

Who's Who in Your Hospital or Practice? Third Party Risk Management

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University Hospitals

<http://www.uhhospitals.org/locations>

With over
200 locations,
great care is
even closer to you.



Cleveland | Ohio 2

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UH Mission, Vision and Core Values

Mission: Why we are here

To Heal. To Teach. To Discover.

Vision: What we want to do

Advancing the Science of Health & the Art of Compassion.

Values: What we believe

Excellence. We have a continuous thirst for excellence and are always seeking ways to improve the health of those who count on us.

Diversity. We embrace diversity in people, thought, experiences and perspectives.

Integrity. We have a shared commitment to do what is right.

Compassion. We have genuine concern for those in our community and treat them with respect and empathy.

Teamwork. We work collaboratively as an integrated team to improve patient care and performance.

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Agenda

- What is TPRM
- Third Party Risk Management (TPRM) at University Hospitals
- Rules and Regulations governing TPRM
- Application and Implementation of TPRM
- Conclusions and Questions

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Seven Elements of an *Effective* Compliance Program

1. Designation of a compliance officer and compliance committee.
2. **Development of compliance policies and procedures, including standards of conduct.**
3. Developing open lines of communication.
4. Appropriate training and education.
5. Internal monitoring and auditing.
6. Response to detected deficiencies.
7. Enforcement of disciplinary standards.

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Setting Expectations-Development of compliance policies and procedures, including standards of conduct.

- Are policies and procedures clearly written, relevant to day-to-day responsibilities, readily available to those who need them, and re-evaluated on a regular basis?
- **Does the hospital monitor staff compliance with internal policies and procedures**
- Have the standards of conduct been distributed to all directors, officers, managers, employees, contractors, and medical and clinical staff members?
- **Has the hospital developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?**
- Does the risk assessment tool include an evaluation of federal health care program requirements?

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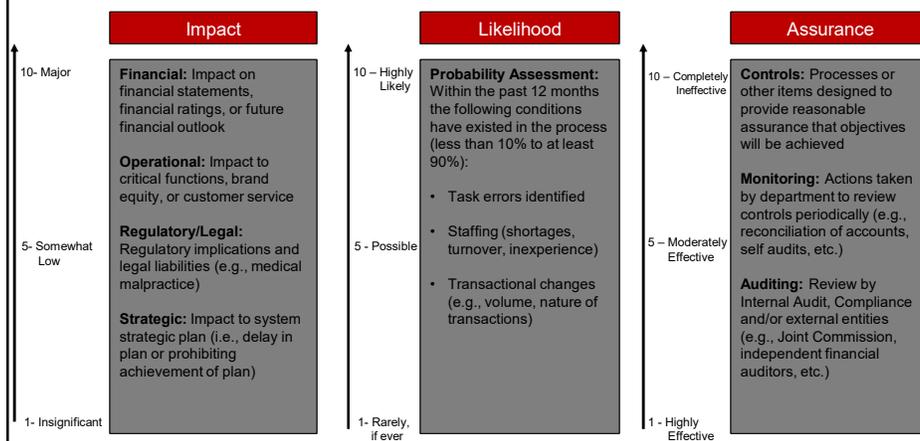
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Setting Expectations- Appropriate Training and Education

- Does the hospital provide qualified trainers to conduct annual compliance training for its staff, including both general and specific training pertinent to the staff's responsibilities?
- Has the hospital evaluated the content of its training and education program on an annual basis and determined that the subject content is appropriate and sufficient to cover the range of issues confronting its employees?
- Has the hospital kept up-to-date with any changes in federal health care program requirements and adapted its education and training program accordingly?
- Has the hospital formulated the content of its education and training program to consider results from its audits and investigations?
- Does the hospital seek feedback after each session to identify shortcomings in the training program, and does it administer post-training testing to ensure attendees understand and retain the subject matter delivered?

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Risk Assessment – How Do We Complete?



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TPRM at University Hospitals

- RFB Process
- Procurement Process
- SCEC
- New Product/vendor form
- OIG exclusion process

Let's say your company purchases 10 boxes of scalpels for \$20/box from your scalpel supplier, and it is found out that the company appears on the OIG exclusion list. Your fine could look something like this:

\$10,000 per item X 10 = \$100,000

\$200 (total purchase price) X 3 = \$600

Grand Total = \$100,600

A \$200 purchase has now cost your organization \$100,600 for one simple reason. Your purchasing department bought them from a vendor on the [OIG exclusion list](#).

