

K&L GATES

TRIAGE: RAPID LEGAL LESSONS FOR BUSY
HEALTH CARE PROFESSIONALS



The Opioid Epidemic:
DEA's Role in Regulating Individuals
and Entities Handling Controlled
Substances

Hilary H. Bowman

CONTROLLED SUBSTANCES ACT

- 21 U.S.C. § 801 *et seq*
- Regulated drugs are categorized into five schedules:
 - **Schedule I** – heroin, LSD, cannabis
 - **Schedule II** – hydrocodone, oxycodone, morphine
 - **Schedule III** – codeine (<90 mg), buprenorphine
 - **Schedule IV**
 - **Schedule V**

DEA REGISTRATION OF INDIVIDUALS

- “Practitioners” (21 U.S.C. § 823(f), (g), § 802)
 - Physicians, dentists, veterinarians, and scientific investigators
- DEA requires a separate registration for each “principal place of business or professional practice” (21 U.S.C. § 822(e))
- Responsibilities include safeguarding controlled substances, prescription pads, reporting suspicious prescription activities, and avoiding contracting with individuals, who have been convicted of a felony related to controlled substances, denied a DEA registration, or have lost a DEA registration due to surrender or revocation

BASIS FOR DEA REGISTRATION DENIAL, SUSPENSION OR REVOCATION

- DEA considers **five factors** when determining whether to deny, suspend or revoke a registration (21 U.S.C. § 824(a)):
 - “materially falsified” an application to the DEA;
 - “convicted of a felony” related to controlled substances;
 - “no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances”;
 - committed acts that are considered “inconsistent with the public interest”; and
 - excluded from participation in a federal health care program.

DEA REGISTRATION OF ENTITIES

- **Manufacturers, distributors, pharmacies, and hospitals** (21 U.S.C. § 823(a), (b), (d) - (f), § 802)
- DEA requires a separate registration for each “principal place of business or professional practice” (21 U.S.C. § 822(e))
- Responsibilities include safeguarding controlled substances, maintaining records of controlled substances, reporting the **loss or theft** of controlled substances, reporting other **suspicious activity** to the DEA
- DEA recently agreed to release nine years of data from the Automated Reports and Consolidated Ordering System (ARCOS) on opioid sales in multidistrict litigation brought by local governments against manufacturers and distributors

Today's Presenter



Hilary H. Bowman

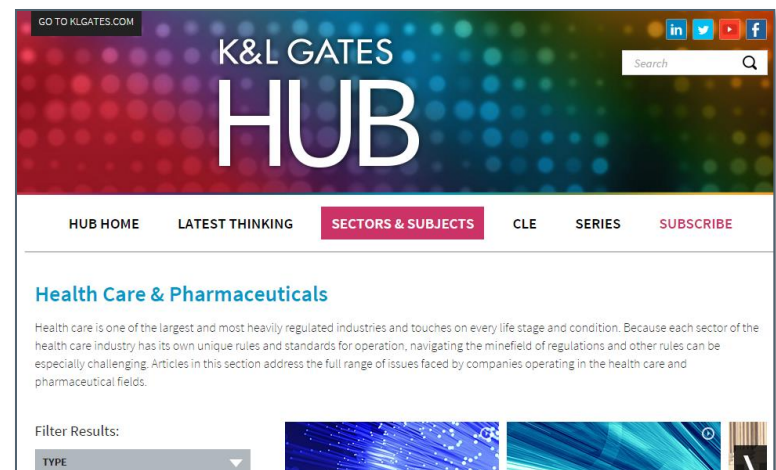
Research Triangle Park

+1.919.466.1125

Hilary.bowman@klgates.com

For more information on our Health Care Practice Group please visit our [website](#).

For additional insights into Health Care Law please visit [K&L Gates HUB](#).



K&L GATES