



INTRODUCTION

Welcome



This course has been designed to play both in *audio on* and *audio off* modes.

If you are in a low bandwidth region, we recommend that you select the *Audio Off* mode now. To select this option, click the Audio icon in the title bar.

PLEASE CLICK THE **FORWARD ARROW** TO BEGIN.





INTRODUCTION

Welcome



As a healthcare company, it is critical that we always do what's right for the many people we serve.

This includes complying with fraud and abuse laws and regulations that are designed to protect federal and state healthcare programs and their patients and customers from improper influence by healthcare professionals (HCPs).



INTRODUCTION

Objectives



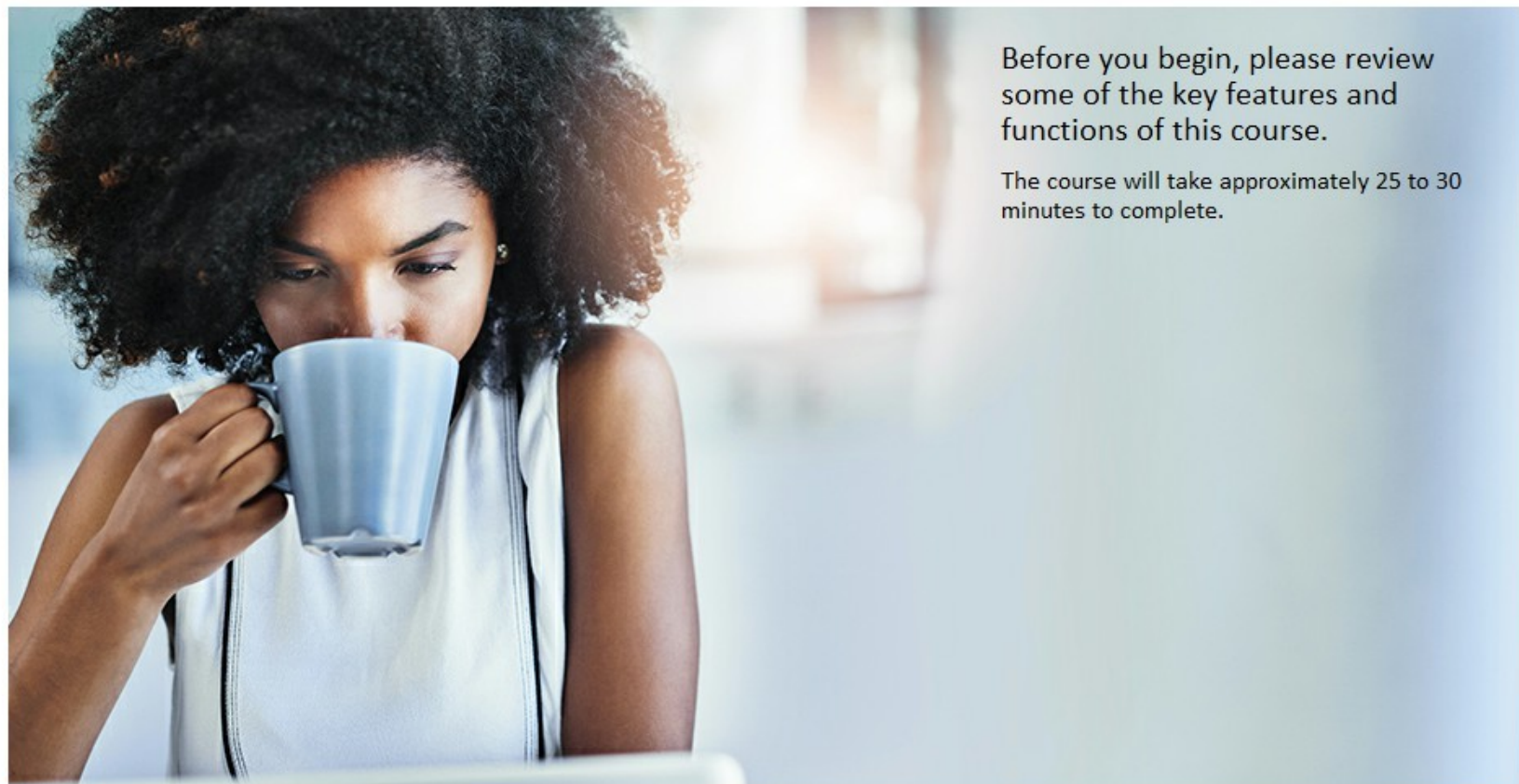
Upon completion of this course, you will be able to:

- Explain why the U.S. government has a specific interest in what we do and how we do it;
- Understand the laws and regulations designed to prevent fraud, waste, and abuse in the healthcare industry;
- Recognize that almost every transaction we have with an HCP or customer is a potential concern for the government;
- Describe the steps we take to ensure our activities are structured to achieve our business objectives ethically and legally; and
- Know where to go for help and support.



INTRODUCTION

Tutorial



Before you begin, please review some of the key features and functions of this course.

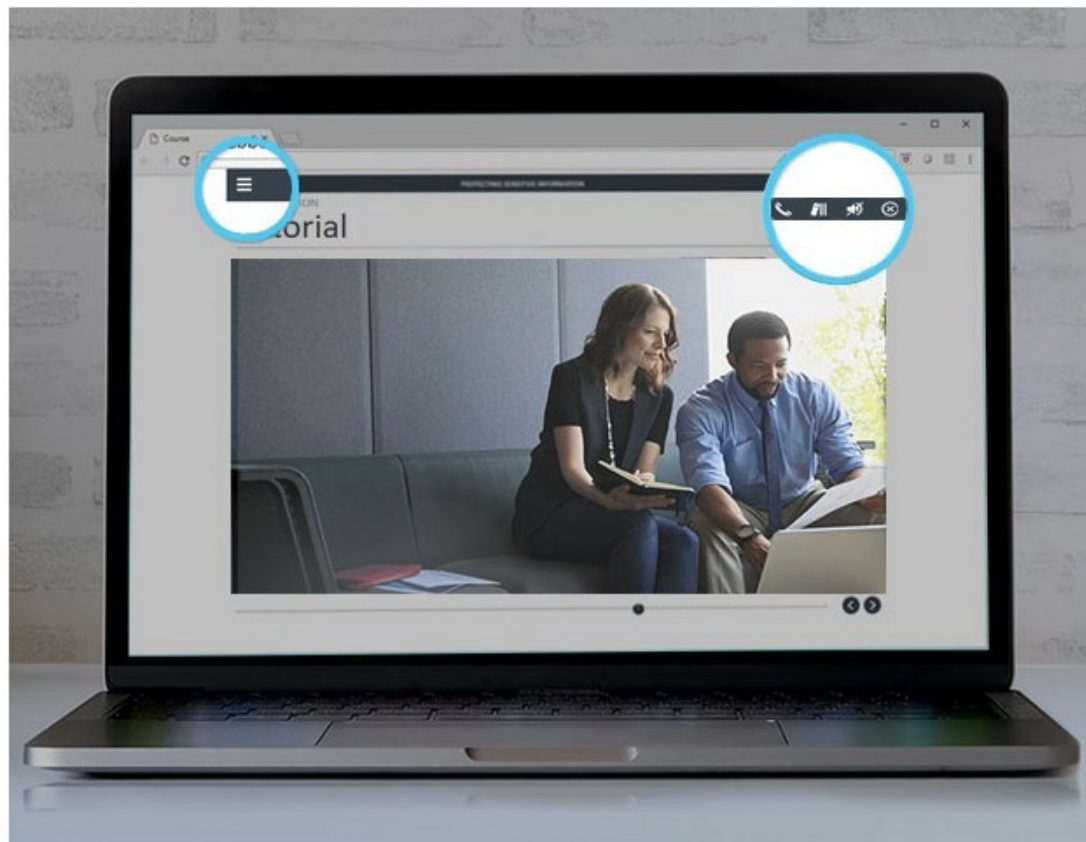
The course will take approximately 25 to 30 minutes to complete.





INTRODUCTION

Tutorial



The icons at the top of the screen provide one-click access to key resources:

- The table of contents,
- Important contact information, and
- Reference material.

In addition, you can use the Audio icon to turn the audio on or off. Click the Exit icon to close the course window.



