
Johnson & Johnson

International Health Care Business Integrity
for Third Party Intermediaries



Welcome

This is the compliance learning module on Johnson & Johnson's International Health Care Business Integrity for Third Party Intermediaries.

This training is intended for principals and employees of Third Party Intermediaries (TPIs) who interact with Health Care Professionals (HCPs) or Government Officials (GOs) on behalf of a Johnson & Johnson Company. This module will help you understand and comply with the applicable Johnson & Johnson policies so that:

- Your interactions with HCPs are focused on the benefits that Johnson & Johnson products bring to patients
- Your interactions with GOs are legally compliant, ethical, and trustworthy



Learning Objectives

After you complete this training module, you should be able to:



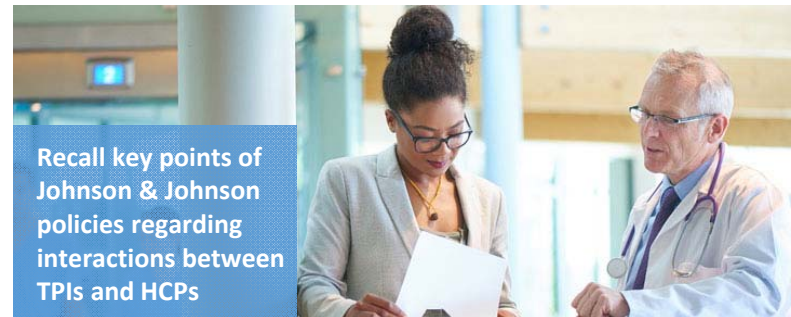
Describe the compliance obligations of Johnson & Johnson Companies and their TPIs regarding anti-corruption and anti-bribery laws concerning GOs



List Johnson & Johnson policy requirements for TPIs that interact with HCPs or GOs



Identify TPIs, GOs, and HCPs



Recall key points of Johnson & Johnson policies regarding interactions between TPIs and HCPs



Explain key anti-bribery and anti-corruption concepts



Recall key points of Johnson & Johnson policies regarding interactions between TPIs and GOs

Our Obligation to Comply With All Laws

Johnson & Johnson Companies and any third parties acting on their behalf must comply with the laws of the countries in which they do business, including anti-bribery and anti-corruption laws.

Johnson & Johnson has more than 265 companies operating in 60 countries. Nearly all of these countries have their own laws:

- Containing anti-bribery and anti-corruption provisions concerning GOs
- Prohibiting bribery in the private sector

Because Johnson & Johnson is a US-based company, Johnson & Johnson and its affiliates, regardless of where they are located globally, are subject to US anti-bribery and anti-corruption laws, in addition to any local laws.



Important Roles

In order to comply with applicable laws and Johnson & Johnson policies, it's important that you understand how three key roles are defined.



Third Party Intermediaries (TPIs)

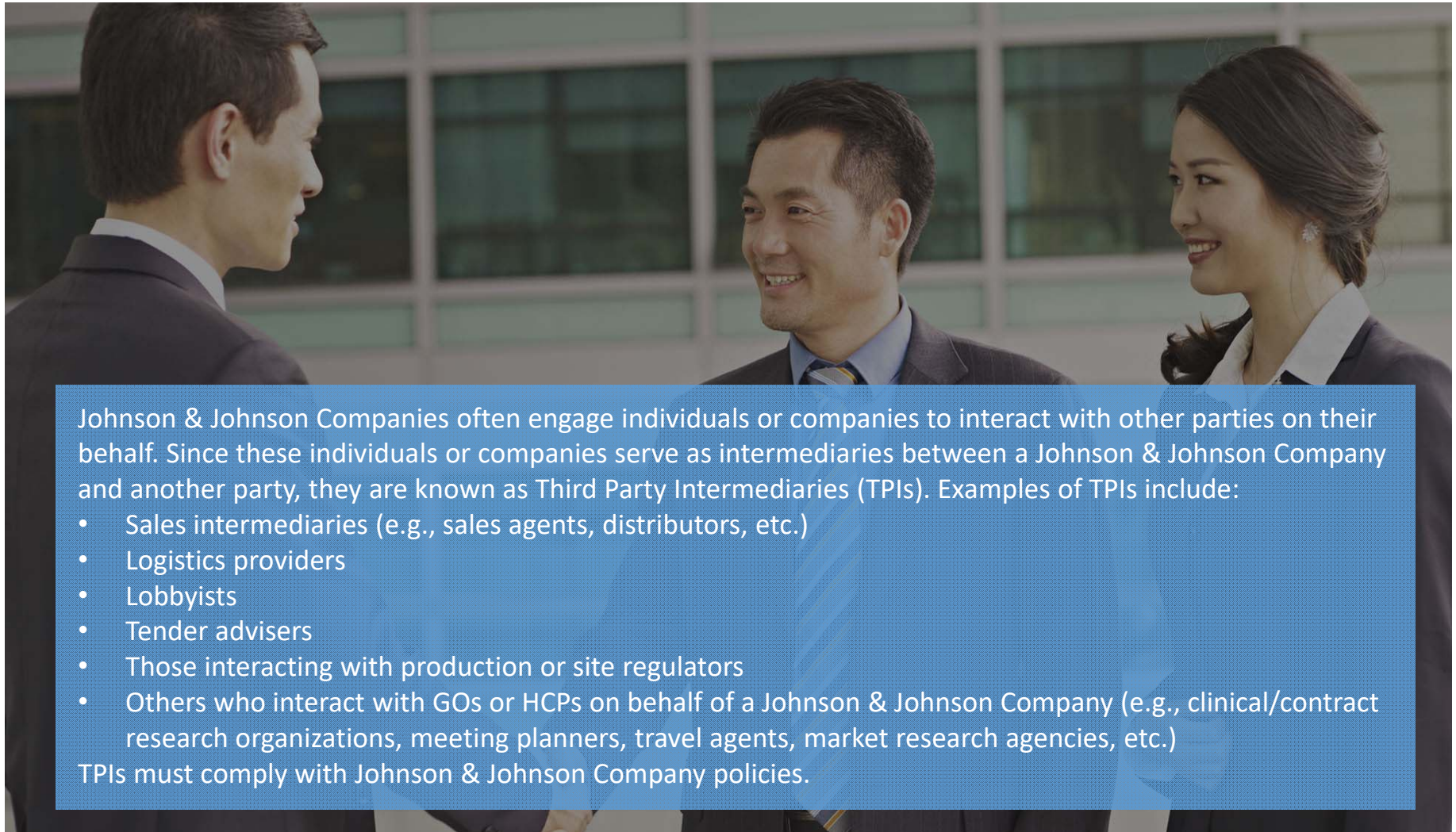


Health Care Professionals (HCPs)



Government Officials (GOs)

Important Roles - Third Party Intermediaries (TPIs)

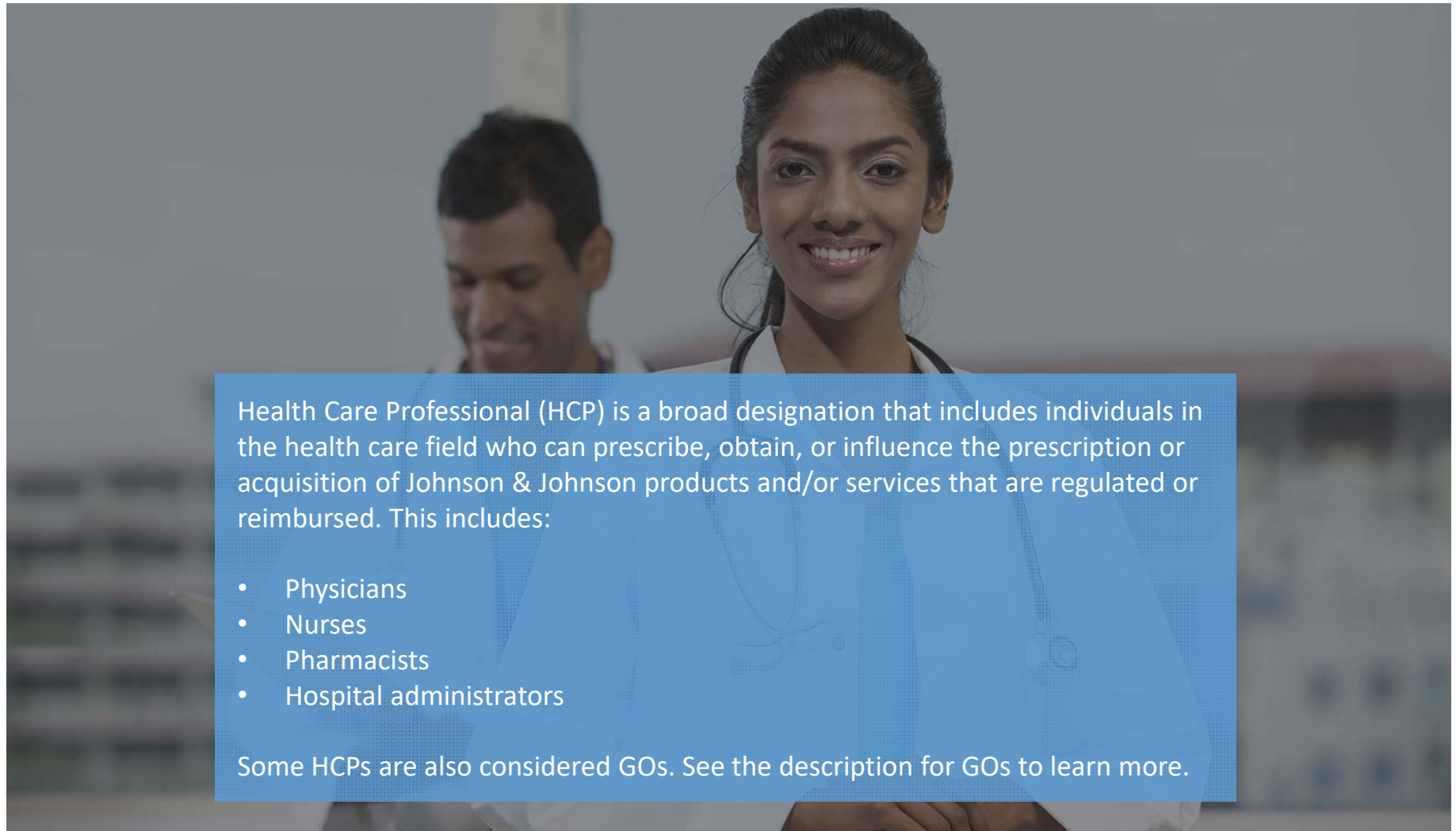


Johnson & Johnson Companies often engage individuals or companies to interact with other parties on their behalf. Since these individuals or companies serve as intermediaries between a Johnson & Johnson Company and another party, they are known as Third Party Intermediaries (TPIs). Examples of TPIs include:

- Sales intermediaries (e.g., sales agents, distributors, etc.)
- Logistics providers
- Lobbyists
- Tender advisers
- Those interacting with production or site regulators
- Others who interact with GOs or HCPs on behalf of a Johnson & Johnson Company (e.g., clinical/contract research organizations, meeting planners, travel agents, market research agencies, etc.)

