
- b. Both agencies have published lists of these red flags that are readily available online. The list from the Board of Pharmacy can be found at: www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf

STEP 2

- a. For every red flag indicator present (to clear and convincing degree), the pharmacist must conduct a "reasonable inquiry" as to why that red flag exists.
- b. Checking the CURES database, while not mandated by law, is certainly one means of conducting this reasonable inquiry. Conversely, checking the CURES database may not be a 100% sure way of resolving every red flag.
- c. Similarly, contacting the prescriber to obtain verification, establish authenticity, and determine the clinical legitimacy of that controlled substance prescription order is another means of conducting this reasonable inquiry. However, the law specifically still contemplates NOT dispensing the controlled substance EVEN AFTER having conferred with the prescriber. In other words, do not overly rely, and certainly do not solely rely, on prescriber communications as the sole means of resolving a red flag.
- d. The pharmacist must document every step of this required reasonable inquiry and the results of their findings therein.

STEP 3

- a. The pharmacist must either resolve or not resolve every existing red flag.
- b. The pharmacist must document every resolution and non-resolution.

STEP 4

- a. If every red flag is resolved, then the pharmacist must dispense the controlled substance.
- b. Even if one red flag is not resolved, then the pharmacist must not dispense the controlled substance.

Additionally, for those prescriptions that are turned away due to the pharmacist's inability to resolve a red flag, CPhA strongly encourages that the pharmacy, under the leadership and direction of its PIC, create a separate dedicated file system for every rejected controlled substance, in which the four-step analysis above is documented in detail and kept as a pharmacy record for at least three years.