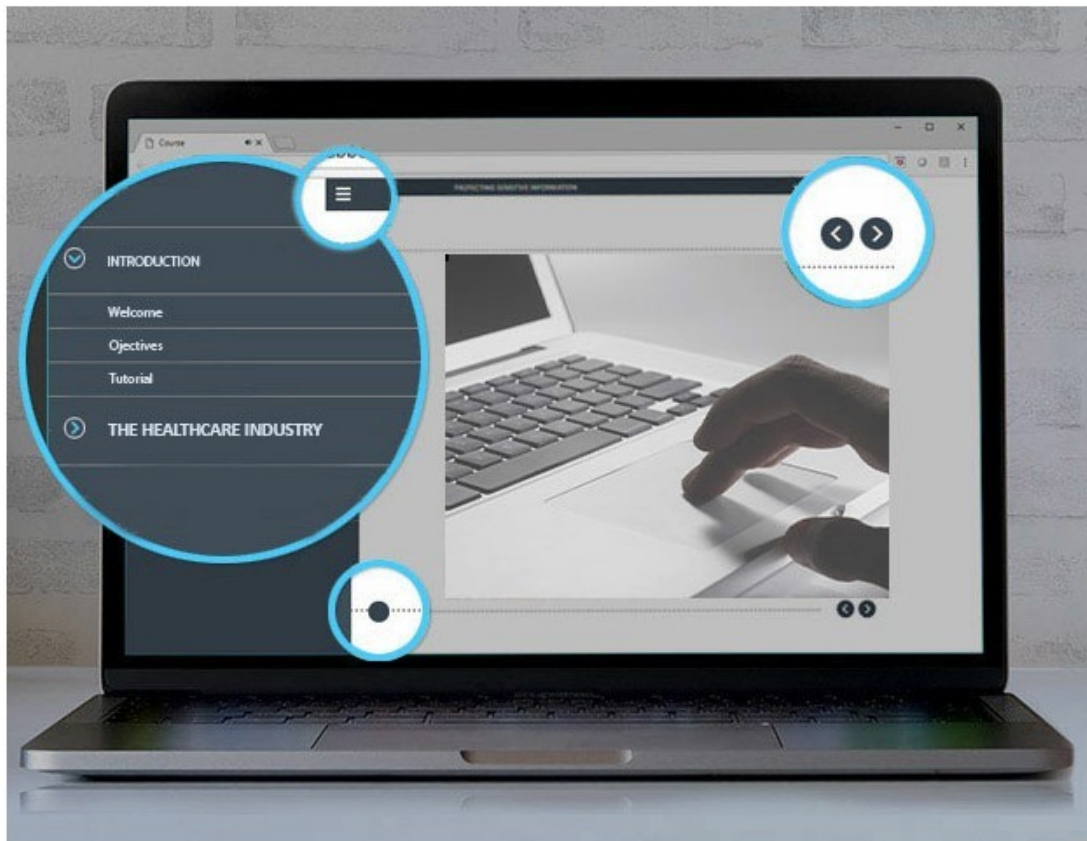
INTRODUCTION

Tutorial



There are several features to help guide you through the course:

- The back and forward arrows allow you to move from screen to screen.
- A horizontal slider bar at the bottom of the screen allows you to see where you are in the course.
- The table of contents lets you navigate from section to section.



INTRODUCTION

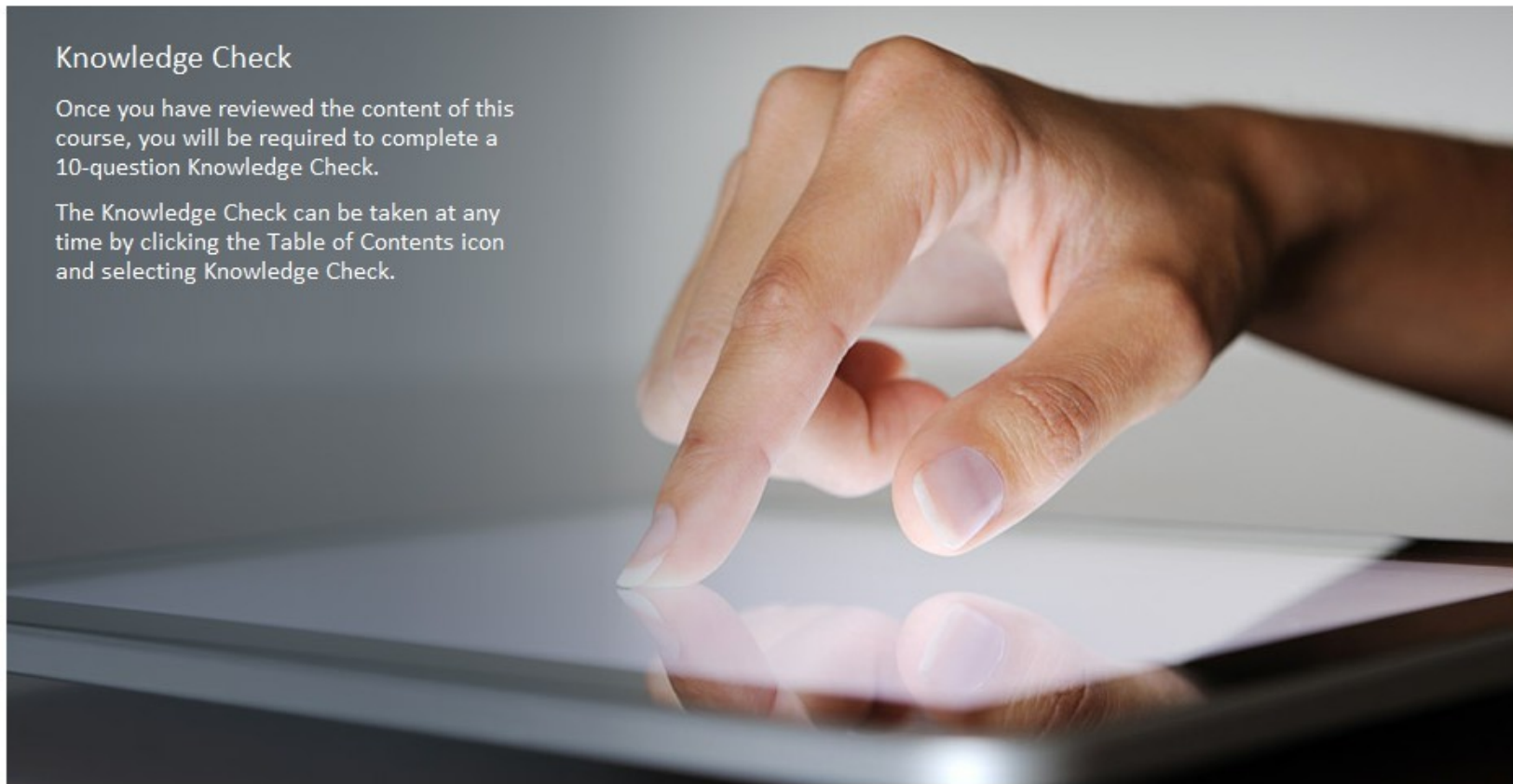
Tutorial



Knowledge Check

Once you have reviewed the content of this course, you will be required to complete a 10-question Knowledge Check.

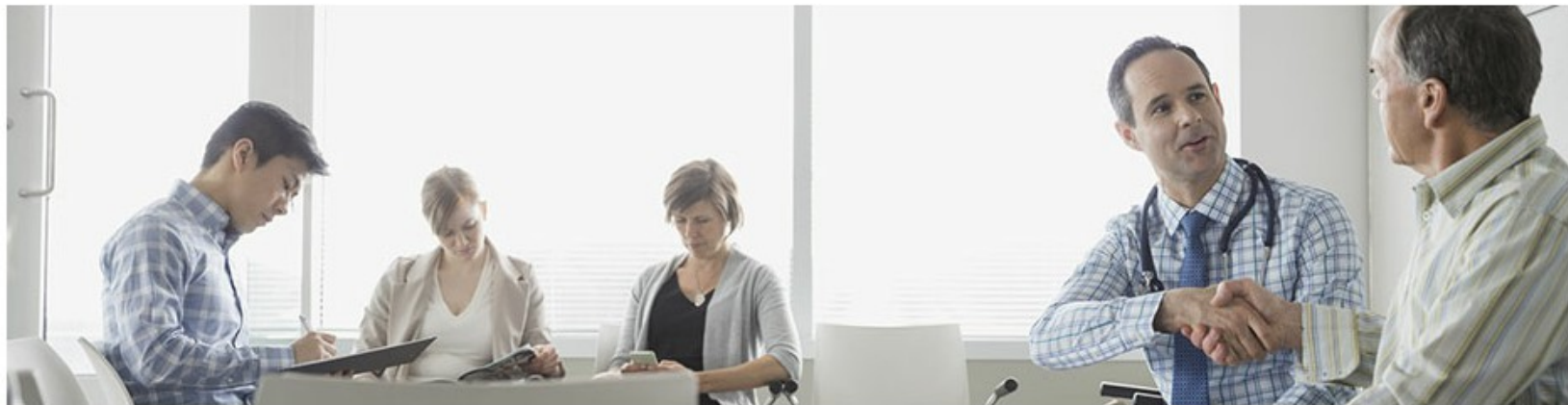
The Knowledge Check can be taken at any time by clicking the Table of Contents icon and selecting Knowledge Check.





THE HEALTHCARE INDUSTRY

Overview



In this section, we are going to look at why the government has a specific interest in protecting federal and state healthcare programs and their customers and patients from improper influence.

The topics below will be covered:

- The Government's Role
- Fraud, Waste, and Abuse



THE HEALTHCARE INDUSTRY

The Government's Role



The U.S. government spends over \$1.5 trillion annually on health care.

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.