TPIs must comply with Johnson & Johnson Company policies.

Important Roles - Health Care Professionals (HCPs)

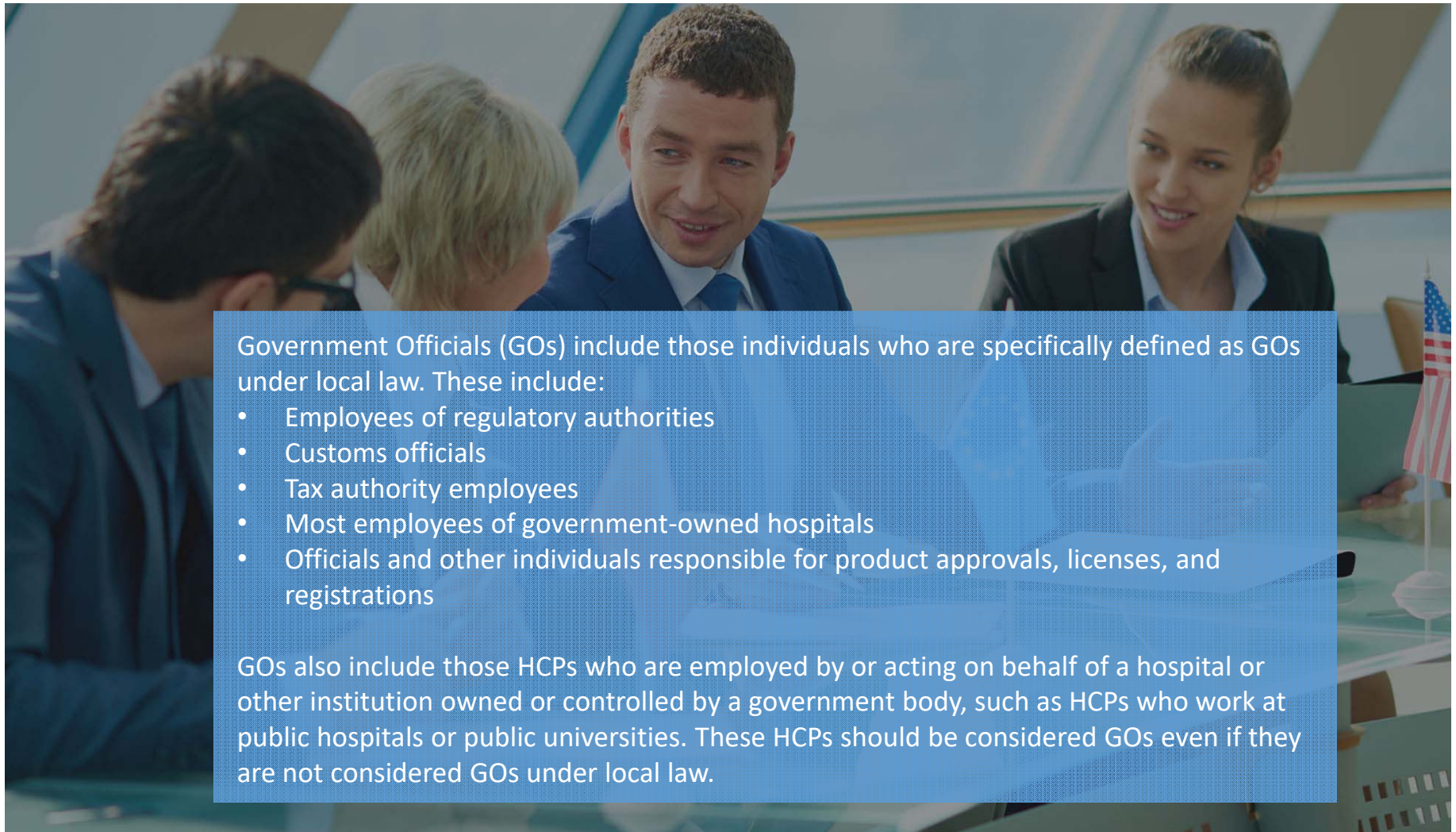


Health Care Professional (HCP) is a broad designation that includes individuals in the health care field who can prescribe, obtain, or influence the prescription or acquisition of Johnson & Johnson products and/or services that are regulated or reimbursed. This includes:

- Physicians
- Nurses
- Pharmacists
- Hospital administrators

Some HCPs are also considered GOs. See the description for GOs to learn more.

Important Roles - Government Officials (GOs)



Government Officials (GOs) include those individuals who are specifically defined as GOs under local law. These include:

- Employees of regulatory authorities
- Customs officials
- Tax authority employees
- Most employees of government-owned hospitals
- Officials and other individuals responsible for product approvals, licenses, and registrations

GOs also include those HCPs who are employed by or acting on behalf of a hospital or other institution owned or controlled by a government body, such as HCPs who work at public hospitals or public universities. These HCPs should be considered GOs even if they are not considered GOs under local law.

How Compliance Applies to TPIs

Under anti-bribery and anti-corruption laws, a Johnson & Johnson Company may be held responsible if a TPI:

- offers or pays a bribe, or
- offers or provides some other item of value to or for the benefit of a GO when it tries to sell Johnson & Johnson products or services, or when it tries to influence a government to benefit a Johnson & Johnson Company.

This is why Johnson & Johnson policy strictly prohibits its TPIs from offering or paying anything of value to any HCP or GO in an attempt to influence that person's decision (e.g., to purchase Johnson & Johnson products, approve a product, approve a product registration, etc.).



Knowledge Check

Let's take a moment to see how well you can identify HCPs and GOs. Indicate whether each of the following individuals is an HCP, a GO, or both by selecting the appropriate check boxes.

HCP	GO	Individual
<input type="checkbox"/>	<input type="checkbox"/>	A pharmacist working at a private hospital
<input type="checkbox"/>	<input type="checkbox"/>	An administrator working at a public hospital
<input type="checkbox"/>	<input type="checkbox"/>	A customs agent
<input type="checkbox"/>	<input type="checkbox"/>	A physician in private practice who also teaches at a government-owned institution on the weekends

Knowledge Check – Correct Response

Indicate whether each of the following individuals is an HCP, a GO, or both by selecting the appropriate check boxes.

HCP	GO	Individual
<input checked="" type="checkbox"/>	<input type="checkbox"/>	A pharmacist working at a private hospital
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	An administrator working at a public hospital
<input type="checkbox"/>	<input checked="" type="checkbox"/>	A customs agent
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	A physician in private practice who also teaches at a government-owned institution on the weekends

The correct choices are shown.

What Does a Violation Look Like?

One or more US anti-bribery or anti-corruption laws are violated when a **covered person** (such as a Johnson & Johnson Company or its TPIs) offers or gives **something of value** either **directly or indirectly** (such as through a third-party sales intermediary) to a **foreign official** to **obtain or retain business** with **corrupt intent**.

In this section, you'll learn the meaning of each of these highlighted terms.

Who Is a Covered Person?

Under US anti-bribery and anti-corruption legislation, **covered persons** include:

- Issuers of registered securities in the US
- All US citizens, residents, companies, and foreign branches of US companies, including foreign employees and foreign agents or distributors
- Foreign companies or individuals who participate in acts of corruption while in the US



What Is Something of Value?

Something of value includes ANY benefit offered or provided to a recipient.

Examples include:

- Cash, reimbursements, extravagant hosted travel, or non-monetary gifts provided to an official
- Scholarships or charitable contributions made in an official's name
- Benefits given to a private person or entity at the instruction of an official



This definition applies to actions taken in support of a corrupt payment, and not just to the payment itself.

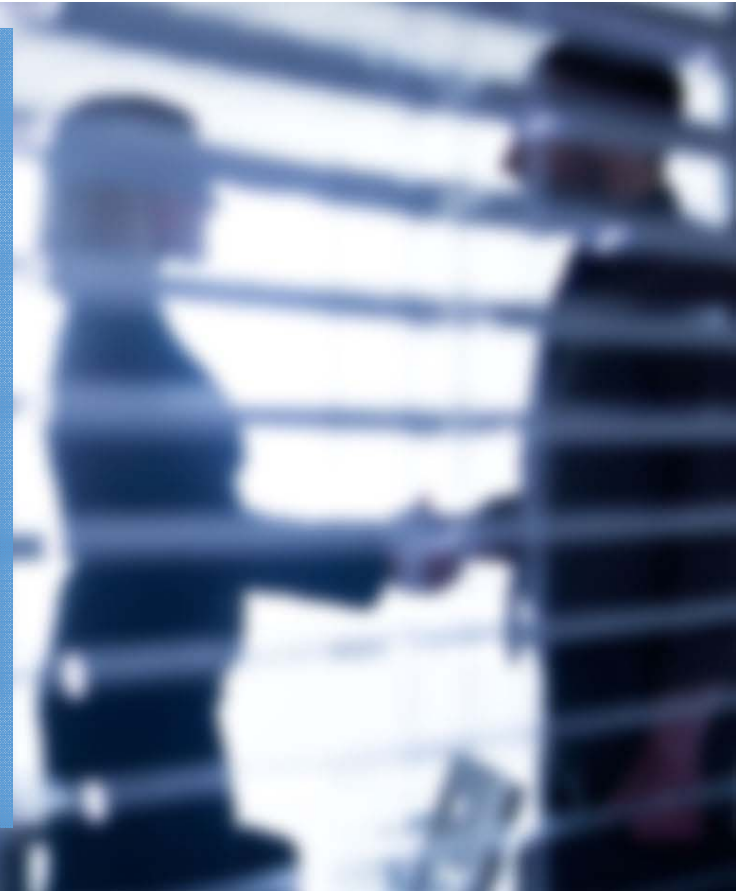
What Is Direct or Indirect Knowledge?

