Healthcare Law, Medical Ethics, and Regulatory Compliance Training Course

02 - 06 Nov 2026

Tokyo

5800 € (Per Person)

Ref: #LAW5436_155713

Course Introduction / Overview:

The modern healthcare landscape is a complex web of legal statutes, ethical dilemmas, and stringent regulatory requirements that demand constant vigilance and expertise. This comprehensive training course is meticulously designed to equip professionals with the critical knowledge and skills needed to navigate this challenging environment effectively. As discussed by prominent bioethicist George J. Annas, the rights of patients are central to ethical medical practice, a theme we will explore in depth. This program delves into the core principles of healthcare law, from patient consent to medical malpractice, and examines the ethical frameworks that guide clinical decision-making, echoing concepts found in seminal works like "Principles of Biomedical Ethics". BIG BEN Training Center has developed this course to bridge the gap between theoretical knowledge and practical application, focusing on real-world scenarios involving regulatory compliance, including HIPAA, the Stark Law, and the Anti-Kickback Statute. Participants will gain a profound understanding of how to build and maintain robust compliance programs, manage risks, and foster a culture of ethical and legal integrity within their organizations, ensuring they are prepared for the evolving challenges of the healthcare industry.

Target Audience / This training course is suitable for:

- Healthcare Administrators and Managers.
- Physicians, Surgeons, and other Clinicians.
- Nurses and Nurse Practitioners.
- Hospital Legal Counsel and Paralegals.
- Healthcare Compliance Officers.
- Risk Management Professionals.
- Pharmaceutical and Medical Device Professionals.
- Health Information Management Specialists.
- Public Health Officials.
- Healthcare Consultants.
- Clinical Research Coordinators.
- Insurance and Claims Adjudicators.

Target Sectors and Industries:

- Hospitals and Health Systems.
- Private Medical Practices and Clinics.
- Long-Term Care and Assisted Living Facilities.
- Pharmaceutical and Biotechnology Companies.
- Medical Device Manufacturing Companies.
- Health Insurance Providers.
- Governmental Health Agencies and Regulatory Bodies.
- Academic Medical Centers and Research Institutions.
- Home Healthcare Agencies.
- Telemedicine and Health-Tech Companies.

Target Organizations Departments:

- Legal and General Counsel.
- Compliance and Ethics.
- Risk Management.
- Clinical Operations and Patient Care.
- Medical Staff Administration.
- Health Information Management (HIM).
- Human Resources.
- Finance and Billing.
- Quality Assurance and Improvement.
- Research and Development.

Course Offerings:

By the end of this course, the participants will have able to:

- Analyze the fundamental principles of healthcare law and their application in clinical settings.
- Apply established ethical frameworks to resolve complex medical dilemmas.
- Navigate the intricacies of federal and state healthcare regulations, including HIPAA and fraud statutes.
- Develop, implement, and monitor effective healthcare compliance programs.
- Identify and mitigate legal risks associated with medical malpractice and professional liability.
- Master the requirements for informed consent and patient confidentiality.
- Manage and respond to healthcare data breaches and privacy violations.
- Understand the legal and ethical implications of emerging technologies like telemedicine and AI.
- Conduct internal investigations into compliance and ethical concerns.
- Promote a culture of legal and ethical integrity within their healthcare organization.

Course Methodology:

The training methodology at BIG BEN Training Center is designed to be immersive, interactive, and highly practical, ensuring that participants can translate learned concepts into actionable skills. We move beyond traditional lectures to create a dynamic learning environment where engagement is paramount. The course heavily relies on the analysis of real-world and hypothetical case studies, allowing participants to dissect complex legal and ethical scenarios in a controlled setting. Interactive group discussions and debates are central to our approach, encouraging the sharing of diverse perspectives and collaborative problem-solving. Role-playing exercises will simulate challenging situations, such as handling a compliance investigation or navigating a difficult patient consent discussion, to build confidence and practical competence. Our expert instructors facilitate sessions that blend foundational knowledge with practical application, providing continuous feedback and guidance. Participants will work in teams on projects to develop sample compliance policies and risk assessment plans, ensuring they leave with tangible tools and a deep, applicable understanding of healthcare law, ethics, and compliance.