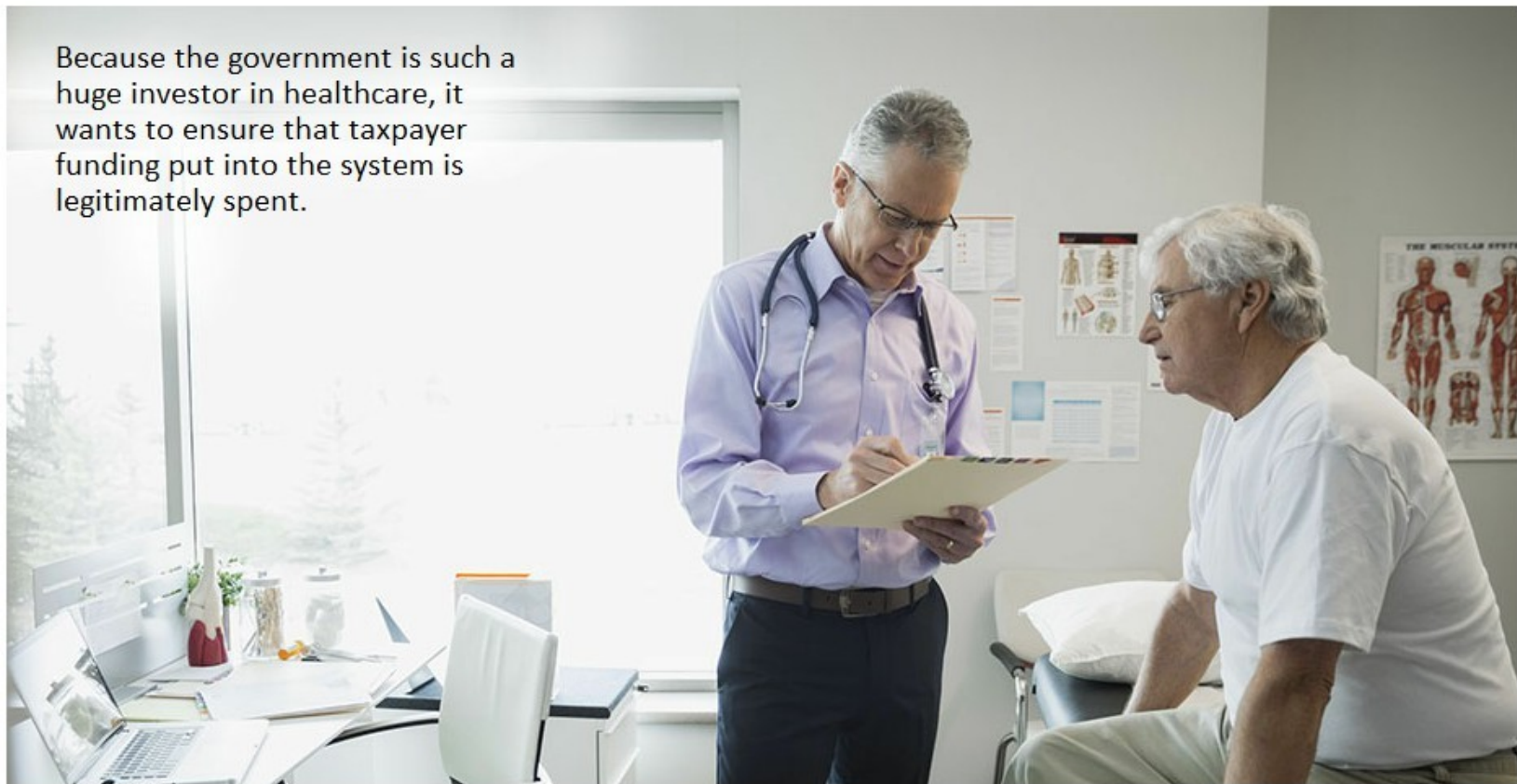


THE HEALTHCARE INDUSTRY

The Government's Role



Because the government is such a huge investor in healthcare, it wants to ensure that taxpayer funding put into the system is legitimately spent.





THE HEALTHCARE INDUSTRY

The Government's Role



First, the government wants to ensure that there is a legitimate need for the products and services it is paying for.

That means if an HCP orders a continuous glucose monitor for a patient, the government wants to make sure the HCP is choosing the monitor based on what is in the best interest of the patient's health.





THE HEALTHCARE INDUSTRY

The Government's Role



One of the ways the government does this is by regulating how we market and sell our products.

The government requires that we only market products for the purposes for which they have been approved. This means that we must not market products for an unapproved indication or in an unapproved age group, dosage, or route of administration. For example, if a product is approved for adults 18 and older, it cannot be marketed to children.

It also requires that our sales and marketing activities avoid creating needs for products where none exist. For example, we must never encourage HCPs to order diagnostic tests that are not medically necessary.



THE HEALTHCARE INDUSTRY

The Government's Role



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.

So, if the government is paying for stents being used in Medicare patients, hospitals are responsible for reporting the costs of the stents they implant. The government wants to ensure that the prices being reported accurately reflect the prices being paid and are not being inflated by, for example, a discount applied to other products when it is really applicable to the stents.





THE HEALTHCARE INDUSTRY

Fraud, Waste, and Abuse



Fraud, waste, and abuse are terms we hear in the news, but what do they mean? And how do we ensure that we are doing business in a way that doesn't raise any concerns about fraud, waste, or abuse?

Let's start with what these terms mean in the healthcare space.



THE HEALTHCARE INDUSTRY

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.

See if you can identify which of the following activities are examples of healthcare fraud.

Check all that apply and click the Submit button below.

- ☐ Double billing.
- ☐ Billing for supplies or services that were not delivered.
- ☐ Providing reasonable travel and accommodations for HCPs in connection with legitimate educational or business purposes.
- ☐ Billing for more expensive supplies, procedures, or tests than were provided (up-coding).
- ☐ Offering, paying, soliciting or receiving bribes or kickbacks (directly or indirectly) to induce patients or referrals.



SUBMIT



THE HEALTHCARE INDUSTRY

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.

See if you can identify which of the following activities are examples of healthcare fraud.

Check all that apply and click the Submit button below.

- ☒ Double billing.
- ☒ Billing for supplies or services that were not delivered.
- ☐ Providing reasonable travel and accommodations for HCPs in connection with legitimate educational or business purposes.
- ☒ Billing for more expensive supplies, procedures, or tests than were provided (up-coding).
- ☒ Offering, paying, soliciting or receiving bribes or kickbacks (directly or indirectly) to induce patients or referrals.

That's correct!

All of the examples, except providing reasonable travel and accommodations to HCPs in connection with legitimate educational or business purposes, are examples of healthcare fraud because they seek to deceive the healthcare system.

CLICK THE FORWARD ARROW TO CONTINUE.





THE HEALTHCARE INDUSTRY

Fraud, Waste, and Abuse



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

See if you can identify which of the following activities are examples of waste.

Check all that apply and click the Submit button below.

- ☐ Placing a re-order and billing for supplies knowing that the patient has not exhausted his/her supplies on hand.
- ☐ Not correcting a computer glitch that billed patients with the incorrect billing code.
- ☐ Providing promotional materials to HCPs that are consistent with applicable legal or regulatory requirements.



SUBMIT





THE HEALTHCARE INDUSTRY

Fraud, Waste, and Abuse



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

See if you can identify which of the following activities are examples of waste.

Check all that apply and click the Submit button below.

- ☒ Placing a re-order and billing for supplies knowing that the patient has not exhausted his/her supplies on hand.
- ☒ Not correcting a computer glitch that billed patients with the incorrect billing code.
- ☐ Providing promotional materials to HCPs that are consistent with applicable legal or regulatory requirements.

That's correct!

The first two are examples of waste because they will result in healthcare spending that isn't based on a legitimate need. Providing promotional materials to HCPs that are consistent with applicable legal or regulatory requirements is appropriate to educate them on our products.

CLICK THE FORWARD ARROW TO CONTINUE.



THE HEALTHCARE INDUSTRY

Fraud, Waste, and Abuse



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

See if you can identify which of the following activities are examples of abuse.

Check all that apply and click the Submit button below.

- ☐ Providing demonstration product to allow an HCP to demonstrate, educate, or train patients on the use of a product.
- ☐ Incentivizing an HCP to buy a set of medical devices when they only need a single item in the set.
- ☐ Limiting an HCP's ability to order tests to higher cost bundles of tests when individual tests may be more appropriate for some patients.



SUBMIT





THE HEALTHCARE INDUSTRY

Fraud, Waste, and Abuse



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

See if you can identify which of the following activities are examples of abuse.

Check all that apply and click the Submit button below.

- ☐ Providing demonstration product to allow an HCP to demonstrate, educate, or train patients on the use of a product.
- ☒ Incentivizing an HCP to buy a set of medical devices when they only need a single item in the set.
- ☒ Limiting an HCP's ability to order tests to higher cost bundles of tests when individual tests may be more appropriate for some patients.

That's correct!

Providing demonstration product to allow an HCP to demonstrate, educate, or train patients on the use of a product is permissible. The other two examples are considered abuse because they are actions that are intended to result in unnecessary or inappropriate healthcare services and patients.

In the next section, we'll review the laws and regulations designed to prevent fraud, waste, and abuse.

CLICK THE FORWARD ARROW TO CONTINUE.



THE HEALTHCARE INDUSTRY

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).