A covered person is prohibited from making payments or offers/promises to pay any person while knowing all or part of that payment will be given **directly or indirectly** to any foreign official in an attempt to influence that official's actions.

Knowing means:

- Actual awareness
- A firm belief as to the existence of such circumstance, or that such circumstance will occur
- A high probability of the existence of such circumstance, unless the person “actually believes that such circumstance does not exist”

Willful blindness means the conscious disregard or deliberate ignorance of known circumstances that should alert one to anti-bribery and anti-corruption violations. Willful blindness is a violation of US anti-bribery and anti-corruption laws.



Who Is a Foreign Official?

GOs from outside of the US (OUS) are considered **foreign officials**.

At all levels, the term “foreign official” is very broadly defined to include:

- International organizations, political candidates and parties, government owned or controlled commercial enterprises, and government employees
- Private persons acting in an official capacity, including ceremonial advisors and consultants
- GOs who work in the health care field, such as physicians, nurses, pharmacists, and purchasing officers employed by government-controlled hospitals or universities

This broad definition is applied by US law enforcement officials even if local laws do not consider these same individuals to be GOs.



Is the Payment to Obtain or Retain Business?

Payments made to or for the benefit of a foreign official and/or his or her family to **obtain or retain business** are NOT permitted if those payments are intended to:

- Influence an official act or decision
- Induce an official to perform, or not perform, acts in violation of official duties
- Secure an improper advantage
- Induce an official to influence acts of government

Such payments can violate anti-bribery and anti-corruption laws even if they are not related to a specific business opportunity.

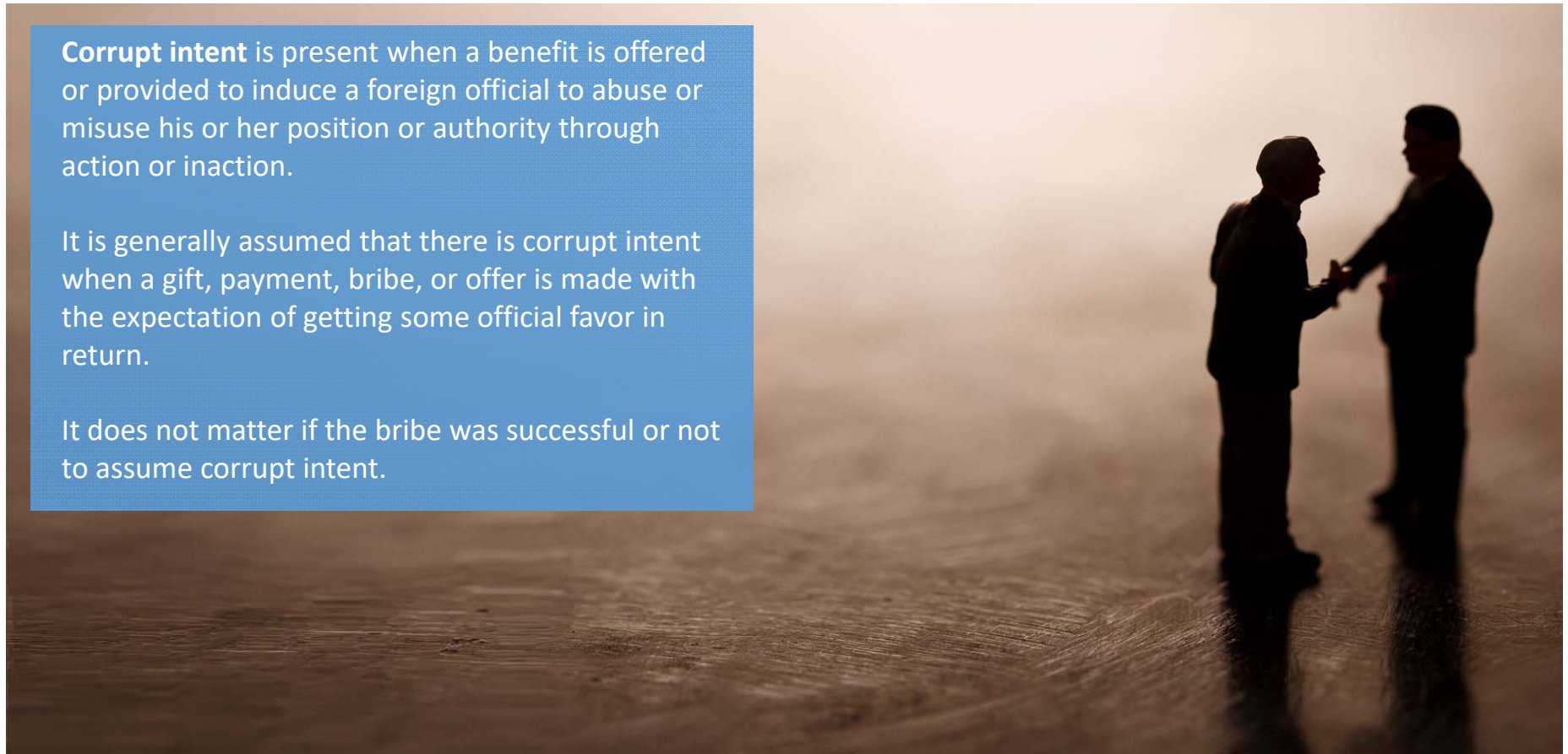


Is There Corrupt Intent?

Corrupt intent is present when a benefit is offered or provided to induce a foreign official to abuse or misuse his or her position or authority through action or inaction.

It is generally assumed that there is corrupt intent when a gift, payment, bribe, or offer is made with the expectation of getting some official favor in return.

It does not matter if the bribe was successful or not to assume corrupt intent.



Knowledge Check

Here is a brief review exercise. According to US anti-bribery and anti-corruption legislation, which of the following statements are true? Indicate the true statements by selecting their check boxes in the True column.

TRUE

Statements

A foreign employee of a US company is not a covered person.

“Something of value” includes charitable contributions made in an official’s name.

Willful blindness to bribery or corruption is a violation of US anti-bribery and anti-corruption legislation.

A physician working at a government-controlled university outside the US is considered a foreign official.

A bribe must be successful to be a violation of US anti-bribery or anti-corruption legislation.

Knowledge Check – Correct Response

Here is a brief review exercise. According to US anti-bribery and anti-corruption legislation, which of the following statements are true? Indicate the true statements by selecting their check boxes in the True column.

TRUE	Statements
<input type="checkbox"/>	A foreign employee of a US company is not a covered person.
<input checked="" type="checkbox"/>	“Something of value” includes charitable contributions made in an official’s name.
<input checked="" type="checkbox"/>	Willful blindness to bribery or corruption is a violation of US anti-bribery and anti-corruption legislation.
<input checked="" type="checkbox"/>	A physician working at a government-controlled university outside the US is considered a foreign official.
<input type="checkbox"/>	A bribe must be successful to be a violation of US anti-bribery or anti-corruption legislation.

The correct choices are shown.

Obligations of TPIs

Third parties that interact or transact business with GOs or HCPs on behalf of a Johnson & Johnson Company must satisfy the requirements below.