Course Agenda (Course Units):

Unit One: Foundations of Healthcare Law and Medical Ethics

- Introduction to the Legal System and Sources of Law in Healthcare.
- Core Principles of Medical Ethics: Autonomy, Beneficence, Non-Maleficence, and Justice.
- The Physician-Patient Relationship and Professional Duties.
- Understanding Torts and Contract Law in a Medical Context.
- Introduction to Corporate Liability and Vicarious Liability.
- The Role of Professional Codes of Conduct and Institutional Ethics Committees.
- Historical Context of Landmark Legal and Ethical Cases in Healthcare.

Unit Two: Patient Rights and Professional Liability

- The Doctrine of Informed Consent and Refusal of Treatment.
- Patient Confidentiality and Health Information Privacy under HIPAA.
- Managing and Securing Protected Health Information (PHI).
- Medical Malpractice: Elements of Negligence and Standards of Care.
- Defenses Against Malpractice Claims and Litigation Processes.
- End-of-Life Issues: Advance Directives, Living Wills, and Euthanasia.
- Legal and Ethical Considerations for Treating Minors and Incompetent Patients.

Unit Three: Healthcare Regulatory and Compliance Frameworks

- Federal Fraud and Abuse Laws: The False Claims Act.
- The Anti-Kickback Statute (AKS) and Safe Harbors.
- The Physician Self-Referral Law (Stark Law) and its Exceptions.
- HIPAA Administrative Simplification: Privacy, Security, and Breach Notification Rules.
- EMTALA (Emergency Medical Treatment and Active Labor Act) Requirements.
- Regulations Governing Clinical Research and Human Subjects Protection.
- Licensure, Credentialing, and Peer Review Processes for Healthcare Professionals.

Unit Four: Corporate Compliance and Risk Management

- Developing and Implementing an Effective Compliance Program.
- The Seven Elements of a U.S. Sentencing Guidelines Compliance Program.
- Conducting Internal Investigations and Audits.
- Strategies for Risk Identification, Assessment, and Mitigation in Healthcare.
- Responding to Government Investigations and Subpoenas.
- Medical Record Management: Documentation, Retention, and Legal Admissibility.
- Compliance Issues in Healthcare Billing, Coding, and Reimbursement.

Unit Five: Contemporary and Emerging Issues in Healthcare

- The Legal and Ethical Landscape of Telemedicine and Digital Health.
- Genetics, Biobanking, and Patient Privacy Concerns.
- Ethical and Legal Implications of Artificial Intelligence (AI) in Medicine.
- Public Health Law, Emergency Preparedness, and Crisis Standards of Care.
- Conscience Rights and Religious Objections in Healthcare Delivery.
- Healthcare Disparities and the Role of Law in Promoting Health Equity.
- Global Health Law and International Regulatory Considerations.

FAQ:

Qualifications required for registering to this course?

There are no requirements.

How long is each daily session, and what is the total number of training hours for the course?

This training course spans five days, with daily sessions ranging between 4 to 5 hours, including breaks and interactive activities, bringing the total duration to 20 - 25 training hours.

Something to think about:

As artificial intelligence becomes more integrated into diagnostics and treatment, how should traditional legal and ethical frameworks adapt to address issues of liability and patient autonomy?

What unique qualities does this course offer compared to other courses?

This course distinguishes itself by offering a deeply integrated and holistic perspective on the intersection of healthcare law, medical ethics, and regulatory compliance, fields that are often taught in isolation. Rather than presenting a siloed overview of each domain, we focus on their dynamic interplay in real-world clinical and administrative scenarios. Our curriculum is uniquely forward-looking, dedicating significant attention to emerging challenges such as the regulation of artificial intelligence, the ethics of genetic testing, and the legal complexities of telemedicine, ensuring participants are prepared for the future of healthcare, not just its present. The methodology is intensely practical, moving beyond theoretical lectures to immerse participants in complex case studies, simulated compliance investigations, and ethical deliberation forums. This hands-on approach ensures that learning is not merely academic but is directly translatable into the professional environment. Participants will leave with not only a comprehensive understanding of the rules but also the critical thinking and problem-solving skills to apply them effectively in nuanced, high-stakes situations, making them invaluable assets to their organizations.