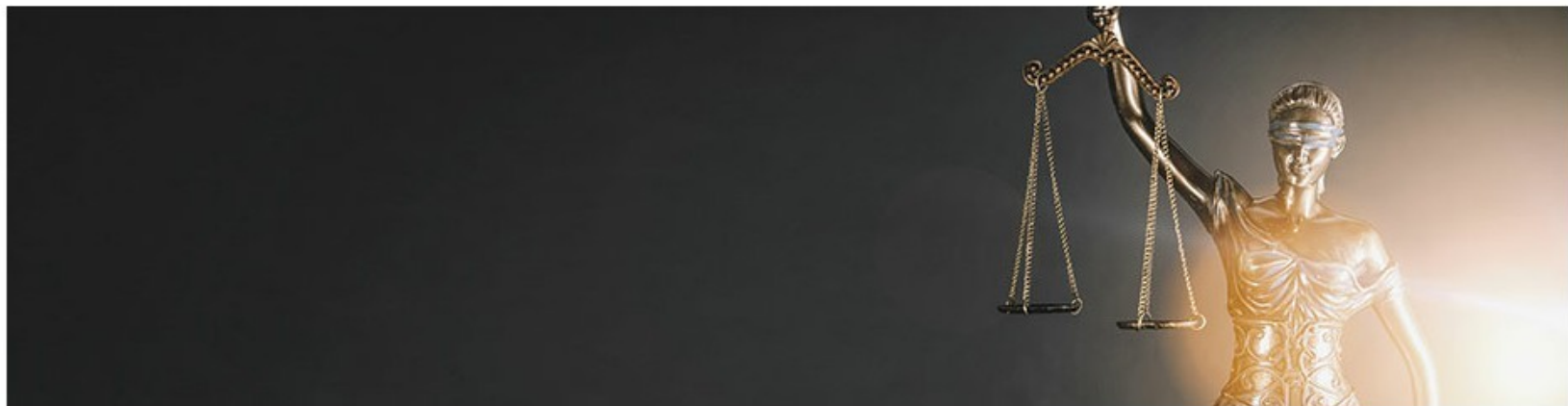
Abuse, in this context, means business practices and actions that are intended to systematically result in unnecessary or inappropriate healthcare services and patients.





RELEVANT LAWS AND REGULATIONS

Overview



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.

As we mentioned earlier, these laws and regulations are aimed at protecting federal and state healthcare programs and their patients from improper influence on the healthcare decisions made by HCPs.

The topics below will be covered:

- The Anti-Kickback Law
- The False Claims Act
- Other Laws and Regulations





RELEVANT LAWS AND REGULATIONS

The Anti-Kickback Law



In simple terms, the Anti-Kickback 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 of the company's products.

The Anti-Kickback law 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**.

CLICK THE **DID YOU KNOW?** BUTTON BELOW TO LEARN MORE.

DID YOU KNOW?



RELEVANT LAWS AND REGULATIONS

The Anti-Kickback Law



Anything of value really means ANYTHING of value including:

- Goods or services provided for free or below fair market value;
- Payments for services that are not provided or not necessary;
- Providing space or equipment for free or below fair market value;
- Certain types of discounts or rebates;
- Gift cards and other cash equivalents;
- Meals, tickets, and entertainment;
- Business opportunities that are not commercially reasonable (e.g., selling below cost);
- Waivers of co-payments or deductibles; and
- Cash or in-kind payments offered or provided directly or indirectly, no matter how small the amount.



RELEVANT LAWS AND REGULATIONS

The Anti-Kickback Law



The scope of the Anti-Kickback law is very broad because it can be applied to any transaction we have with an HCP.

Whether we are educating a lab technician on a product, hiring an investigator to conduct research on our behalf, offering evaluation equipment to a hospital group, or offering a business meal to attendees at speaker programs – any transaction in which we offer something of value is subject to scrutiny under this law.

The government has created a number of safe harbors, or exceptions to the law, to allow for certain practices. We'll discuss how Abbott helps you comply with these standards in more detail later in this course.

CLICK THE **DID YOU KNOW?** BUTTON BELOW TO LEARN MORE.

DID YOU KNOW?





RELEVANT LAWS AND REGULATIONS

The Anti-Kickback Law



The Anti-kickback law doesn't just apply to Abbott employees. It also applies to Abbott agents, including our distributors.





RELEVANT LAWS AND REGULATIONS

The False Claims Act



The Federal False Claims Act is another law aimed at protecting government interests by preventing fraud, waste, and abuse in government healthcare programs.

The law imposes stiff penalties on companies and individuals who either submit false information to the government or cause someone else to do so.



RELEVANT LAWS AND REGULATIONS

The False Claims Act



Healthcare companies can face government prosecution under the False Claims Act in many different ways.

The most obvious of which is if healthcare companies submit, cause someone else to submit, or are aware that false information is being submitted about the actual cost of the equipment, tests, and devices the government is paying for. For example, if a healthcare company doesn't have the medical documentation required to support a claim, but bills for it anyway, that company may be liable for submitting a false claim.



RELEVANT LAWS AND REGULATIONS

The False Claims Act



Healthcare companies can also face prosecution for promoting products to HCPs for uses for which they have not been approved, in other words, for off-label uses, if the HCPs then submit claims for those products to the government.

Likewise, healthcare companies can face prosecution for engaging in illegal kickback activities with HCPs. If, for example, an HCP is receiving illegal kickbacks from a healthcare company, then all claims submitted by that HCP to the federal government for the products made by the company and purchased or recommended by the HCP might be considered fraudulent.

CLICK THE **DID YOU KNOW?** BUTTON BELOW TO LEARN MORE.

DID YOU KNOW?





RELEVANT LAWS AND REGULATIONS

The False Claims Act



Did you know that both the party offering a kickback and the party receiving the kickback can be held responsible under the Anti-Kickback law and False Claims Act? The government regularly enforces both of these laws against HCPs and healthcare companies.





RELEVANT LAWS AND REGULATIONS

Other Laws and Regulations



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

Please reference the U.S. Ethics and Compliance Policy and Procedures (USP&P) and your division's policies and procedures, as applicable, for guidance about interactions with patients.



RELEVANT LAWS AND REGULATIONS

Other Laws and Regulations



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. Because of this, you are responsible for understanding the regulations governing your area of work.

States also have their own laws and regulations designed to prevent fraud, waste, and abuse, and ensure medically necessary services are provided. These laws and regulations often go beyond the scope of federal laws and regulations. For example, Massachusetts and Vermont have much stricter laws and regulations governing interactions with HCPs.



RELEVANT LAWS AND REGULATIONS

Other Laws and Regulations



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

As a member of the of the Advanced Medical Technology Association (AdvaMed), Abbott supports the AdvaMed Code which provides guidance on best practices for medical technology companies on how to interact with HCPs within the scope of U.S. fraud and abuse laws and regulations. AdvaMed Code guidance is reflected in applicable Abbott policies and procedures such as the USP&P.





RELEVANT LAWS AND REGULATIONS

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.

CLICK EACH PANEL TO LEARN MORE ABOUT ENFORCEMENT ACTIONS AGAINST THESE COMPANIES.



Millennium Health



Medtronic



Walgreens



RELEVANT LAWS AND REGULATIONS

Consequences



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CLICK EACH PANEL TO LEARN MORE ABOUT ENFORCEMENT ACTIONS AGAINST THESE COMPANIES



Millennium Health

In 2016, Millennium Health paid \$256 million to settle allegations that it gave free items to induce physicians to refer expensive and profitable lab tests to the company. The allegations also stated that the company billed federal healthcare programs for excessive and unnecessary drug and genetic testing.

Source: <https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic>



RELEVANT LAWS AND REGULATIONS

Consequences



Violations of fraud and abuse and regulations carry a range of penalties and sanctions.

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CLICK EACH PANEL TO LEARN MORE ABOUT ENFORCEMENT ACTIONS AGAINST THESE COMPANIES



Medtronic

In 2018, Medtronic agreed to pay \$51 million to resolve three claims against Covidien and ev3 Inc., two companies that are now part of the company. The payments resolved charges that ev3 sales representatives pushed the off-label uses of their liquid embolic system outside of its narrow-approved use and for larger than approved doses through inappropriate messaging and payments to HCPs. Medtronic agreed to implement new compensation structures and compliance/reporting obligations for the relevant sales force.

Source: <https://www.massdevice.com/medtronic-to-pay-51m-to-settle-covidien-ev3-doj-investigations/>

Then, in 2019, Medtronic's Covidien unit paid over \$17 million to settle allegations that it violated the False Claims Act by providing free or discounted practice and market development support to physicians to induce purchases of its vein ablation products. Covidien provided support in the form of customized marketing plans for physician practices. These plans included lunch and dinner meetings, as well as vein screening events, to drive new patients.

<https://www.justice.gov/opa/pr/covidien-pay-over-17-million-united-states-allegedly-providing-illegal-remuneration-form>





RELEVANT LAWS AND REGULATIONS

Consequences



Violations of fraud and abuse 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.

CLICK EACH PANEL TO LEARN MORE ABOUT ENFORCEMENT ACTIONS AGAINST THESE COMPANIES



Walgreens

In 2019, Walgreens agreed to pay \$269 million to settle two healthcare fraud settlements related to allegations of improper billing. The allegations claim that Walgreens billed federal healthcare programs for insulin pens it distributed to people who didn't need them, and overbilled Medicaid by not disclosing lower drug prices it offered in a discount program. In both settlements, Walgreens admitted and accepted responsibility for conduct the government alleged in its complaints under the False Claims Act.

Source: <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2692-million-recovery-walgreens-two-civil-healthcare>



RELEVANT LAWS AND REGULATIONS

Consequences



Over the last two decades, the government has increased its investigation and prosecution of healthcare fraud, waste, and abuse.

The reason for this is simple.

It is estimated that the U.S. government recovers \$5 for every \$1 it spends fighting healthcare fraud.



RELEVANT LAWS AND REGULATIONS

Consequences



In 2018, there were over 330 federal prosecutions for fraud, waste, and abuse in the healthcare industry and \$2.3 billion was recovered.

Considering the government estimates that the true cost of healthcare fraud is closer to tens of billions each year, it is likely that the number of investigations will only increase. The government also has numerous specialized law enforcement task forces working on healthcare fraud issues including a Medicare and Medicaid Fraud task force.