Undergo due diligence



Anti-corruption Training



Keep accurate books and records

Obligations of TPIs – Due Diligence

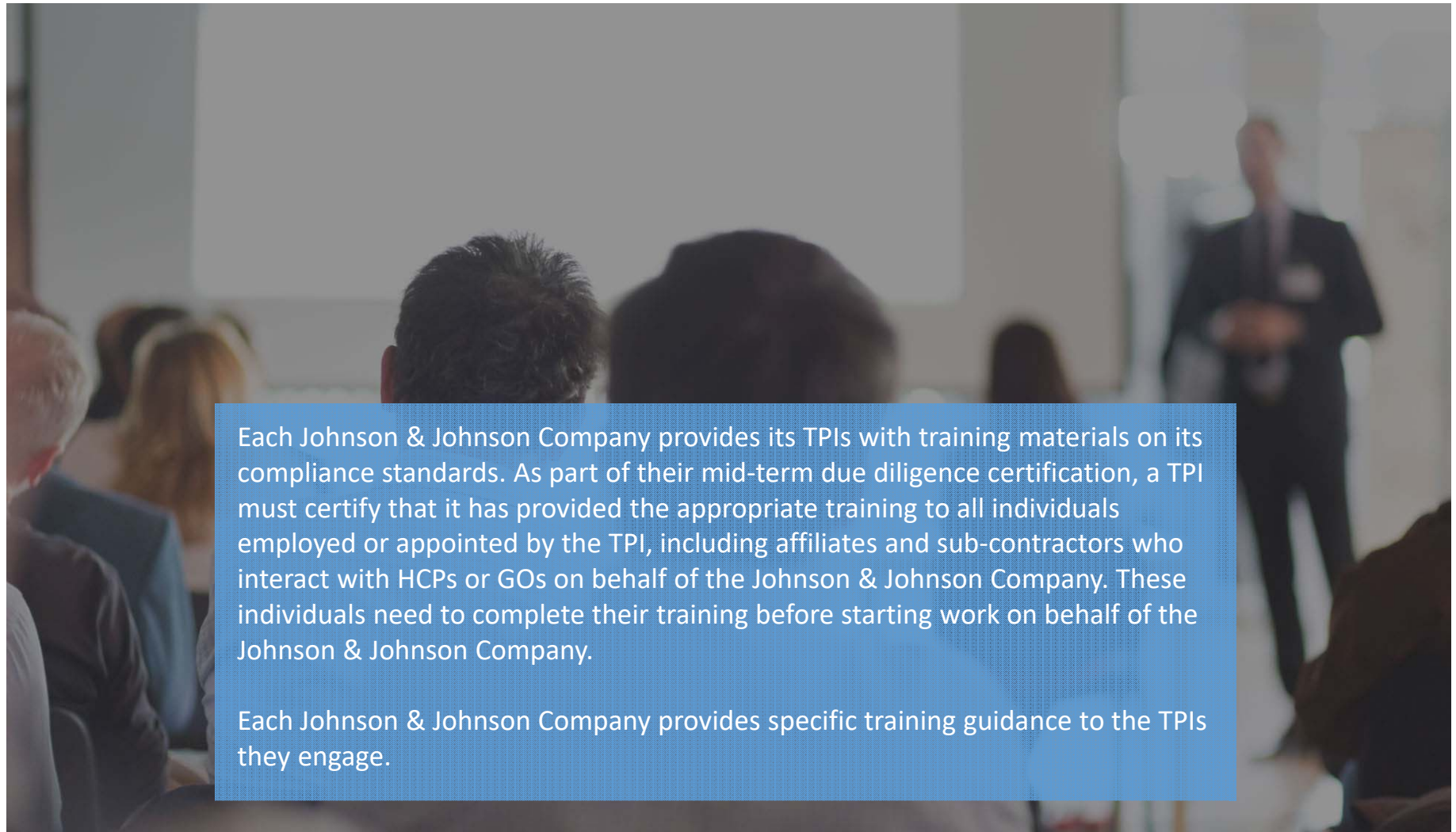
All TPIs engaged by Johnson & Johnson Companies are selected following a thorough, documented due diligence process. Due diligence also occurs for contract changes and, potentially, for sub-intermediaries.

As part of this process, Johnson & Johnson Companies document their relationships with TPIs in written agreements that include appropriate representations by the TPI concerning compliance with:

- All applicable anti-bribery and anti-corruption laws
- The rights of Johnson & Johnson Companies to audit books and records related to services provided
- The rights of Johnson & Johnson Companies to terminate the agreement for violation of any anti-bribery or anti-corruption laws

Each Johnson & Johnson Company provides specific due diligence instructions to the TPIs they engage.

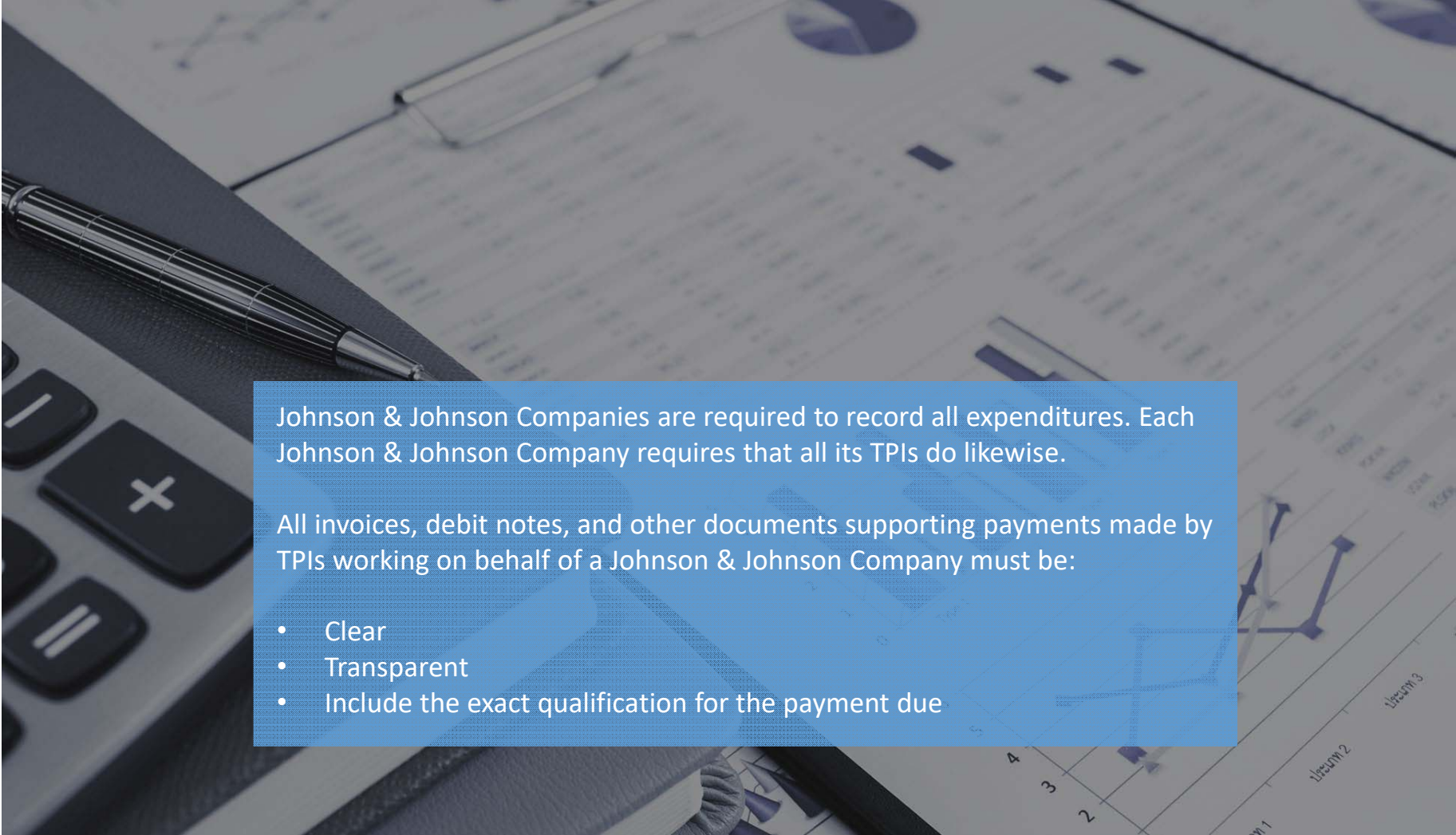
Obligations of TPIs – Anti-corruption Training



Each Johnson & Johnson Company provides its TPIs with training materials on its compliance standards. As part of their mid-term due diligence certification, a TPI must certify that it has provided the appropriate training to all individuals employed or appointed by the TPI, including affiliates and sub-contractors who interact with HCPs or GOs on behalf of the Johnson & Johnson Company. These individuals need to complete their training before starting work on behalf of the Johnson & Johnson Company.

Each Johnson & Johnson Company provides specific training guidance to the TPIs they engage.

Obligations of TPIs – Books & Records



Johnson & Johnson Companies are required to record all expenditures. Each Johnson & Johnson Company requires that all its TPIs do likewise.

All invoices, debit notes, and other documents supporting payments made by TPIs working on behalf of a Johnson & Johnson Company must be:

- Clear
- Transparent
- Include the exact qualification for the payment due

Johnson & Johnson Policies on HCP Interactions

TPIs who interact with HCPs on behalf of a Johnson & Johnson Company must understand and comply with the Johnson & Johnson Company's policies concerning HCPs and:

- Fee-for-service contracting
- Meals, travel, lodging, and other hospitality
- Provision of gifts and other items of value

This section covers the key points of these policies.

Note: TPIs also need to understand and comply with any other policies that may be communicated to them by a Johnson & Johnson Company.



Knowledge Check

Here's a question about HCP fee-for-service arrangements. Assume for a moment that a Johnson & Johnson Company has asked you to line up an HCP to act as a program speaker. What do you think are valid reasons for engaging an HCP to be a speaker?

- The HCP is qualified to speak on the topic.
- You want to encourage the HCP to prescribe Johnson & Johnson products more often.
- The HCP typically prescribes Johnson & Johnson products, and you want to recognize the HCP for it.
- There is a genuine business need for the HCP's speaking service.

Knowledge Check

Here's a question about HCP fee-for-service arrangements. Assume for a moment that a Johnson & Johnson Company has asked you to line up an HCP to act as a program speaker. What do you think are valid reasons for engaging an HCP to be a speaker?



The HCP is qualified to speak on the topic.



You want to encourage the HCP to prescribe Johnson & Johnson products more often.



The HCP typically prescribes Johnson & Johnson products, and you want to recognize the HCP for it.



There is a genuine business need for the HCP's speaking service.

The correct choices are shown.

Fee-for-Service Arrangements with HCPs

Fee-for-service arrangements with HCPs (such as agreements to serve as speakers, advisory board members, training consultants, etc.) should have legitimate, documented business needs and never be made with the intent to provide compensation or remuneration in exchange for business—actual or expected.

- Services should be documented in a detailed agreement that specifies the complete compensation package. (See your Johnson & Johnson Company contact for examples.)
- Compensation should be at fair market value for the services provided.
- Services performed must be documented before payment is made.
- Invoices should be detailed enough to enable proper recordkeeping and auditing.
- Associated travel, lodging, and meal expenses should be reasonable, not excessive, and not include side trips, unrelated trip extensions, or individuals who are not providing services to Johnson & Johnson.