Figure 7. Which function benefits most from a well-functioning vendor risk management process or program?
Three responses permitted

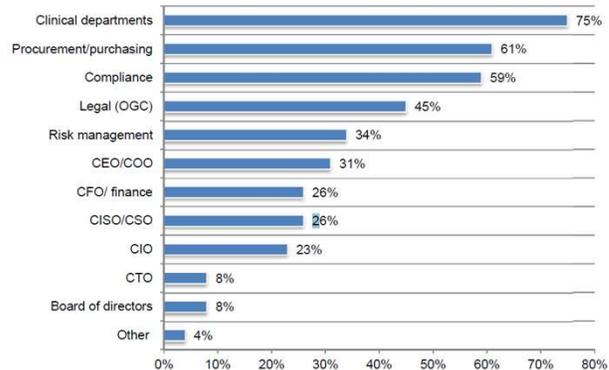
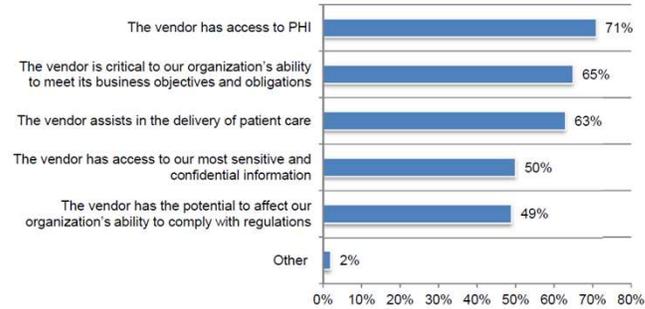


Figure 9. How do you determine which vendors to prioritize for due diligence and assessment?
Three responses permitted



What are the common types of third-party risks?

Operational risk

Third-parties pose potential [operational risks](#) if they provide services integral to continued business operations. If the third-party experiences a business interruption that shuts down the service, your organization may experience a business interruption.

Reputational risk

While operational risk applies to your business's ability to continue to provide customers a service or product, [reputational risk](#) applies to how customers view your organization. If your third-party experiences a [data breach](#) or business interruption, then your organization may experience decreased customer trust or loyalty in the aftermath.

Compliance risk

As more industry standards and regulations incorporate third-party vendor risk as a [compliance requirement](#), you need to ensure that you apply your organization's risk tolerance to your third-party business partners as well. For example, if a primary control within your organization is to update security patches every thirty days, then you should hold third-parties accountable to that same standard and monitor to verify their controls' effectiveness.

What are the common types of third-party risks?

Financial risk

There are two main forms of financial risk in regard to working with third-party vendors: excessive costs and lost revenue. This risk arises when vendors are unable to meet the fiscal performance requirements that have been set by your organization. It's crucial that you identify which vendors have a direct impact on sales or revenue, as systems that are used to track sales activity pose an additional threat to security.

Strategic risk

Strategic risk occurs when a vendor and your organization aren't aligned on strategic business decisions and objectives. Continuous monitoring of your third-party vendors is key to ensuring that strategic risks don't lead to compliance, financial, or reputational risk.

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Risk Assessment

- What one event, if it were to occur, would be the biggest negative disruptor of business in your area?
- What one event, if it were to occur, would be the biggest positive disruptor/enhancement of business in your area?
- What are the **three most key processes** in your business area, which, if they failed, would cause you the most damage/disruption?

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Ex. #1- Cardinal Health Recall

- Cardinal Health recalled surgical gowns in January 2020.
- The gowns had been manufactured in China. A week after the U.S. Food and Drug Administration announced the recall; Cardinal announced that its Chinese gown manufacturer had been using an outside contractor not registered with the FDA.
- The unregistered subcontractor's factory left windows open, lacked proper hand-washing stations, had an unsecured door and food was found in the manufacturing area, according to a report in Modern Healthcare

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Cardinal Health Recall

- Shortage of gowns nationally
- Surgeries stopped
- Loss of revenue
- Potential hospital shutdown

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Ex. #2- In The News...

- <https://fox8.com/news/medina-man-faces-charges-for-rape-child-pornography/>



Ex. #3- Identity Fraud and Vendors

In 2020 a manager's identify was stolen to purchase goods from various vendors.

Some vendors did not check the source or confirm the identity and either began procuring and assembling the goods or shipped them.

Turns out the address was a parking lot near Yankee stadium and vendors never received payment or incurred expenses for manufacturing products that were not legitimately ordered.