For the healthcare industry, that means the likelihood of heightened scrutiny, investigations, prosecutions, and convictions.



RELEVANT LAWS AND REGULATIONS

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

Overview



In this section, we are going to look at how the government's fraud, waste, and abuse concerns have come to shape what we do and how we do it.

The topics below will be covered:

- Interactions with HCPs
- Other Potential Concerns
- How We Address These Concerns
- Particular Risks





THE IMPACT ON OUR BUSINESS

Interactions with Healthcare Professionals



Whether it is paying for a business meal, setting up a site visit, arranging a product discount, loaning a piece of equipment, or hiring an HCP to perform a service, nearly every transaction we have with an HCP 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.



THE IMPACT ON OUR 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. The government has a vested interest in ensuring that only appropriate support is offered to HCPs who prescribe a product or order a test to help to get the patient the best care.

For example, Abbott may be able to provide appropriate training on a product or service, but offering enhanced administrative support (e.g., billing support) for high-prescribing practices would be prohibited because such activities could inappropriately influence an HCP's prescribing decision.



THE IMPACT ON OUR BUSINESS

Interactions with Healthcare Professionals



We may not offer inappropriate incentives to influence purchasing or treatment decisions of HCPs either directly or indirectly. This means the government 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 IMPACT ON OUR BUSINESS

Interactions with Healthcare Professionals



These types of transactions are an integral part of what we do.

Providing training, for example, can help educate and inform HCPs and customers about the benefits, risks, and safe and effective use of our products.

Awarding research grants can lead to the discovery of valuable scientific and clinical information.

Even activities like taking HCPs to business meals can provide important opportunities to exchange educational, scientific, and business information.



THE IMPACT ON OUR BUSINESS

Interactions with Healthcare Professionals



However, these legitimate activities have also been used by some healthcare companies to mask or disguise otherwise inappropriate transactions.

Kickbacks, for example, have been offered under the guise of “consulting agreements.”

Discounts have been used to shift costs from one product to another.

Incentives, like lavish trips, have been offered under the guise of “product training.”



THE IMPACT ON OUR BUSINESS

Interactions with Healthcare Professionals



And so, the government asks questions to establish the legitimacy of nearly every transaction we engage in.

For example, in the case of an advisory board meeting that has been set up to gain expert advice on the marketing direction of a new product, they might ask:

- Is the meeting necessary?
- Have the consultants been hired based on their academic and clinical qualifications and expertise?
- Does the compensation offered represent fair market value?
- Is the venue conducive to communication?
- Are the meals modest by local standards?



THE IMPACT ON OUR BUSINESS

Interactions with Healthcare Professionals



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.

For example, an investigator who enrolls patients in a clinical trial for Abbott may also be an Abbott customer. She may be receiving samples from us. She may be our guest at business meals. She may even receive an educational grant from us.

As a result, the government does not differentiate between the different contexts in which we interact with HCPs.

If an HCP or customer uses, purchases, or recommends an Abbott product, all interactions with that HCP or customer may be subject to scrutiny. In the case of the clinical trial, the government wants to ensure that we chose the investigator because of her knowledge and expertise, and not because she will buy more product if she is our investigator.



THE IMPACT ON OUR BUSINESS

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.



THE IMPACT ON OUR BUSINESS

Other Potential Concerns



The FDCA lays out a complex regulatory framework that is designed to prevent off-label promotion of drugs and devices.

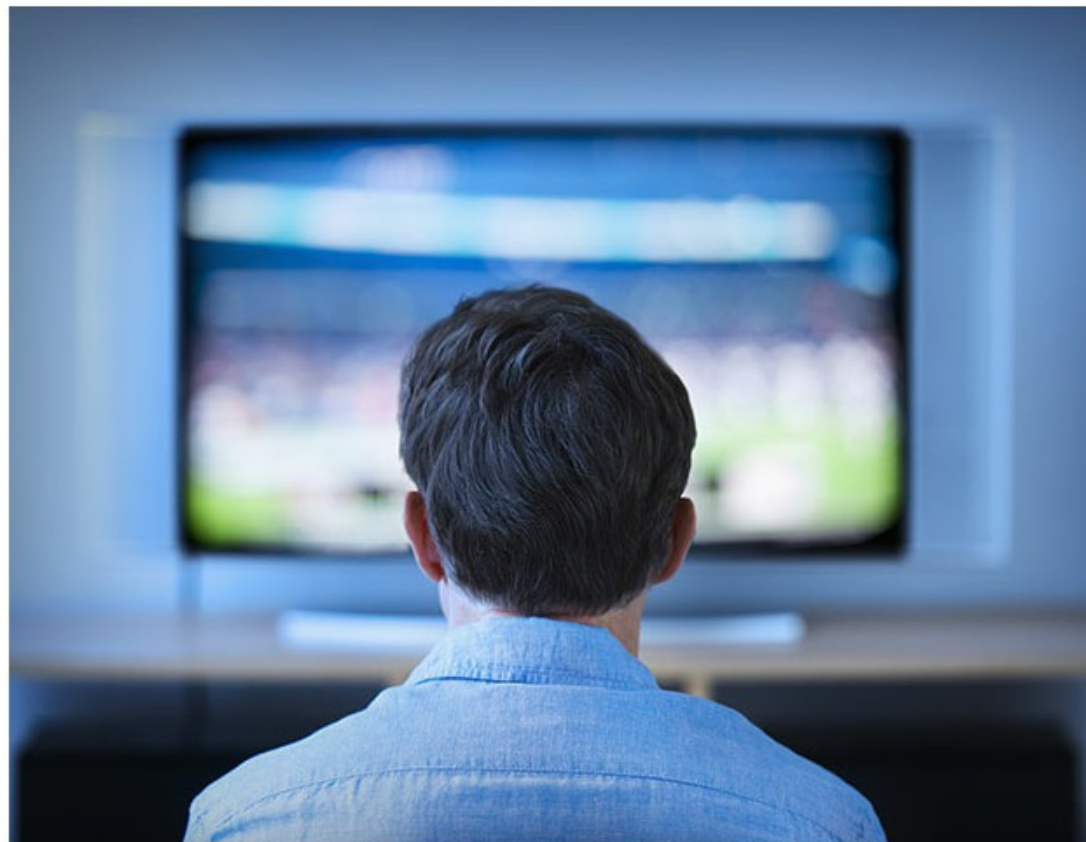
Promotional activities should be designed to be consistent with product labeling and approvals. For example, if a product is not approved for pediatric usage, sales and marketing activities should not be designed to focus on pediatric providers (i.e. sales representative call plans should not include pediatric providers; pediatric physicians should not be included in speakers bureau or invited to speaker programs).





THE IMPACT ON OUR BUSINESS

Other Potential Concerns



The FTC governs advertising directly to consumers and requires that it must be truthful and not misleading, and, when appropriate, backed by scientific evidence.

These laws and regulations apply regardless of where the ads appear – in print, TV, mail, the internet, or radio. The FTC looks closely at advertising claims that may impact a consumers' health such as claims about foods, dietary supplements, and infant formulas.





THE IMPACT ON OUR BUSINESS

Other Potential Concerns



In addition to facing steep fines and penalties for improper promotional activities, this conduct may also lead to allegations that a company caused the submission of false claims for its products.

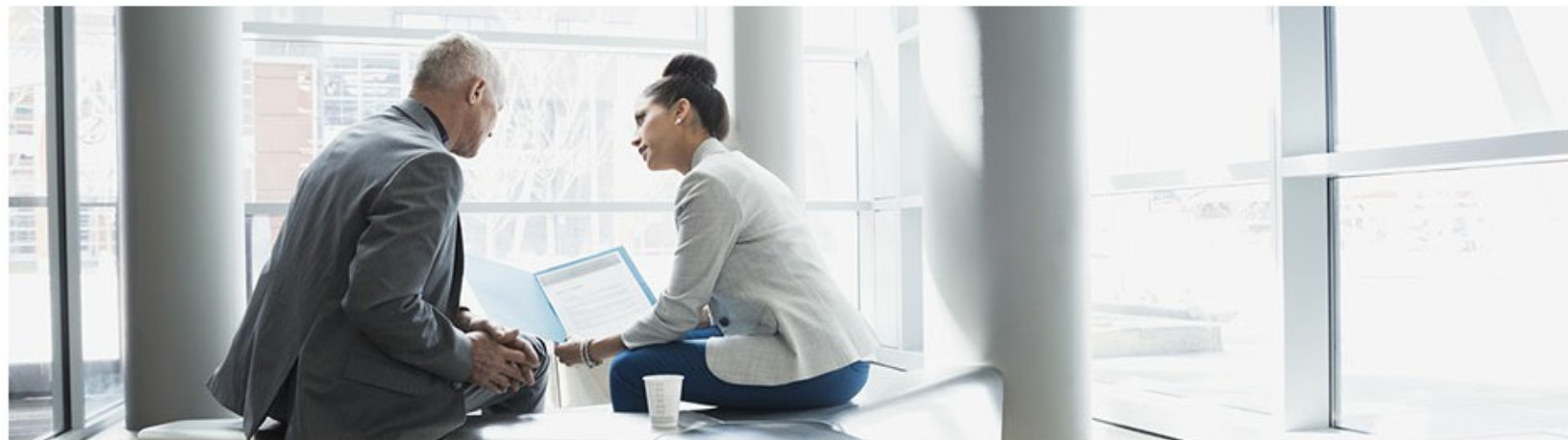
Promotional activities should be undertaken with appropriate care and caution to guard against any allegations that the claims made are misleading or not truthful.





