

The Healthcare Industry: Quick Reference



The U.S. government has a specific interest in protecting federal and state healthcare programs and their customers and patients from improper influence.

THE GOVERNMENT'S ROLE

Not only is the government the nation's largest single healthcare purchaser through its financing of Medicare and Medicaid programs, it also invests heavily in public health education, research and development activities, and product approval processes.

Because the government is such a huge investor in healthcare, it wants to ensure that taxpayer funding put into the system is legitimately spent. One of the ways the government does this is by regulating how we market and sell our products. The government also has a clear financial interest in ensuring that the price it pays for a product or service represents the true and fair cost for that product or service.

FRAUD, WASTE, AND ABUSE

Healthcare fraud is when a person or entity seeks to deceive the healthcare system for financial gain, usually through the use of false or misleading information.

Waste is healthcare spending that isn't based on a legitimate need (i.e., isn't medically necessary).

Abuse, in this context, means business practices and actions that are intended to systematically result in unnecessary or inappropriate healthcare services and patients.



Relevant Laws and Regulations: Quick Reference



In order to protect its investment in healthcare and the millions of patients who receive healthcare benefits through government programs, federal and state governments have enacted a number of fraud and abuse laws and regulations.

THE ANTI-KICKBACK LAW

The law prohibits anyone working on behalf of a healthcare company from offering, soliciting, receiving, or paying anything of value to an HCP in exchange for the purchase, prescription, recommendation or referral for the company's products. It may apply even where a legitimate business need exists for an arrangement or offer if any ONE purpose of it was to induce or reward referrals or orders. The scope of the law is very broad because it can be applied to any transaction we have with an HCP.

THE FALSE CLAIMS ACT

Healthcare companies can face government prosecution under the False Claims in many ways including:

- Submitting or causing someone else to submit false information about the actual cost of the medicines, tests, and devices the government is paying for;
- Promoting products to healthcare

professionals (HCPs) for uses for which they have not been approved, if the HCPs then submit claims for these products; and

- Offering illegal kickbacks to HCPs – if those kickbacks relate to products for which reimbursement claims are made.

OTHER LAWS AND REGULATIONS

Like the Anti-Kickback law, the beneficiary inducement statute makes it unlawful to transfer anything of value to a Medicare or Medicaid patient that the company knows or should know may influence a beneficiary's choice of provider, practitioner, or supplier of items or services.

Abbott is subject to regulations from a variety of federal agencies including the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Veteran's Affairs Administration. Failure to comply with these regulations can also come with stiff fines and penalties. States also have their own laws and

regulations designed to prevent fraud, waste, and abuse, and ensure medically necessary services are provided.

The healthcare industry has a variety of industry codes and standards which set forth voluntary guidelines to minimize fraud, waste, and abuse and ensure medically necessary services are delivered to patients.

CONSEQUENCES

Violations of fraud and abuse laws and regulations carry a range of penalties and sanctions. Companies can face large criminal and civil fines, as well as potential exclusion from participation in federal healthcare programs, such as Medicaid and Medicare, while individuals can receive fines and even prison sentences.

Over the last two decades, the government has increased its investigation and prosecution of healthcare fraud, waste, and abuse. This trend is likely to continue.



The Impact on Our Business: Quick Reference



Nearly every transaction we have with an HCP or customer is a potential concern for the government because of the risk that these transactions could be used as an incentive or reward for doing business.

INTERACTIONS WITH HEALTHCARE PROFESSIONALS

The government wants to ensure that HCP decision-making is free from influence and focused on what is in the best interest of the patient. It looks more closely at business transactions we have with HCPs, including:

- Hiring an HCP to advise us on the scientific merits of a product or medical device;
- Providing funding for research or an educational program;
- Paying for a meal as part of a business discussion;
- Arranging a charitable contribution; and
- Providing samples and other products at no charge.

The government asks questions to establish the legitimacy of nearly every transaction we engage in. Even activities that are not sales and marketing-related raise concerns for the government because HCPs often have many relationships and points of contact within the industry.

OTHER POTENTIAL CONCERNS

Promotional activities and messaging are another area of heightened scrutiny for the government, particularly for large manufacturers like Abbott. For products like medical devices and diagnostics equipment, the Food Drug and Cosmetic Act (FDCA) sets standards for promotional activities. For our nutrition products and other products marketed directly to consumers, the Federal Trade Commission (FTC) standards govern promotional messaging.

Discounts and rebates provided to healthcare purchasers may be problematic if they don't meet the standards in the law. Contracting activities in the healthcare space are also heavily scrutinized by the government.

HOW WE ADDRESS THESE CONCERNS

Abbott's USP&P, which covers routine business interactions with HCPs and other groups, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste, and abuse concerns.

The government has also provided additional guidance in the form of "safe harbor" regulations. These regulations list certain practices (such as providing equipment rentals or paying for bona fide services) that the government deems do not violate Medicare/Medicaid fraud and abuse laws, as long as certain criteria are met. These criteria have been woven into Abbott's USP&P – defining for us exactly what we can and cannot do.

PARTICULAR RISKS TO THE COMPANY

Certain activities in the areas of pricing and sales arrangements are of particular risk to Abbott, because of the many gray areas surrounding them.

If you are involved in pricing and sales arrangements, it is important that you stay within the specific parameters of what has been defined as allowable by Abbott, and that you follow the precise requirements in our policies and procedures.

If you have any questions, always consult with the OEC or Legal before proceeding.