First Name: [REDACTED]
Last Name: [REDACTED]
Email: info@uhchospitals.org
Phone Number: [REDACTED]
State: Ohio
Message: Hello, Sales.

Due to COVID-19 skyrocketing in Ohio, UH Cleveland Medical Center urgently wants to expand its facility.

We would like to request if you can source and rent the below product to us for our ongoing project.

1. Lenovo X1 Carbon (Quantity 80 Units)
2. Apple MacBook Pro 16" Core i7 (Qty 50 Units)

Date Needed: 09/14/2020-Return Date: 12/20/2020

Note: our payment term is Net 30 days payment.

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I would appreciate your prompt response at your earliest convenience.

Regards.

[REDACTED]
Chief Procurement Officer
UH Cleveland Medical Center
11100 Euclid Ave,
Cleveland, OH 44106
Phone: [REDACTED] | <http://www.uhhospital.org>
[REDACTED]@uhchospitals.org | info@uhchospitals.org
Terms and conditions: I agree to the Rush Computer Rentals Terms of Use and Privacy Policy

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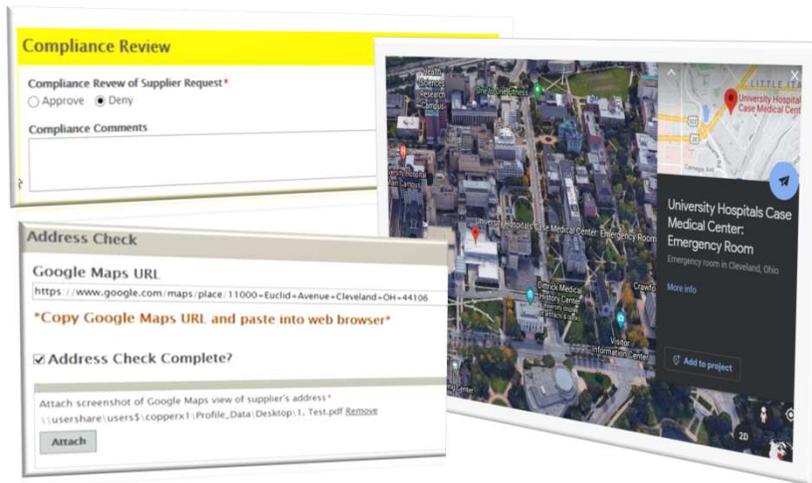
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Vendors Lessons Learned



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UH Lessons Learned- Enhancements



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Top Regulations Governing Vendors



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- **Centers for Medicare and Medicaid (CMS)**
Chapter 21 § 40 of the Medicare Managed Care Manual
42 C.F.R. §§ 422.503(b)(4)(vi), 422.504(i), 423.504(b)(4)(vi), 423.505(i)

42 CFR Parts 405, 424, 455, 457, and 498
- **Utilization Review Accreditation Commission (URAC)**
Core 9- Delegation Oversight
- **Department of Justice (DOJ)**
Evaluation of Corporate Compliance Programs (Updated 6/2020)

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- **Joint Commission (JC)**

Standards include HR standards for employment of hospital personnel and contractors “providing patient care and/or services”

Healthcare organizations must manage contracted personnel just as they manage their direct employees

Healthcare organizations have full discretion in determining to whom these standards should apply

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Tip of the Iceberg

- Exclusion Checks
- Conflict of Interest Checks
- Contractual Addendums
- Questionnaires



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Program Integrity Enhancements to the Provider Enrollment Process

- Requires providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers.
- In addition, it also gives CMS and state plans additional authority to deny or revoke a provider's or supplier's enrollment based on a provider's or supplier's abusive or endangering behavior.
 - Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 405, 424, 455, 457, and 498 [CMS-6058-FC] RIN 0938-AS84 Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process)

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Program Integrity Enhancements to the Provider Enrollment Process

- The language is broad, as it requires providers to disclose, within the previous five (5) years, any current or previous and direct or indirect "affiliation" with a provider or supplier that has uncollected debt; has been or is subject to a payment suspension under a federal health care program; has been excluded from Medicare, Medicaid or CHIP; or has had its Medicare, Medicaid or CHIP billing privileges denied or revoked ("disclosable events").
- A disclosable event permits the Secretary to deny a provider's or supplier's enrollment based on such an affiliation when the Secretary determines that the relationship poses an undue risk of fraud, waste or abuse.