THE IMPACT ON OUR BUSINESS

Other Potential Concerns



Contracting activities in the healthcare space are also heavily scrutinized by the government.

The government has laid out standards for providing appropriate discounts, rebates, and product bundling in its safe harbor provisions to the Anti-Kickback law.

Discounts and rebates provided to healthcare purchasers may be problematic if they don't meet the standards in the law. Products that are bundled together for a single price may be problematic if purchasers aren't given information about how to allocate the prices of each product properly so they can accurately report pricing information to the government.

We'll talk about some of the tools Abbott has available to address these and other concerns in the next section.





THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Customers, Retailers, Distributors, Patients, and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste, and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Healthcare Professional (HCP)



Healthcare Institution (HCI)



Government Official



Retailer



Distributor



Patient



Consumer



THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Custom Retailers, Distributors, Patients and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Healthcare Professional (HCP)

Any medically licensed or scientifically trained professional using or expected to use such license or training in his or her work providing health care (examples include physicians, pharmacists, nurses, researchers and laboratory staff), as well as any person making purchasing or usage decisions for an HCI (examples include administrators and purchasing personnel for medical facilities) about Abbott products. This definition applies no matter where the provision of health care occurs, whether in a private facility, or one owned by or affiliated with government. Some HCPs employed by public institutions may be considered Government Officials.





THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Custom Retailers, Distributors, Patient and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Healthcare Institution (HCI)

Any entity or facility, including any institution, foundation, association, or organization, which employs HCPs, or any site where HCPs provide health care to Patients. HCIs are often end purchasers or customer accounts for Abbott products used or prescribed by HCPs. Examples of HCIs include hospitals, group practices, surgical centers, public clinics, private clinics, and pharmacies which sell prescription Abbott products.





THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Custom Retailers, Distributors, Patient and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Government Official

Any person who is employed by an entity which is owned, controlled, funded or operated by any level of government in any country, as well as any person acting as a government agent or representative. Examples of Government Officials that are relevant to our businesses include public hospital purchasing managers, representatives from regulatory authorities and government departments, elected officials, and bureaucrats or administrators of government services, such as licensing, registration, customs and utilities.





THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Custom Retailers, Distributors, Patients and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Retailer

Any store or chain of affiliated stores that sells products to Patients and/or Consumers. Examples include market stalls, supermarkets/grocery stores, and retail pharmacies.





THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Custom Retailers, Distributors, Patient and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Distributor

Any third party who is engaged by Abbott to distribute and sell Abbott products. This category may include wholesalers and certain Retailers depending on the nature of the engagement and scope of activities performed for Abbott.





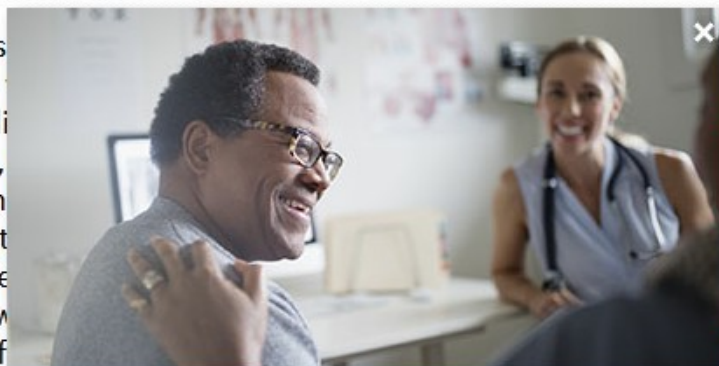
THE IMPACT ON OUR BUSINESS

How We Address These Concerns



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CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Patient

An individual person with any disease state or condition whose treatment requires prescription or decision-making by an HCP before an Abbott product can be dispensed or used. Examples include people whose medical conditions require prescription medication or surgical intervention.





THE IMPACT ON OUR BUSINESS

How We Address These Concerns



Abbott's USP&P, which covers routine business interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Custom Retailers, Distributors, Patient and Consumers, was developed to ensure that our interactions with HCPs and customers are free from the government's fraud, waste and abuse concerns.

CLICK ON EACH TERM TO SEE HOW IT'S DEFINED IN THE USP&P.



Consumer

A person who has purchased or may purchase an Abbott product that does not require a prescription.



THE IMPACT ON OUR BUSINESS

How We Address These Concerns



In this exercise, see if you can identify the requirements that Abbott has in place to address some of the government's fraud, waste, and abuse concerns.

SELECT A GOVERNMENT CONCERN IN THE FIRST COLUMN AND A MATCHING ABBOTT REQUIREMENT IN THE SECOND COLUMN.

GOVERNMENT CONCERNS		ABBOTT REQUIREMENTS	
Consulting meetings are being used to disguise otherwise improper payments.	<input type="radio"/>	<input type="radio"/>	Consultants must be selected based on relevant criteria such as qualifications and expertise.
Consultants are being selected based on sales.	<input type="radio"/>	<input type="radio"/>	Employees must ensure discounts are not offered to obtain business other than the contracted product/service.
Compensation does not represent fair market value for the services provided.	<input type="radio"/>	<input type="radio"/>	Employees must ensure that any discounts are documented in the contract and communicate to the customer his/her obligation to report them.
Lavish meals are being used as incentives.	<input type="radio"/>	<input type="radio"/>	Organizers must identify a clear business need for the meeting.
Discounts are not being disclosed or are being misrepresented.	<input type="radio"/>	<input type="radio"/>	Compensation must represent fair market value as determined by Abbott's fair market value tool.
Discounts are being used to shift costs.	<input type="radio"/>	<input type="radio"/>	Employees must ensure discounts do not encourage utilization beyond a customer's need.
Discounts are being structured in such a way that customers are encouraged to purchase more of the product than is necessary.	<input type="radio"/>	<input type="radio"/>	Meals must be modest by local standards.



THE IMPACT ON OUR BUSINESS

How We Address These Concerns



In this exercise, see if you can identify the requirements that Abbott has in place to address some of the government's fraud, waste, and abuse concerns.

SELECT A GOVERNMENT CONCERN IN THE FIRST COLUMN AND A MATCHING ABBOTT REQUIREMENT IN THE SECOND COLUMN.

GOVERNMENT CONCERNS

Consulting meetings are being used to disguise otherwise improper payments.

Consultants are being selected based on...

Compensation does not represent fair market value for the services provided.

Lavish meals are being used as incentives...

Discounts are not being disclosed or are being misrepresented.

Discounts are being used to shift costs.

Discounts are being structured in such a way that customers are encouraged to purchase more of the product than is necessary.

ABBOTT REQUIREMENTS

Consultants must be selected based on relevant criteria such as qualifications and expertise.

Employees must ensure discounts are not offered to obtain business other than the contracted product/service.

Employees must ensure that any discounts are documented in the contract and communicate to the customer his/her obligation to report them.

Organizers must identify a clear business need for the meeting.

Compensation must represent fair market value as determined by Abbott's fair market value tool.

Employees must ensure discounts do not encourage utilization beyond a customer's need.

Meals must be modest by local standards.

WELL DONE!

Please note: There are additional Abbott requirements for business meetings and product discounts. Please visit the USP&P for all requirements associated with business meetings.

SELECT THE FORWARD ARROW TO CONTINUE.





THE IMPACT ON OUR BUSINESS

How We Address These 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.





THE IMPACT ON OUR BUSINESS

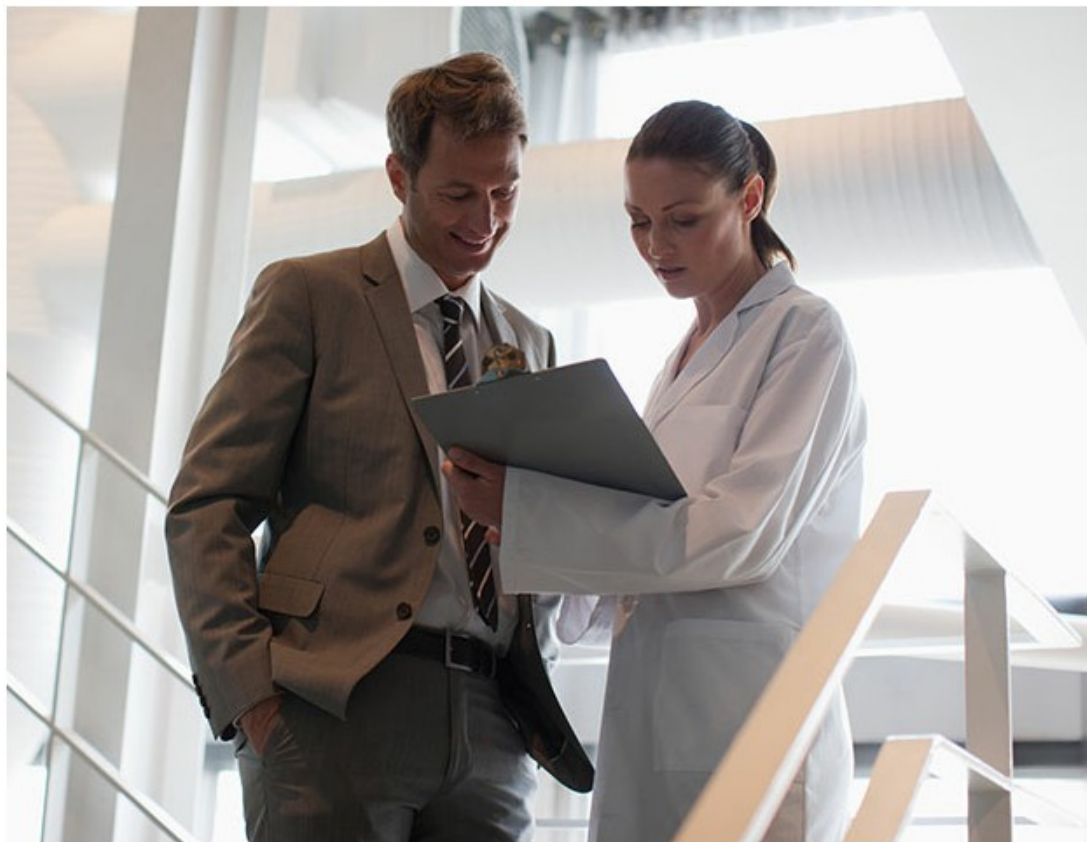
How We Address These Concerns



What is important to understand is that these “safe harbors” are almost always narrowly defined and that they require healthcare companies to meet very specific criteria.