Scenario 1

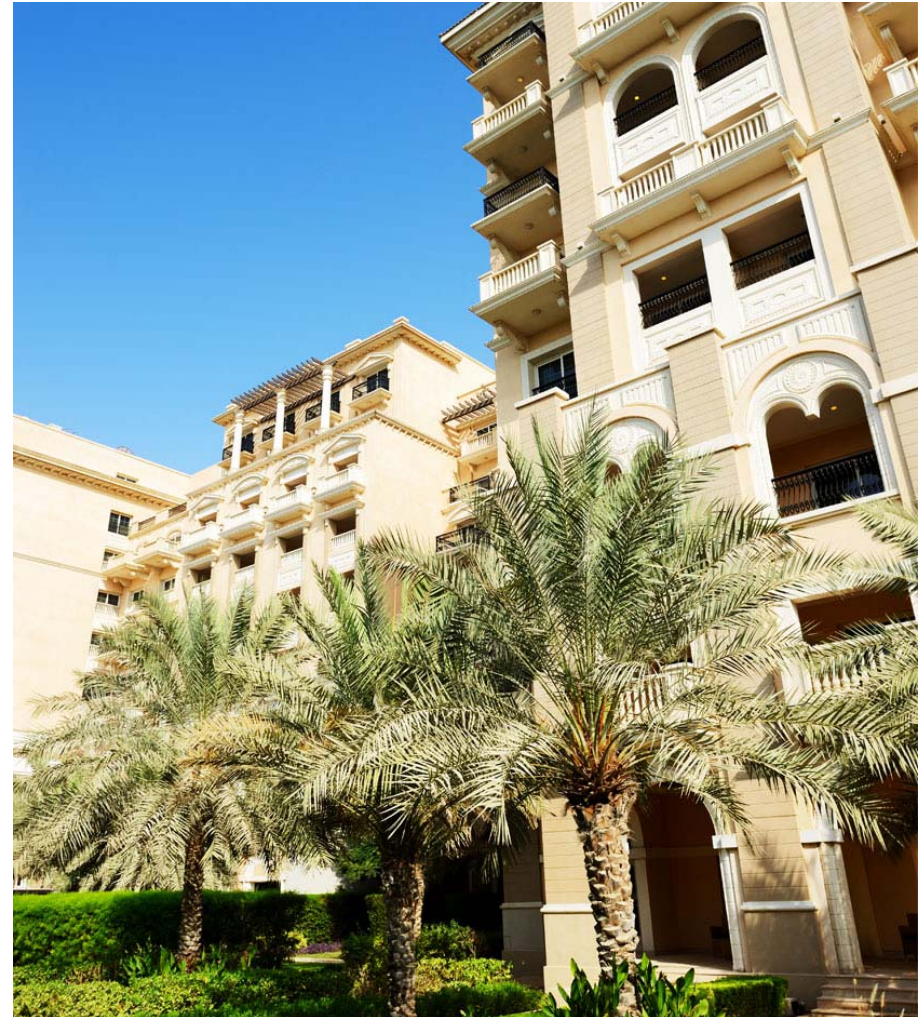
Scenario

Response

What about meal and accommodation planning for HCPs? Suppose a Johnson & Johnson Company has asked you to coordinate a training session for an HCP on a new surgical technique. The HCP is the number one cardiac surgeon in the country. You happen to know that this surgeon likes to stay in a nearby luxury resort. However, the resort's room rates are higher than Johnson & Johnson's guidelines for HCP lodging expenses.

What should you do?

Proceed to the next slide to review answer choices.



Scenario 1

Scenario

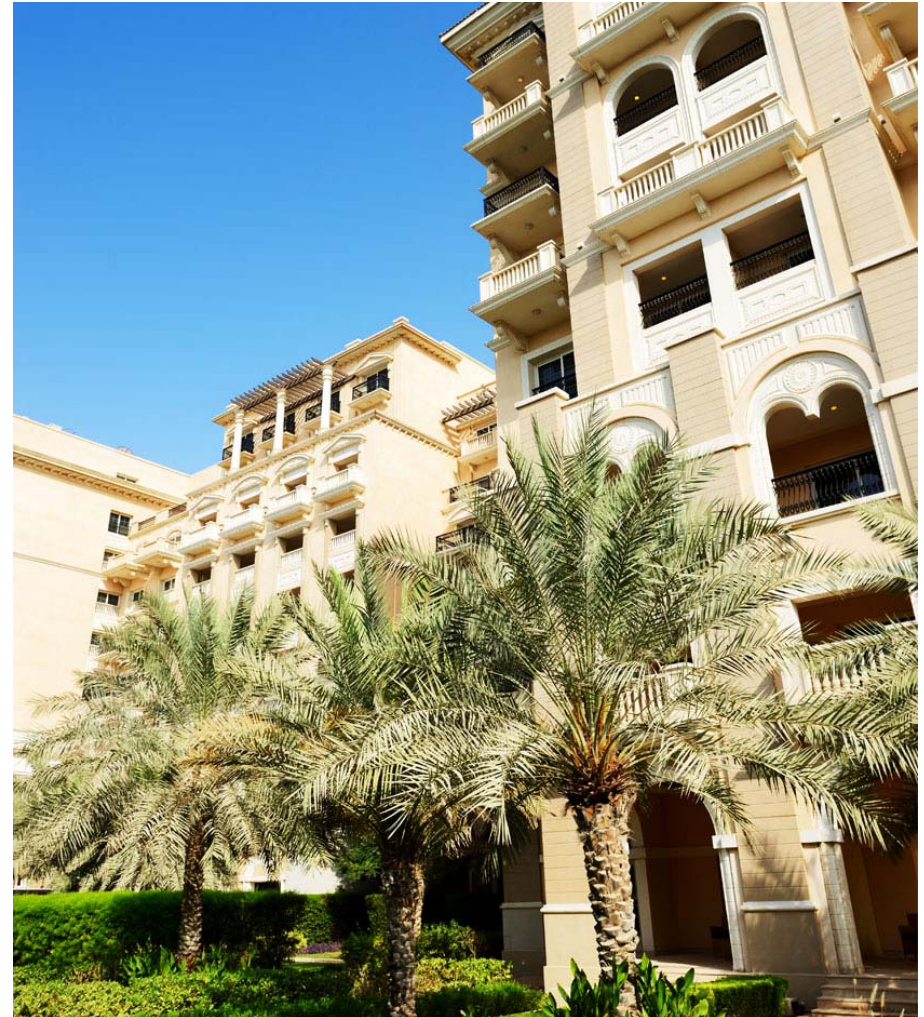
Response

Which of the following actions do you think would be acceptable? Select all that apply.

- Book the surgeon in another hotel with rates that fall within Johnson & Johnson guidelines
- Book the surgeon in the resort even though its rates exceed Johnson & Johnson guidelines
- Book the surgeon in the resort and pay the difference between Johnson & Johnson's guidelines and the resort's rate out of your own pocket

Return to the previous slide if you would like to review the scenario.

Proceed to the next slide to review feedback.

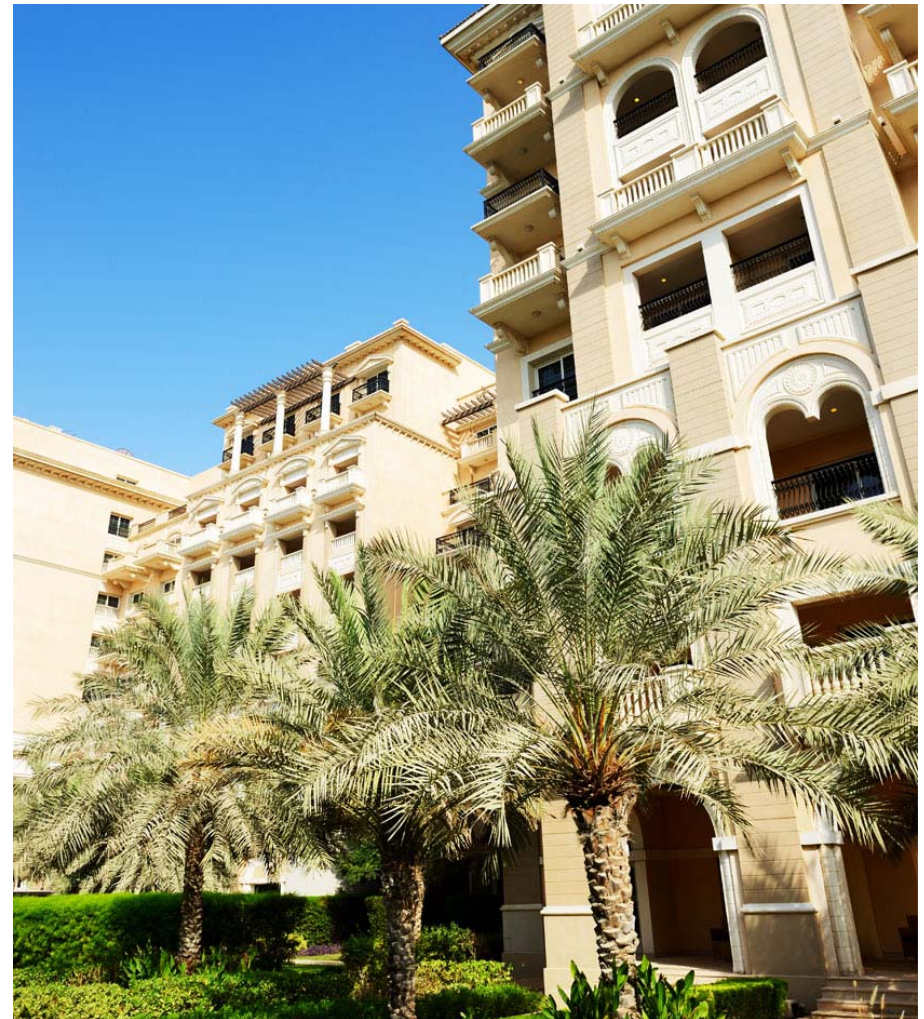


Scenario 1

FEEDBACK

The only correct action is to book the surgeon in another hotel with rates that fall within Johnson & Johnson guidelines.

If you'd like to review the scenario, return to the previous slides.