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Program Integrity Enhancements to the Provider Enrollment Process

Definition of Affiliation:

- (1) a 5% or greater direct or indirect ownership interest that an individual or entity has in another organization;
- (2) a general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization;
- (3) any interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts the day-to-day operations of another organization either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization;
- (4) an interest in which an individual is acting as an officer or director of a corporation; and,
- (5) any reassignment relationship.

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Developing a Risk Assessment Tool

Identify vendors and their roles in your organization.



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Developing a Risk Assessment Tool

Understand the Vendor in/out process.



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Developing a Risk Assessment Tool

Identifying the regulations that apply.



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Developing a Risk Assessment Tool

Obtaining department(s) buy-in.



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Developing a Risk Assessment Tool

Develop a *customized* assessment.



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Developing a Risk Assessment Tool

Implement the assessment tool.



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Assessment

Impact – measurement of the greatest potential consequences of risk if there were *no controls or mitigation activities in place*.

Very Low	Low	Moderate	High	Very High
<ul style="list-style-type: none"> • Little or no financial impact • No liability or threats to brand equity • Critical functions will not be impaired 	<ul style="list-style-type: none"> • Inconvenient impact on critical business functions • Small and temporary impact to brand equity • Strategic plan will not be impaired 	<ul style="list-style-type: none"> • Moderate financial impact • Significant liability (e.g., lawsuits) potential • Identified issues are inconsistent with the organization's values 	<ul style="list-style-type: none"> • Regulatory penalties are required • Financial ratings drastically revised • Long-term brand equity impairment 	<ul style="list-style-type: none"> • Large impact on net income • Regulatory agencies seize control of assets or are granted absolute decision-making authority • Organization's strategic plan cannot be achieved

Likelihood - probability of risk occurring over the next year if there were *no controls or mitigation activities in place*.

Very Low (<10% probability)	Low (<30% probability)	Moderate (<50% probability)	High (<75% probability)	Very High (<90% probability)
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HIGH Risk

High	<ul style="list-style-type: none">Vendor performs a delegated function or a function required by Gov. contract.Vendor's function directly impacts patient care.Vendor has direct contact with patients.Vendor has access to PHI.Vendor has decision making authority.Vendor is in a position to commit FWA.Vendor is offshore and or outsources critical functions offshore.Vendor's function are critical to organization operations.Vendor has physical and or virtual access to sensitive areas.
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MEDIUM Risk

Med	<ul style="list-style-type: none">Vendor performs a delegated function or a function required by Gov. contract.Vendor's function indirectly or minimally impacts patient care.Vendor has indirect or minimal contact with patients.Vendor has minimal access to PHI.Vendor has minimal decision making authority.Vendor is in a position to commit FWA.Vendor is onshore but offshores non-critical functions.Vendor's function is critical but does not have ability to halt ops.Vendor has limited physical or virtual access.
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LOW Risk

Low

Vendor does not perform a delegated function or a function required by Gov. contract.
Vendor's function does not directly impacts patient care.
Vendor has no direct contact with patients.
Vendor has no access to PHI.
Vendor has no decision making authority.
Vendor is not in a position to commit FWA.
Vendor functions is all onshore.
Vendor's function does not affect organizations ops.
Vendor has no physical or virtual access.

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Other Criteria to include

- Vendor Name
- Doing Business As
- Tax ID
- Supplier ID
- Address
- Function/Role
- Entity or line of Business
- Contract
- BAA
- FDR or URAC

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Vendor Relations Visitation and Control

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Vendor Visitation & Credentialing

- Symplr: Vendor Registration System
 - Currently in use at all UH hospitals
 - In progress: implementation at health centers, specifically sites with UH Radiology
 - Future state: implementation at all clinic locations
- Vendors must schedule and register for visits
- Vendors must be accompanied by UH employees during visit

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Vendor Visitation & Credentialing

- Vendors do not have active participation in procedures.
- Vendors do not have access to patient information or the EMR
 - If this is needed, the Compliance Office will review scenario
- Promotional materials
 - Vendors cannot post their materials in public Hospital space

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What **Symplr** provides for you:

- Real-time reporting of vendor visits
- Annual background check & monthly Government Watch List (GWL) checks on both the vendor rep **and** company
- 100% web-based software solution
- Kiosk & check-in station locations
- A dedicated Account Manager for ongoing support and account maintenance

As a staff member, you play a key role in ensuring the success of the compliance program within your facility by:

- Knowing the proper protocol for your facility and being able to instruct new vendors on how to get registered with symplr
- Keeping up with your specific department requirements, such as: appointments required, specific credentials, vendor point of contact, ect.
- Making sure vendors are registered and compliant in the symplr system by looking for one of the below badges, worn by the vendor during their visit.

