

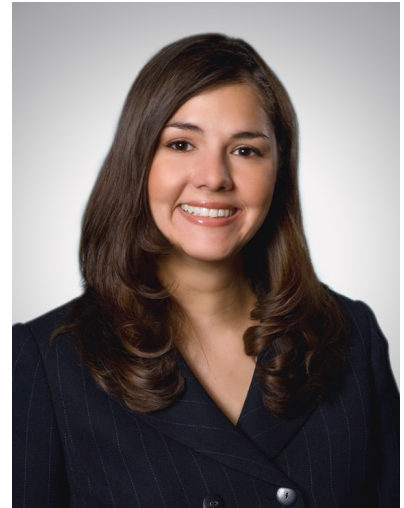
Simone Colgan Dunlap

Partner

Simone Colgan Dunlap is national chair of the firm's Health & Life Sciences Industry Team and a member of the Health Law Group. Her practice is focused on regulatory compliance, related risk management, and corporate/contracting matters for a variety of clients, including: drug and device manufacturers, pharmacy benefits managers (PBMs), third-party administrators (TPAs), health care insurers, discount medical plan organizations (including prescription discount card administrators), pharmacies, specialty pharmacies, home health agencies, hospitals, physician organizations, physicians, pharmacists, and nurses.

Representative Experience

- Drafts and negotiates distribution agreements for drugs and devices, business associate agreements, group purchasing organization agreements, data use agreements, licensing agreements, pharmacy services agreements, specialty pharmacy services agreements, HUB agreements, marketing agreements, Risk Evaluation and Mitigation Strategies (REMS) consulting agreements, independent contractor agreements, and numerous other commercial contracts.
- Structures and drafts agreements for novel products and services that leverage her understanding of health care regulatory issues and business needs.
- Provides strategic advice to clients on a diverse array of regulatory compliance issues, including: investigations and enforcement actions; permitting and licensure; controlled substances distribution and prescription dispensing; FDA compliance; change-of-ownership / mergers and acquisitions; contracting with government payers; review of promotional materials for drug products; medication therapy management programs; federal and state fraud and abuse compliance (e.g., Anti-Kickback Statute and Stark); telemedicine, telepharmacy, compounding, physician-dispensing, clinical trials; and records retention.
- Advises clients on federal health privacy laws, including HIPAA/HITECH as well as state laws governing the confidentiality of health information, medical records, mental health records, and records containing other sensitive information.
- Served as a seconded attorney for McKesson Corporation for six months. In this role, Simone coordinated drafting and regulatory review of contracts for three business units: McKesson Specialty Arizona Inc., Onmark, Inc., and McKesson Specialty Care Distribution Joint Venture L.P. In addition, she was responsible for



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identifying regulatory compliance issues associated with new products, supervising outside counsel, coordinating and developing discovery management strategies, and developing recommendations for process improvement.

- Develops template contracts and related procedures for review and negotiation.
- Coordinates and deploys attorney teams to provide short-term and long-term customized contracting support during peak work periods, emergencies, and for special projects in a manner that integrates the client's contracting preferences.

Legal Services

- Data Privacy & Security
- Health & Life Sciences
 - Health Care Transactions
 - FDA Regulatory Practice
 - Health Information Technology, Privacy & Security
 - Pharmacy
 - Specialty Pharmacy
 - Telehealth

Education and Honors

- University of Michigan Law School (J.D., *cum laude*, 2008)
 - University of Michigan Journal of International Law, Business Development Editor
- Whitman College (B.A., *with honors*, 2002)

Bar Admissions

- Arizona

Court Admissions

- U.S. District Court, District of Arizona, 2009

Professional and Civic Activities

- International Association of Privacy Professionals (IAPP)
- National Association of Specialty Pharmacy (NASP)
- Quarles & Brady Diversity Committee
- Quarles & Brady Phoenix Women's Forum (Former Chair)
- Ms. JD's Third Annual Conference on Women in Law: Avenues to Advancement (Conference Co-Chair)
- U.S. Department of State, Office of Legal Affairs at the United States Mission to the United Nations in Geneva (Legal Intern)
- Hon. Stephen M. McNamee, U.S. District Court, District of Arizona (Judicial Intern)

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- Wills For Heroes (Attorney Volunteer)
 - Maricopa County Volunteer Lawyers Program (Intern and Attorney Volunteer)
 - American Health Law Association (AHLA)
 - National Association of Women Lawyers (NAWL)
 - Maricopa County Bar Association (MCBA)
 - Arizona Asian American Bar Association (AAABA)
 - National Asian Pacific American Bar Association (NAPABA)
 - Ms. JD

Professional Recognition

- Selected for inclusion in Southwest Super Lawyers® – Rising Stars (2017–present: Health Care)
- Named "Top 50 Pro Bono Attorney" in 2010 by the Arizona Foundation for Legal Services & Education