Scenario 2

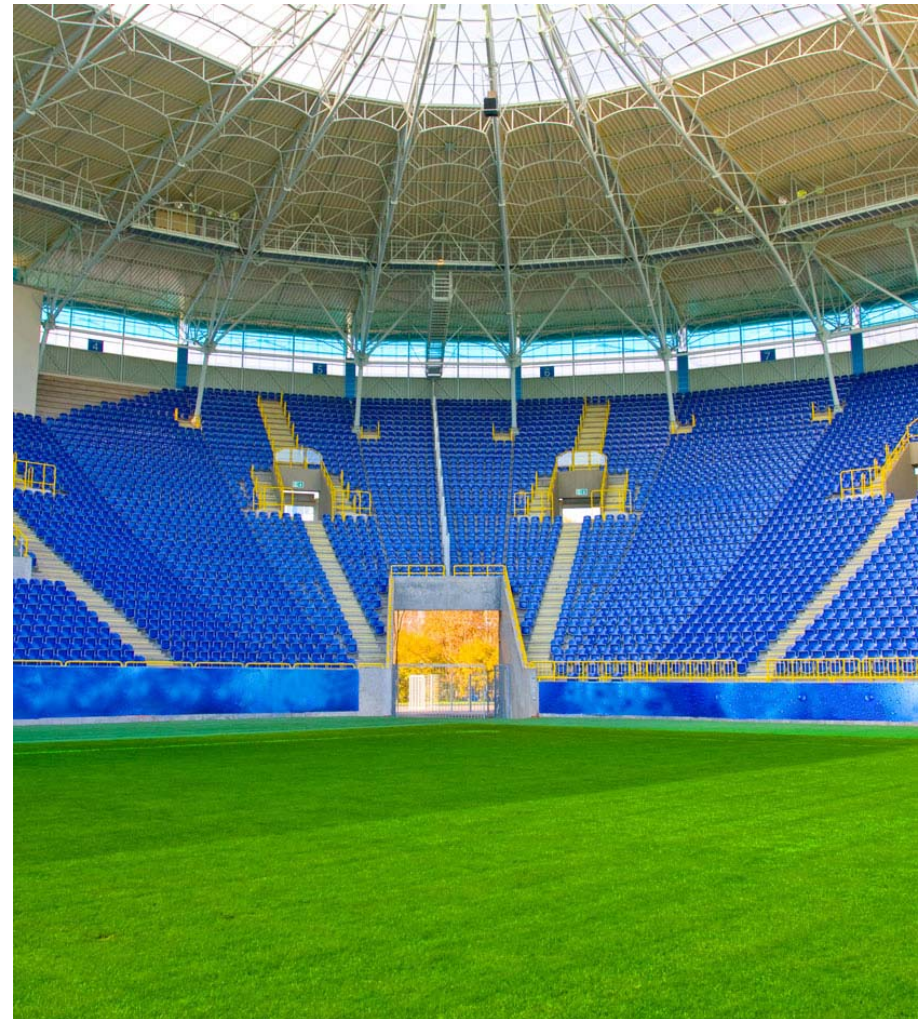
Scenario

Response

Let's look at another scenario involving meal and accommodation planning for an HCP. Suppose a Johnson & Johnson Company has asked you to coordinate another training session for an HCP. You happen to know that he is a big sports fan. Your company has a luxury box at the local sports stadium, and there's an event the same weekend as the HCP will be in town.

What should you do?

Proceed to the next slide to review answer choices.



Scenario 2

Scenario

Response

Which of the following actions do you think would be acceptable? Select all that apply.

- Invite the HCP to watch the event in your company's luxury box, but inform him that he will have to pay for his own meals and beverages.
- Don't invite the HCP to watch the event since it is against Johnson & Johnson policy to provide entertainment or recreation to an HCP.
- Provide the HCP with tickets for less expensive seats to the event.

Return to the previous slide if you would like to review the scenario.

Proceed to the next slide to review feedback.

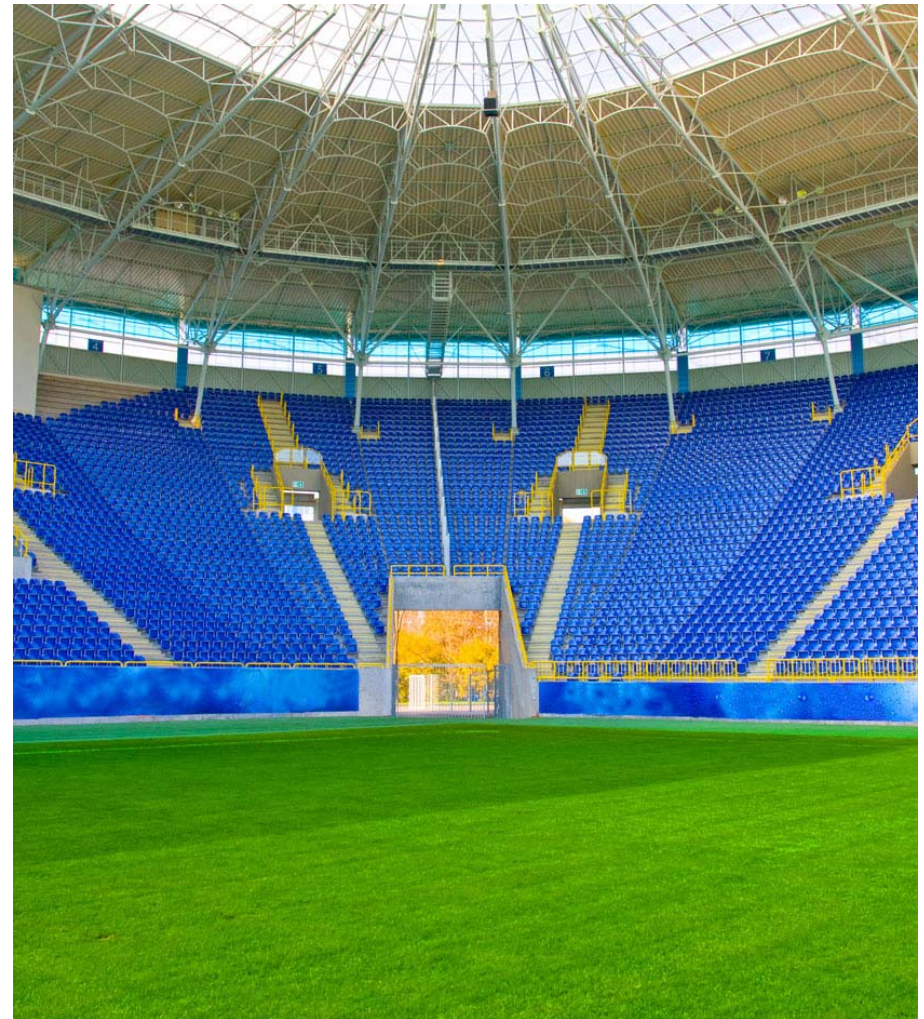


Scenario 2

FEEDBACK

Entertainment or recreation may not be provided to HCPs. The only correct action is to not invite the HCP to the event.

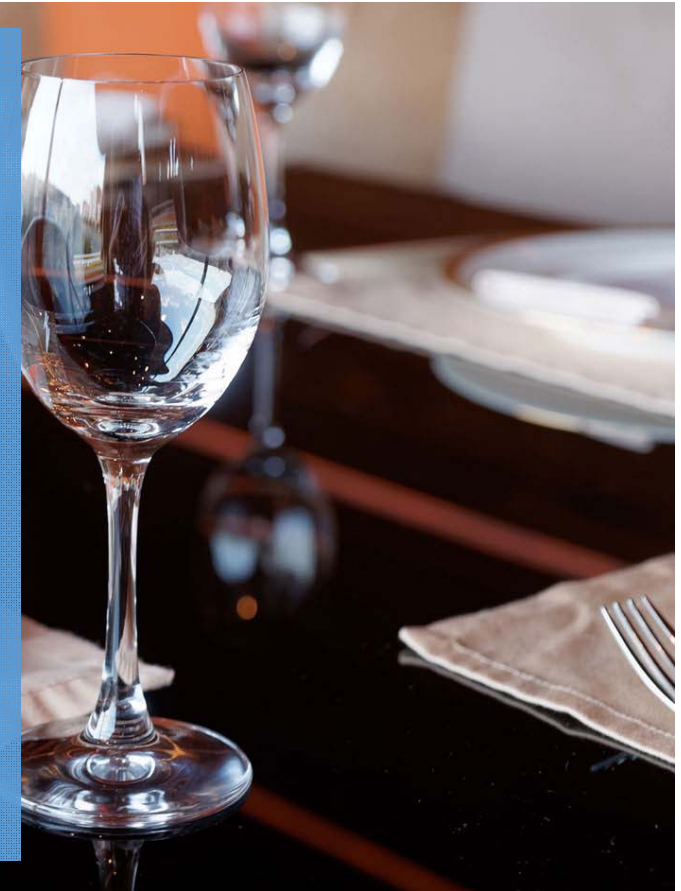
If you'd like to review the scenario, return to the previous slides.



Meals, Travel, Lodging and Other Hospitality

Where it is permissible to provide meals, travel, or lodging to an HCP (such as in the context of a fee-for-service arrangement), the following requirements apply:

- Reasonable, documented expenses for travel, lodging, and meals must be reimbursed in accordance with the Johnson & Johnson Travel and Entertainment Policy and applicable local policies.
- The location and venue of any meeting with an HCP must be suitable for and conducive to the exchange of business or scientific information.
- Meals and refreshments must be modest in value and supplemental, in time and focus, to the business part of the meeting.
- Entertainment or recreation may not be provided to HCPs.
- Payments should be tied to milestones and/or deliverables; there should be no advance lump-sum payments.
- There are no exceptions for interactions involving one-day events and/or small monetary amounts.



