



Machele Dunavant Shields

Strategic Advisor
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MACHELLE DUNAVANT SHIELDS is a Strategic Advisor for EBG Advisors, Inc. She has more than 20 years of experience in all aspects of compliance and ethics, privacy (HIPAA), and reimbursement support and strategy.

Specifically, Ms. Shields:

- Provides compliance and regulatory services to life science companies, including device/technology reimbursement strategy (coding, coverage, and payment)
- Advises on the infrastructure needs of start-up device companies and all aspects of compliance program design, operation, and implementation across the entire health care spectrum—physicians, hospitals, Medicare Advantage, device and pharmaceutical companies, and other health care providers
- Develops and implements fraud and abuse compliance programs for all areas of health care
- Performs monitoring and oversight for DPAs, CIAs, and corrective action plans
- Provides HIPAA/HITECH privacy, security, and compliance program implementation and support services
- Conducts compliance program assessments and Medicare/Medicaid readiness assessments
- Conducts compliance and privacy/security gap analyses and risk analyses
- Handles all aspects of monitoring, auditing, compliance diligence, and internal investigations
- Provides contract support services with a focus on compliance, regulatory, and federal and state privacy laws
- Advises on health care administration and compliance and academic medicine
- Drafts OIG advisory opinions

Prior to her joining EBG Advisors, Ms. Shields was the Senior Executive Healthcare Policy and Compliance Advisor for the Health Law Practice of an international law firm, as well as the President of that firm's wholly owned regulatory affiliate. Prior to that, she served as Vice President and Chief Compliance Officer for one of the world's "top 10" medical device companies. During that time, she executed and implemented a Corporate Integrity Agreement (reimbursement focused) and laid the foundation for a second Corporate Integrity Agreement.

Ms. Shields is a Tennessee Supreme Court Rule 31 Listed General Civil Mediator and a Medical Group Management Association (MGMA) Certified Medical Practice Executive. She has also been certified by the Health

Care Compliance Association (HCCA) in Compliance, Privacy, and Research Compliance, and holds three coding certifications from the AAPC and American Health Information Management Association (AHIMA). She speaks regularly at industry meetings and is frequently a guest speaker at the University of Memphis School of Law regarding ethics and compliance.

Representative Experience

- Developed a defensible coding/extrapolation strategy that reduced a \$3.6 million recoupment to \$86,000
- Served as a federal monitor team lead for 18 months for a device company's deferred prosecution agreement
- Served as a monitor for an Office of Civil Rights' HIPAA Corrective Action Plan with a large academic medical center (for three years)
- Conducted compliance diligence as part of a \$3.9 billion acquisition
- Handled compliance preparation for a multistate hospice
- Developed and implemented a corrective action plan for an academic medical center in a 340B audit that was conducted by the Health Resource & Services Administration and included the manufacturer repayment process
- Developed a corrective action plan for a hospital with alleged violations of the Emergency Medical Transport and Active Labor Act (EMTALA), and imposed the "immediate jeopardy" process by the Centers for Medicare & Medicaid Services
- Managed a medical practice with clinical- and academic-based physicians, which included serving as a billing compliance committee member for a 400+ physician faculty medical group and handling fraud/abuse and privacy issues and compliance plan development, implementation, and monitoring
- Developed a new medical faculty department specifically targeted as the primary care entrance for a 110,000-square-foot multi-specialty center, including handling departmental integration and centralized organization of staffing models, competency models, budgets, billing compliance, protocols (clinical and administrative), procedures, governance, patient flow, cost-benefit analyses, and pro formas
- Oversaw human resource development, departmental policy and maintenance procedures, CLIA certification, and compliance with OSHA and Accreditation Association for Ambulatory Health Care (AAAHC) regulations

Education

- Seton Hall University School of Law (M.S.J., *with distinction*, 2017)
 - Concentrations in "Health and Hospital Law" and "Pharmaceutical & Medical Device Law & Compliance"
- Seton Hall University School of Law (Graduate Certificate, 2015)
 - Pharmaceutical & Medical Device Law & Compliance
- California Coast University (B.S.H.A., *summa cum laude*, 2011)
- California Coast University (M.B.A., 2003)

- California Coast University (B.S., 1996)

Certifications

- Certified in Healthcare Research Compliance (CHRC), HCCA
- Certified Coding Specialist – Physician (CCS-P), AHIMA
- Certified Medical Practice Executive (CMPE), MGMA
- Certified Professional Coder (CPC), AAPC
- Certified Professional Coder – Hospital (CPC-H), AAPC
- Certified in Healthcare Compliance (CHC), HCCA
- Certified in Healthcare Privacy Compliance (CHPC), HCCA
- EMT-IV Technical Certificate

Memberships & Affiliations

- American Association of Professional Coders, Past President Local Chapter
- American Health Information Management Association
- Healthcare Compliance Association, Auditing and Monitoring Tools Editorial Board (2010-2018)
- Life Science Tennessee, Economic Development and Entrepreneurship Committee (2016-2018) and Mentor (2016-2018)
- Medical Group Management Association
- Southeast BIO (SEBIO), Past Board Member
- Southeastern Medical Device Association (SEMDA), Past President, Past Executive Committee, Medtech Women Past Founding Board Member
- Zero to 510k Accelerator, Mentor