

## Pharmacies, DEA & Robinson- Patman/340B Drug Programs

### Related Practices

Antitrust & Trade Regulation

Health Care

Hospitals and Health Care  
Systems

## Overview

Dykema's health care practice is a full-service practice, providing solid solutions to the challenges that face today's health care professionals and providers. We have long represented the full range of pharmacy providers from institutional to retail, offering them the comprehensive services and counsel they need to navigate a complex legal landscape.

Our counsel is supported by a deep understanding of legal nuances pertaining to:

- State Board of Pharmacy licensure and compliance.
- Drug Enforcement Administration, or DEA, registration and compliance.
- The purchase, sale, and custody of controlled substance or "scheduled drugs."
- Robinson-Patman Act anti-price discrimination policies.
- Nonprofit Institutions Act, or NPIA or "own use" discount drug programs.
- 340B Drug Pricing Program participation.
- Compliance with the Prescription Drug Marketing Act or PDMA.

## Experience Matters

The Dykema team:

- Regularly advises institutional and retail pharmacies regarding state licensure, DEA registration and ongoing compliance with state and federal (DEA) pharmacy and drug control statutes and regulations.
- Has assisted many institutional pharmacies with the licensure, Medicare and Medicaid change of ownership issues that arise in mergers and sales of hospitals and other care entities.
- Has helped design and obtained a favorable Advisory Opinion from the Federal Trade Commission (FTC) on behalf of the Alpena Public Schools for its self-insured NPIA, "own use" discount drug employee benefit program.
- Obtained a favorable FTC Advisory Opinion on behalf of the University of Michigan for its NPIA, own-use discount drug employee benefit program.
- Regularly advises our health system clients regarding the appropriate use and transfer of prescription drugs to health system patients and among health system programs, advising them regarding compliance with the Robinson-Patman Act, the NPIA and the Prescription Drug Marketing Act.
- Has provided guidance to 340B hospitals on the appropriate use of 340B drugs in the context of sales to patient and to patient-employees.

Pharmacies, DEA & Robinson-Patman/340B Drug Programs (Cont.)

## **Publications**

"The Plaintiff Bar's Latest Attack on Generic Drug Manufacturers: How a new FDA Rule Could Dismantle Recent Legal Victories"

December 10, 2014

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