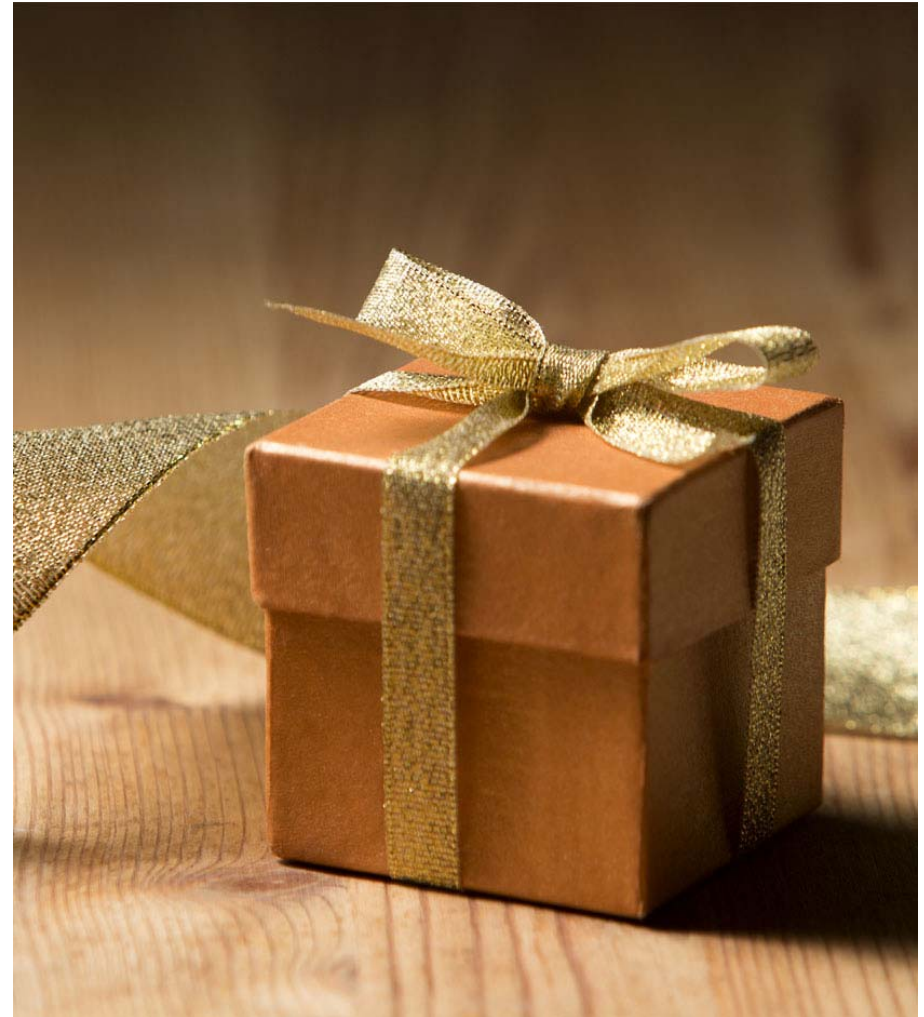
Scenario 3

Scenario

Response

Now let's look at HCP gifts. Assume you are going to make a call on an HCP on behalf of a Johnson & Johnson Company. There is an upcoming holiday in the HCP's country and it's the local custom to give a small gift around this holiday. You'd like to give her something. What do you need to consider when selecting an appropriate gift?

Proceed to the next slide to review answer choices.



Scenario 3

Scenario

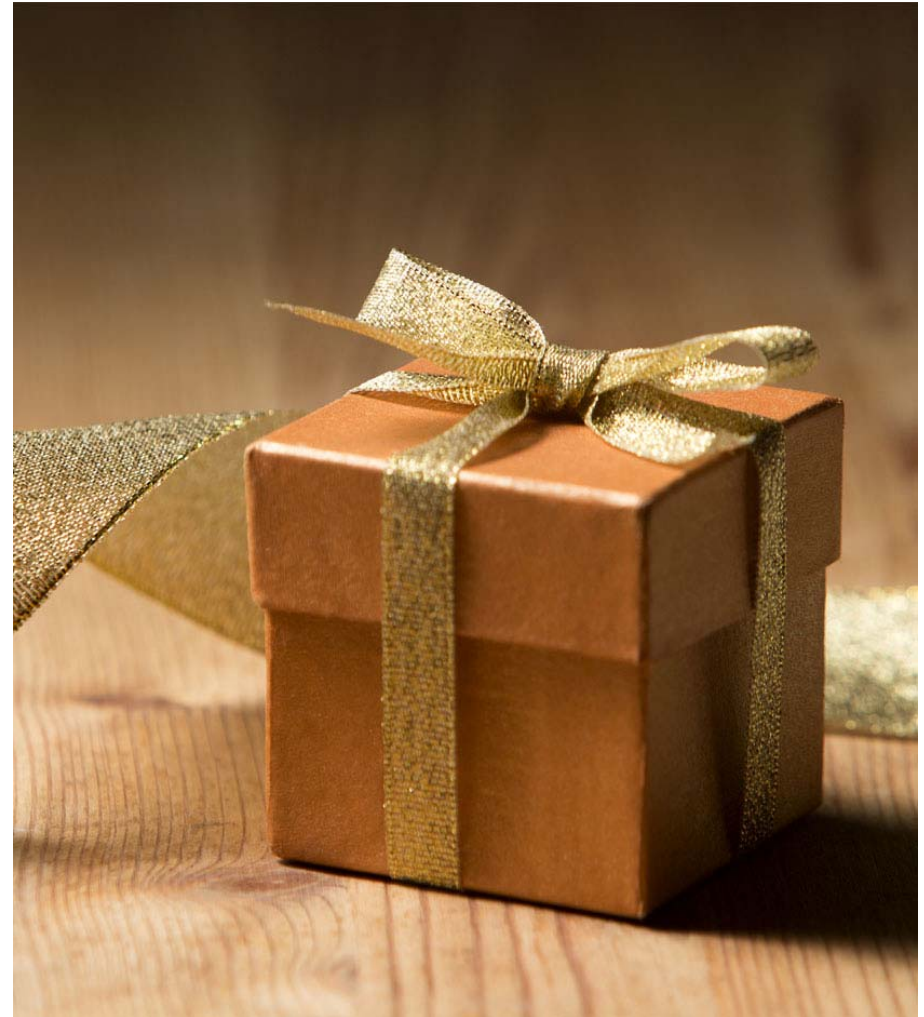
Response

What do you need to consider when selecting an appropriate gift for the HCP? Select all that apply.

- It should be consistent with local customs.
- It should fall within Johnson & Johnson guidelines for HCP gifts.
- It should be valuable enough to impress the HCP.

Return to the previous slide if you would like to review the scenario.

Proceed to the next slide to review feedback.



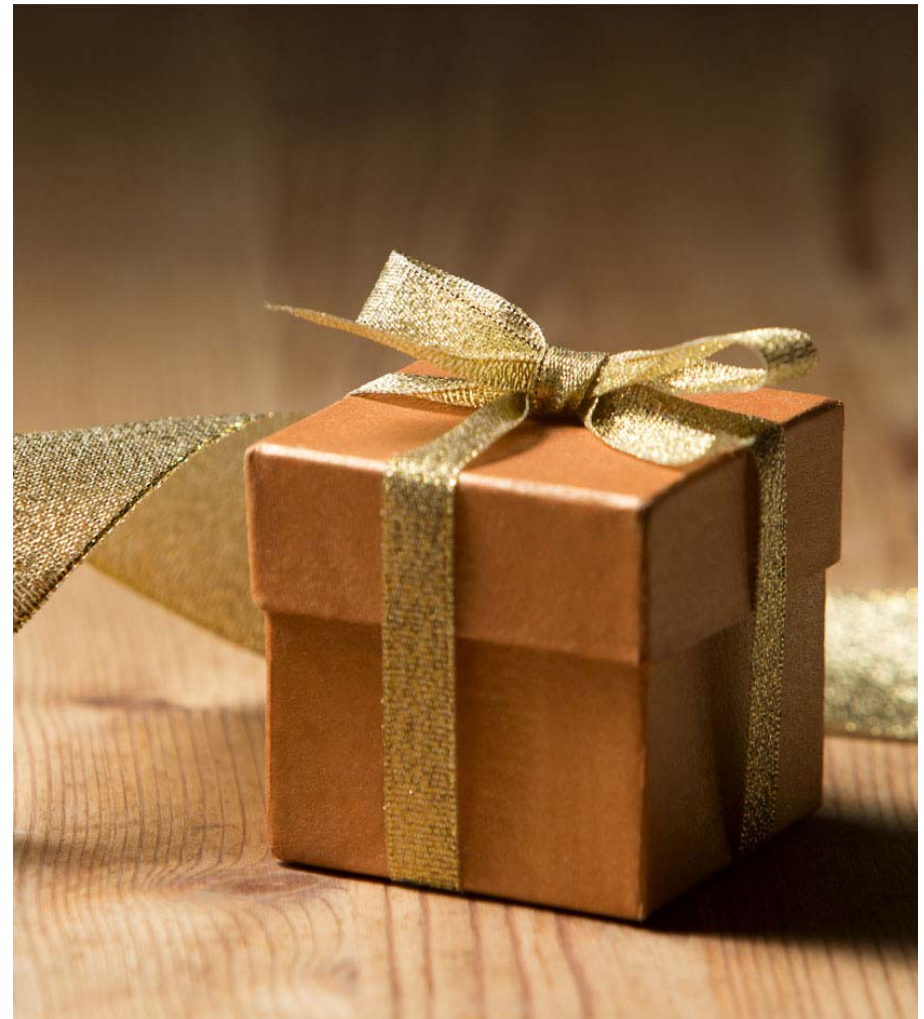
Scenario 3

FEEDBACK

The gift should be consistent with local customs and fall within Johnson & Johnson guidelines for HCP gifts.

While J&J guidelines may occasionally allow gifts to HCPs, please note that local guidelines may be stricter. Please consult your local Johnson & Johnson contact for more information.

If you'd like to review the scenario, return to the previous slides.



Gifts to HCPs

Occasional gifts may be given to HCPs if those gifts meet Johnson & Johnson guidelines.