These criteria have been woven into Abbott's USP&P – defining for us exactly what we can and cannot do.

As an Abbott employee, you must follow the USP&P and ask questions if you have any doubts about what is allowable.





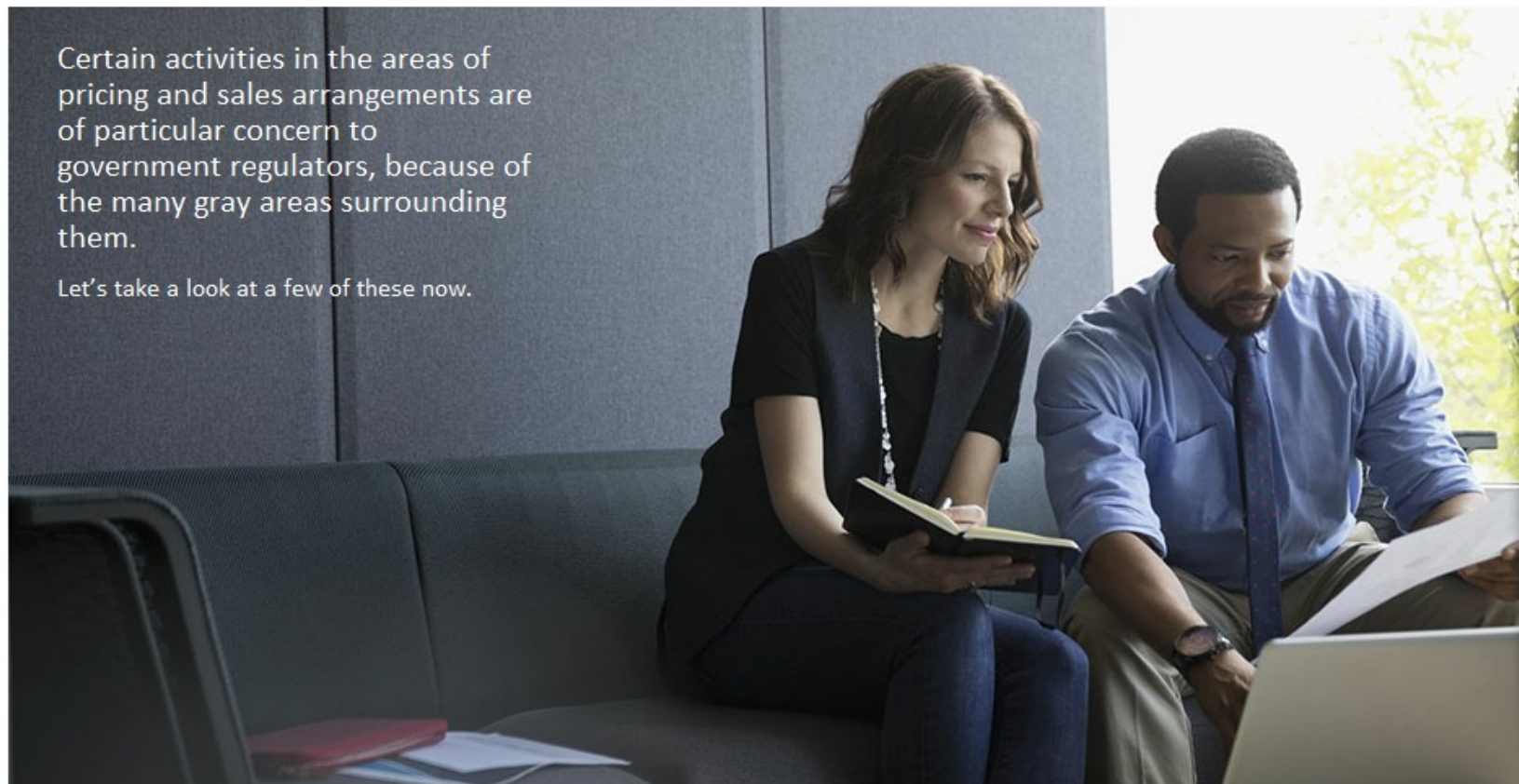
THE IMPACT ON OUR BUSINESS

Particular Risks



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

Let's take a look at a few of these now.





THE IMPACT ON OUR BUSINESS

Particular Risks



Imagine...

You are an account manager. The purchasing manager of a large hospital group whom you are currently supplying assays contacts you. The manager informs you that the group is looking to double the number of assays it is purchasing from you per month over the lifetime of their current contract. However, the account manager wants an additional 10% discount applied – and she wants it applied retrospectively.

Would it be okay to agree to this arrangement?

Yes

No



THE IMPACT ON OUR BUSINESS

Particular Risks



Imagine...

You are an account manager. The purchasing manager of a large hospital group whom you are currently supplying assays contacts you. The manager informs you that the group is looking to double the number of assays it is purchasing from you per month over the lifetime of their current contract. However, the account manager wants an additional 10% discount applied – and she wants it applied retrospectively.

Would it be okay to agree to this arrangement?

Yes

No

That's correct!

Abbott has very specific requirements regarding discounts and rebates based on the government's "safe harbor" regulations.

Pricing information, including any discounts or rebates, must be established prior to the first sale for which it applies.

This information must be detailed in the contract so that the customer can properly disclose and reflect such price reductions on any claims submitted to the government.

The company also must notify its customer that they have an obligation to report such price reductions to Medicare/Medicaid and other government healthcare programs.





THE IMPACT ON OUR BUSINESS

Particular Risks



Imagine...

You are an account manager. You meet with the sales manager of a large pharmacy chain to finalize a plan for the pharmacy to stock your continuous glucose monitor. The manager asks if you would be willing to pay him 15% for every customer he can switch to your product. When you tell him that Abbott does not allow "fee-for-switch" payments of this kind, he asks if Abbott would be willing to provide monetary assistance to train his customers on the appropriate use of your product.

You would like to finalize the contract today. Do you think it would be okay to agree to this arrangement?

Yes

No



Particular Risks



Imagine...

You are an account manager. You meet with the sales manager of a large pharmacy chain to finalize a plan for the pharmacy to stock your continuous glucose monitor. The manager asks if you would be willing to pay him 15% for every customer he can switch to your product. When you tell him that Abbott does not allow "fee-for-switch" payments of this kind, he asks if Abbott would be willing to provide monetary assistance to train his customers on the appropriate use of your product.

You would like to finalize the contract today. Do you think it would be okay to agree to this arrangement?

Yes

No

That's correct!

While Abbott employees are permitted to train customers on the appropriate use of a product, providing customers with payments for conversions from a competitive product will raise fraud and abuse concerns. The government has taken a much closer look at the relationship between pharmacies and organizations in a position to influence a patient's prescription. All fees paid to such organizations should be reviewed by the OEC and Legal.



THE IMPACT ON OUR BUSINESS

Particular Risks



Imagine...

You are negotiating with the purchasing manager of a hospital about the purchase of vascular devices and equipment for the hospital's heart failure center. The manager has requested a bulk discount which is outside Abbott's current discount guidelines. Instead you suggest that Abbott supplies the hospital with 10 iMacs, free of charge - all of which will be pre-loaded with the latest software to support the vascular devices.

Is there a problem with this arrangement?

Yes

No



Particular Risks



Imagine...

You are negotiating with the purchasing manager of a hospital about the purchase of vascular devices and equipment for the hospital's heart failure center. The manager has requested a bulk discount which is outside Abbott's current discount guidelines. Instead you suggest that Abbott supplies the hospital with 10 iMacs, free of charge - all of which will be pre-loaded with the latest software to support the vascular devices.

Is there a problem with this arrangement?

Yes

No

That's correct!

Transactions involving the sale of Abbott products that include either free or nominally priced goods or services, especially those that either are unrelated to the product (such as "frequent buyer" credits redeemable for personal benefit items) or can be used for multiple uses (such as free computers) may be problematic.

You should always consult with the Legal Division on how to structure transactions involving free goods and services to ensure the arrangements comply with the government's safe harbor regulations.



THE IMPACT ON OUR BUSINESS

Particular Risks



As we have just seen, transactions involving pricing and sales arrangements are complex, and often require detailed legal analysis.

