

# US HEALTHCARE COMPLIANCE

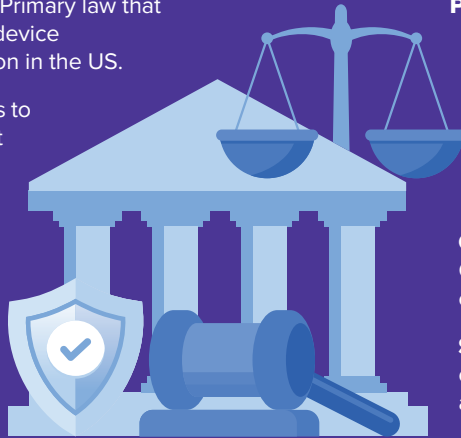
Our goal is to help patients. But we must never forget that we pursue this goal in a highly regulated industry. Laws and regulations govern how we develop, manufacture, and promote our products. Our Company is committed to complying with all applicable laws and regulations. This commitment is the shared responsibility of all our employees.

## KEY LAWS AND REGULATIONS

**Food, Drug, and Cosmetic Act (FDCA)** - Primary law that regulates biopharmaceutical and medical device development, manufacturing, and promotion in the US.

**False Claims Act (FCA)** - Allows individuals to file suit on behalf of the government against any person or company that knowingly submits or causes the submission of a false or fraudulent claim to a federal healthcare program.

**Anti-Kickback Statute (AKS)** - Makes it illegal to offer or provide anything of value to a healthcare professional (HCP) to induce that HCP to write a prescription or make a purchase that is reimbursable by a federal healthcare program.



**Physicians Payment Sunshine Act** – Requires biopharmaceutical and medical device companies to report all payments and other transfers of value they make to physicians and other covered entities that meet federal reporting requirements.

**Health Insurance Portability and Accountability Act (HIPAA)** - Establishes national standards for protecting an individual's medical records and other protected health information (PHI).

**Code of Federal Regulations Title 21 (21 CFR)** - Portion of the US Code of Federal Regulations that contains the regulations established by the Food and Drug Administration (FDA).

**State and Local Laws** – Many states and localities enforce their own unique set of rules and regulations that biopharmaceutical and medical device companies must abide by.

## Government and Industry Guidelines



- Office of Inspector General (**OIG**) Guidelines
- Department of Justice (**DOJ**) Evaluation of Corporate Compliance Programs
- The Pharmaceutical Research and Manufacturers of America (**PhRMA**) Code on Interactions with Healthcare Professionals
- Advanced Medical Technology Association (**AdvaMed**) Code of Ethics on Interactions with US Healthcare Professionals

## Consequences of Non-Compliance

- Penalties for individuals and companies (fines, prison time, exclusion from government programs)
- Corporate Integrity Agreement (CIA) and/or a Deferred Prosecution Agreement (DPA)
- Damage to our reputation
- Investigations that distract resources from our goal



## Our Compliance Program

Our Compliance team is here to help you and our Company stay compliant with all laws and regulations by:

- Providing policies, procedures, and training
- Monitoring and managing our compliance risks
- Conducting fair and confidential investigations when necessary
- Always being available if you have any questions



## Your Responsibility

We all perform functions that directly or indirectly support regulated activities.

- Follow all Company policies, procedures, and training.
- If you are ever asked to help with an investigation, be honest and cooperative.
- If you know or suspect that the law, our Code of Conduct, or any Company policy has been violated, inform your manager or the Compliance department.
  - All reports are taken seriously and reviewed in a prompt and confidential manner.
  - Our Company enforces a strict non-retaliation policy.



## Questions?

Contact your manager, Legal, or Compliance.