Gifts to HCPs should:

- Be modest, inexpensive, customary
- Be permitted by local law or regulation
- Have educational or scientific value
- Benefit patients
- Be relevant to the practice of the HCP
- Not be restricted by local industry associations/codes

While J&J guidelines may occasionally allow gifts to HCPs, please note that local guidelines may be stricter. Please consult your local Johnson & Johnson contact for more information.

Cash gifts must NOT be given to HCPs. This includes cash equivalents, such as cash cards.

Knowledge Check

We've talked about HCP gifts, but what about gifts for GOs? Do the same guidelines for HCP gifts apply to gifts for GOs?

- Yes, the same guidelines apply.
- No, the guidelines are much stricter concerning gifts for GOs.
- No, the guidelines are more relaxed concerning gifts for GOs.

Knowledge Check

We've talked about HCP gifts, but what about gifts for GOs? Do the same guidelines for HCP gifts apply to gifts for GOs?

- Yes, the same guidelines apply.
- No, the guidelines are much stricter concerning gifts for GOs.
- No, the guidelines are more relaxed concerning gifts for GOs.

The correct choice is shown. The guidelines are much stricter concerning gifts for GOs.

Gifts and Hospitality for GOs

In most countries, government employees, elected and appointed officials, and oftentimes paid and unpaid consultants or advisors to the government are subject to special ethics rules.

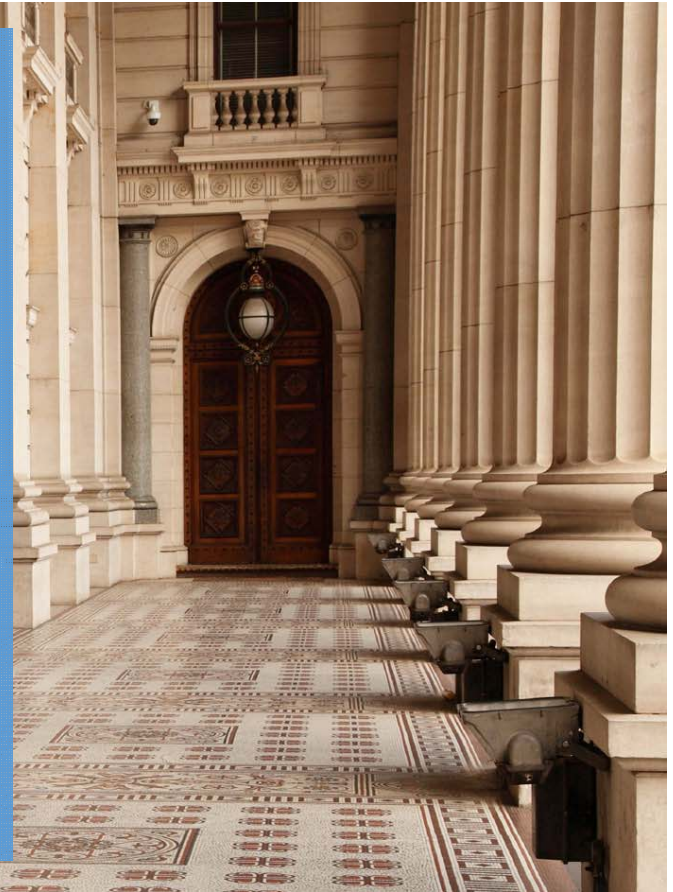
In general, such individuals are prohibited from soliciting or accepting any gift or any other item of value.

In those rare instances where giving a gift or other benefit to a GO is permitted, that gift or benefit should:

- Be modest and inexpensive in value
- Not exceed the legal maximum value
- Otherwise comply with local law

Cash gifts are not permissible under any circumstances.

Hospitality expenditures for GOs should be reasonable, customary, and comply with local law.



All Other Interactions with Government Employees

Interactions with government employees may include interactions with:

- Product and site regulators
- Auditors
- Inspectors
- Import/export authorities
- Pricing authorities
- Product registration personnel
- Tender authorities
- Many others

TPIs should follow all local laws when interacting with a government employee and should never offer or accept a benefit presented with the intent to influence decisions.

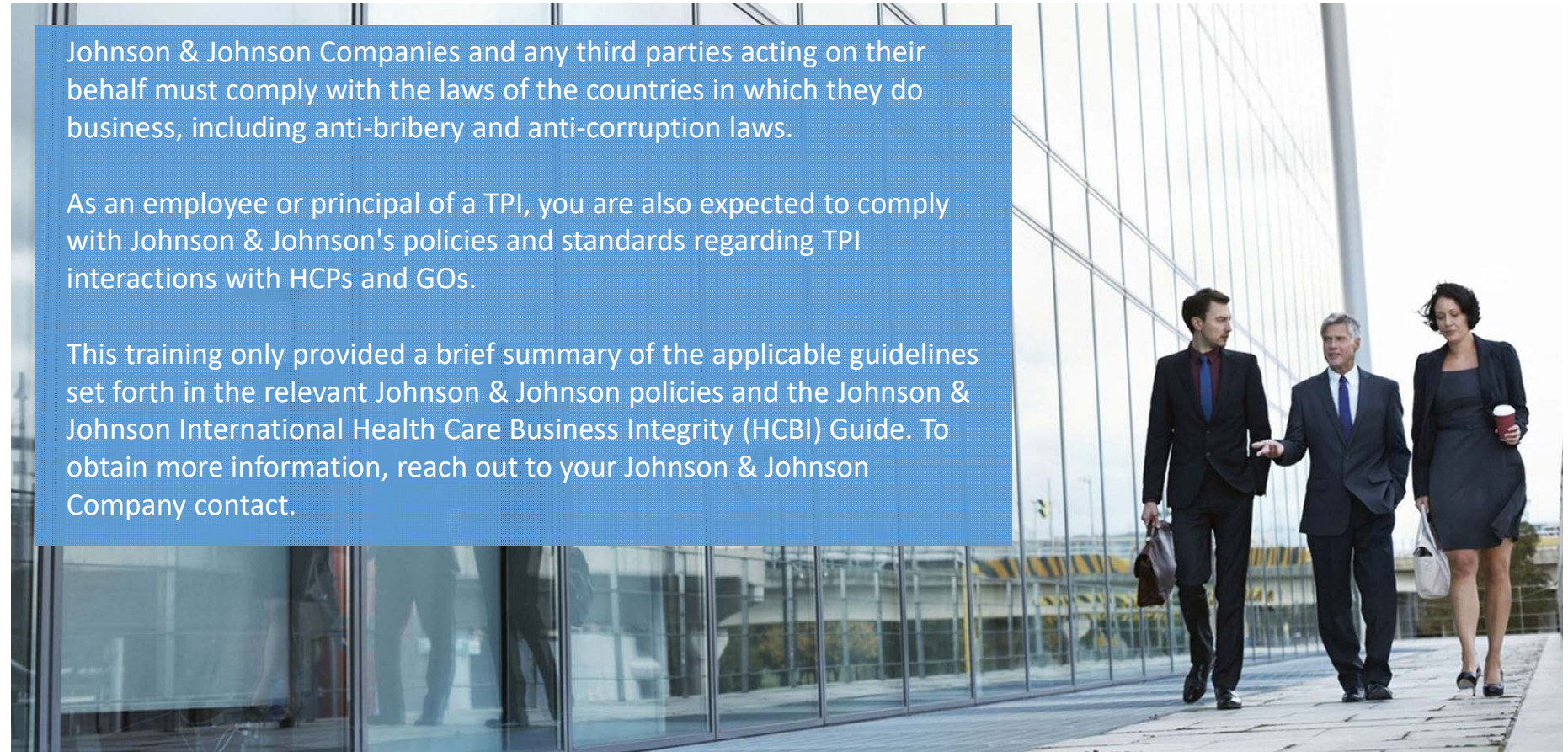


Summary

Johnson & Johnson Companies and any third parties acting on their behalf must comply with the laws of the countries in which they do business, including anti-bribery and anti-corruption laws.

As an employee or principal of a TPI, you are also expected to comply with Johnson & Johnson's policies and standards regarding TPI interactions with HCPs and GOs.

This training only provided a brief summary of the applicable guidelines set forth in the relevant Johnson & Johnson policies and the Johnson & Johnson International Health Care Business Integrity (HCBI) Guide. To obtain more information, reach out to your Johnson & Johnson Company contact.



The Credo Hotline

Johnson & Johnson also has a toll-free hotline you can use 24 hours a day, 7 days a week to:

- Anonymously report any ethical or legal concerns
- Submit questions regarding ethical or legal concerns

For instructions on using the hotline, go to:
www.credohotline.com.



Acknowledgement

By completing the *International Health Care Business Integrity for Third Party Intermediaries* training, you acknowledge you will comply with the standards and requirements as presented. You also acknowledge the following:

- Johnson & Johnson Companies are committed to maintaining effective health care business integrity programs.
- It is the policy of Johnson & Johnson Companies to require intermediaries engaged to act on their behalf to comply with US anti-bribery and anti-corruption legislation as well as all applicable local anti-corruption laws and regulations.
- Johnson & Johnson Companies strictly prohibit Third Party Intermediaries to offer or pay any Government Official in an attempt to influence that official's decisions.
- Third-party intermediaries retained by Johnson & Johnson Companies will be required to comply with certain Company policies and with the Company's standards in the context of interactions by the intermediary with Health Care Professionals and with Government Officials.
- The agreement between the Johnson & Johnson Company and the intermediary I represent may be terminated for non-compliance with applicable policies or for violation of US anti-bribery or anti-corruption legislation, local anti-corruption laws, or other local laws.

If you are completing this course in self-study mode:

- Print the certificate on the next slide (complete all the fields on the certificate).
- Scan the certificate to a file and then email the file to <insert person or group name and email address>.
- It is recommended that you keep a copy of your certificate for your records.

If you are completing this course in a classroom setting:

- Be sure to sign the class roster.
- The facilitator will submit the class roster of the participant's names, course name and training completion date to <insert person or group name and email address>.

Certificate of Completion

This document certifies that

Name

Has completed the training program:

**International Health Care Business Integrity
for Third Party Intermediaries**

Completion Date: _____

Signature: _____