If you are involved in pricing and sales arrangements, it is important that you stay within the specific parameters of what is allowed 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.



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.





OUR RESPONSIBILITIES

Overview



In this section, we will look at some simple things each of us can do to ensure we avoid violating fraud and abuse laws and regulations.

The topics below will be covered:

- General Principles
- Getting Support



OUR RESPONSIBILITIES

General Principles



As you have learned in this course, the government has an enormous stake in what we do and how we do it.

As a result, it scrutinizes most of the transactions we have with HCPs and customers.

It does this because it wants to make sure that these activities are not being used to inappropriately reward or buy business, which in turn could increase costs for the government.





OUR RESPONSIBILITIES

General Principles



As an Abbott employee, there are a few simple things you can do to avoid violating federal and state fraud and abuse laws and regulations.



OUR RESPONSIBILITIES

General Principles



When working with individuals who are in a position to purchase, use, prescribe, or recommend our company's products, carefully consider anything that you offer that might be interpreted as an attempt to improperly influence the decision to use our products.

Always follow the company's policies and procedures relating to transactions with HCPs and customers – even if you are not involved in sales and marketing-related activities.

These policies and procedures reflect up-to-date government guidance on what to do and what not to do to avoid violating fraud and abuse laws and regulations.





OUR RESPONSIBILITIES

General Principles



Never report or cause someone else to report inaccurate information about the actual costs of products and services they submit to the government.

Always disclose all discounts and other price reductions to customers, so that they can pass on appropriate discounts and reductions when submitting claims for reimbursement.





OUR RESPONSIBILITIES

General Principles



Always stay within the specific parameters of what has been defined as allowable by Abbott.

Never attempt to “legitimize” an otherwise unacceptable activity by merely renaming or categorizing the activity with the description of a practice covered by a “safe harbor.” For example, if an arrangement attempts to make an improper payment to a HCP in order to get them to recommend our product, disguising that payment as an additional discount on product purchases doesn’t ensure that the payment won’t be qualified as a kickback.

If you are unsure about what is allowable (especially in the area of pricing and sales arrangements), always speak to someone in the OEC or Legal before taking action.



OUR RESPONSIBILITIES

Getting Support



If you have a question or concern about a potential fraud, waste, or abuse violation, speak to your manager. Your manager knows you and your work environment and is closest to the issue.

You can also report your concern to the OEC (investigations@abbott.com) or Legal, or call our multilingual Ethics and Compliance Helpline available globally 24/7.



OUR RESPONSIBILITIES

Our Responsibilities: Quick Reference



Always stay within the specific parameters of what has been defined as allowable by Abbott.

GENERAL PRINCIPLES

When working with individuals who are in a position to purchase, use, prescribe, or recommend our company's products, carefully consider anything that you offer that might be interpreted as an attempt to improperly influence the decision to use our products. Always follow the company's policies and procedures relating to transactions with HCPs and customers – even if you are not involved in sales- and marketing-related activities. Never report or cause someone else to report inaccurate information about the actual costs of products and services they submit to the government. Always disclose all discounts and other price reductions to customers, so that they can pass on appropriate discounts and reductions when submitting claims for reimbursement. Always stay within the specific parameters of what has been defined as allowable by Abbott. If you are unsure about what is allowable (especially in the area of

pricing and sales arrangements), always speak to someone in the OEC or Legal before taking action.

GETTING SUPPORT

If you have a question or concern about a potential fraud, waste, or abuse violation, speak to your manager. Your manager knows you and your work environment and is closest to the issue. You can also report your concern to the OEC (investigations@abbott.com) or Legal, or call our multilingual Ethics and Compliance Helpline available globally 24/7.



RESOURCES

Where to Get Help



MANAGER

If you have a question or concern about a potential fraud, waste, or abuse violation, speak to your manager.



WRITTEN STANDARDS

- For our company's fundamental set of expectations about interactions with others, consult our [Code of Business Conduct](#).
- Consult Abbott's U.S. Ethics and Compliance Policy and Procedures (USP&P) for guidance on interactions with HCPs and other groups including Healthcare Institutions (HCIs), Government Officials, Customers, Retailers, Distributors, Patients, and Consumers.
 - Click [here](#) to access the USP&P located in iComply.



OFFICE OF ETHICS AND COMPLIANCE (OEC)

- The OEC is a corporate resource available to address your compliance questions or concerns, including fraud, waste, and abuse issues.
 - Visit the [Contact OEC](#) page on the [OEC website](#) on Abbott World.
- Visit our multilingual OEC Helpline at [speakup.abbott.com](#) to voice your concerns about potential fraud, waste, and abuse issues. The OEC Helpline is available 24 hours a day 7 days a week. You can also email investigations@abbott.com.



LEGAL DIVISION

If you have questions about laws and regulations that govern our relationships with customers and business partners, the Legal Division can assist you.

- Click [here](#) to access the Legal home page on Abbott World.



CENTERS FOR MEDICARE AND MEDICAID RESOURCES

- CMS Medicare Parts C and D General Compliance Training [Course](#).
- CMS Combating Medicare Parts C and D Fraud, Waste, and Abuse [Course](#).





RESOURCES

Reference Material



QUICK REFERENCE CARDS

Click [here](#) to review summaries of each section of this course.



COURSE TRANSCRIPT

Click [here](#) for a full transcript of the course.





KNOWLEDGE CHECK

Introduction



The Knowledge Check that follows consists of 10 questions. You must score 80% or higher to successfully complete this course.

If you haven't done so already, take a few minutes to review the Quick Reference Cards, which are available in the Resources section.

When you are ready, click the **Knowledge Check** button.

Knowledge Check





KNOWLEDGE CHECK

Question 1



Liu, an Abbott sales representative, is pressured by Dr. Collins, a customer, to pay an incentive to use her products. If Liu pays the incentive, who would most likely face prosecution under the Anti-Kickback law?

- ☐ 1. Liu.
- ☐ 2. Liu and Dr. Collins.
- ☐ 3. Liu, Dr. Collins, and Abbott.





KNOWLEDGE CHECK

Question 2



Under the False Claims Act, healthcare companies and their employees can face prosecution for which of the following?

Check all that apply.

- ☐ 1. Submitting or causing someone else to submit false information about the actual cost of the medicines, tests, and devices the government is reimbursing for.
- ☐ 2. Promoting products to HCPs for uses for which they have not been approved.
- ☐ 3. Offering illegal kickbacks to HCPs.





KNOWLEDGE CHECK

Question 3



A few months after a product training program, you conduct a return on investment analysis to see whether there have been any changes in the buying habits of the HCPs who were in attendance. Do you think this changes the way the government might view this activity?

- ☐ 1. Yes.
- ☐ 2. No.





KNOWLEDGE CHECK

Question 4



What concern(s) does the government have about discounts and other price reductions?

- ☐ 1. Discounts may be undisclosed.
- ☐ 2. Discounts may be misrepresented.
- ☐ 3. Discounts may be used to shift costs.
- ☐ 4. Discounts may be structured in such a way as to encourage customers to purchase more of a product than is necessary.
- ☐ 5. All of the above.





KNOWLEDGE CHECK

Question 5



Activities that are not sales or marketing-related are less likely to be fraud, waste, and abuse concerns for the government.

- ☐ 1. True.
- ☐ 2. False.





KNOWLEDGE CHECK

Question 6



Jason, a sales manager for Abbott Diagnostics, suggests that his team create information guides for its customers on how to maximize their federal reimbursement. One of Jason's sales representatives tells him the HCPs he has met with have been using this information to submit false claims to the government for reimbursement.

Could Abbott face liability under the False Claims Act for causing false claims to be submitted?

- ☐ 1. Yes.
- ☐ 2. No.





KNOWLEDGE CHECK

Question 7



Which of the following activities is never okay?

- ☐ 1. Hiring an HCP to advise Abbott on the scientific merits of a product or medical device.
- ☐ 2. Providing discounts or rebates to a customer without detailing them in the contract.
- ☐ 3. Paying for a modest meal for an HCP as part of a business discussion.
- ☐ 4. Arranging for an appropriate charitable contribution.





KNOWLEDGE CHECK

Question 8



Which of the following activities in the area of pricing and sales arrangements are of particular risk to Abbott, because of the many gray areas surrounding them?

Check all that apply.

- ☐ 1. Discounts and rebates.
- ☐ 2. Providing free goods and support services.
- ☐ 3. Payments for conversions from a competitive product.





KNOWLEDGE CHECK

Question 9



The purchasing manager of a hospital group requests an increase of the discount earned by the group on Product A. Unfortunately, given Abbott's current discount guidelines, you are unable to increase the discount to a level that you think will please the purchasing manager. So, you decide to offer a discount on another product – Product B – as this will help to lower the group's overall costs. Is this okay?

- ☐ 1. Yes.
- ☐ 2. No.





KNOWLEDGE CHECK

Question 10



An Abbott Diabetes Care marketing manager suggests implementing a program that pays \$50 to pharmacists every time they get a customer to switch from a competitor's continuous glucose monitor to an Abbott continuous glucose monitor.

Which of the following statements is false?

- ☐ 1. This program could interfere with the pharmacists' medical decision making.
- ☐ 2. This program may encourage the purchase of a product reimbursed by a federal health care program.
- ☐ 3. The payments are permitted because switching benefits all parties.
- ☐ 4. This program probably violates the Anti-Kickback law.

ALL QUESTIONS REMAIN UNANSWERED

Submit