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A Symplr membership allows individuals access to our nationwide community of facilities with the four vendor levels listed below – and each level permits access to various areas within your facility.

ALL ACCESS (ALL)

This level provides you with access to any and all areas in a facility. You should choose this level if you need access to procedure areas (like the OR and Cath Lab) to support clinical staff. This is the highest level of credentialing and will require you to submit the most documents.

Examples: medical device reps, agency nurses, techs, company consultants.

PATIENT CARE ACCESS (PTC)

This level enables you to enter patient care areas or areas where Protected Health Information (PHI) is available. You should choose this level if you do not need access to procedure areas, but do need access to patient care areas.

Examples: pharma reps & managers, service techs, general medical sales, lab, and distributor reps, consultants, interpreters and non-contracted reps (IT, legal, financial).

ADMINISTRATIVE ACCESS (ADM)

This level enables you to access all general or administrative areas of a facility. You should choose this level if you do not need access to procedure or patient care areas but do need access to all other areas in a facility.

Examples: admin, delivery, and GPO reps, maintenance and construction workers.

PROVIDER ACCESS (PRO)

This level enables you to access only Physician offices – you will not be able to go anywhere else in a facility. This level is typically chosen by pharmacy reps who do not access patient care areas.

Examples: pharma reps

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Vendor Badge Examples

Hard Badge

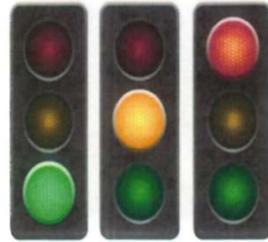


Paper Badge (Kiosk)



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Symplr Traffic Light System Indicates Credential Status



Green Light = Individual is in full compliance

Yellow Light = Individual is still in compliance but has a requirement set to expire within 45 days

Red Light = Individual is not in compliance, a requirement is either incomplete or expired in their account

Credentials managed by Symplr

BACKGROUND CHECK

Your account includes an annual background check – at no additional cost.

EXCLUSION SCREENING

Monthly checks against all available Federal and State exclusion lists.

IMMUNIZATIONS

Including Tuberculosis, Influenza, Hepatitis B, and more – with automated expiration alerts.

HOSPITAL POLICIES

Review and e-sign any required hospital policies and documents.

FREE COMPANY CREDENTIALING

Your account includes compliance credentialing for your company at no extra cost.

Vendor Requirements

Person Credentials	View	Next Due On
OR Protocol Training	View	Jan 01, 2099
Bloodborne Pathogens	View	Mar 04, 2019
National Background Check	View	Jan 09, 2019
Product / Service Training	View	Apr 03, 2033
HIPAA Training	View	Nov 30, 2018
HEP B Vaccination	View	Jan 01, 2099
TB Skin Test Negative (PPD)	View	Jul 27, 2018
General Expectations & Hospital Safety (Includes Electrical, Fire-RACE/PASS & Radiation Safety)	View	Mar 24, 2112
Exclusion Screening	View	Apr 16, 2019
Influenza	View	Sep 30, 2018
UH Annual Compliance Training Review	View	Oct 26, 2018

Person Policies	Date Signed
New Product Authorization Letter	Mar 20, 2013
UH Vendor Handbook 2017	Dec 15, 2017
SC-4 UH Supply Chain Policy 2017	Dec 15, 2017

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SymplrPass (At Hospital Locations)



Desk top



Kiosk

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Vendor Responsibilities

- Download Symplr App to smartphone
- Create meeting with time and who appointment with
- Go to designated Symplr scanner, scan phone
- If green, a paper badge will print with date, time and who appointment is with
- If Red, no badge will print and vendor is not able to meet until credentials are up-to-date

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Scheduled Webinars

- These will be set-up and an email will be sent with the dates, times and log-in information.
- Please have whoever in your location that will check credentialing, attend this. They will then be registered in Symplr and given their username and password.

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Vendor Relations Visits, Meals, Gifts, Promotional Materials

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Vendor Relations – Meals and Gifts

Vendor: Any third party – including an individual or company – that does business with or is seeking to do business with UH.

Basic Principles:

- Vendor gifts must be infrequent
- Vendor gifts must be related to education or for the benefit of patients
- Vendors may never give gifts or meals to induce, directly or indirectly, the use of vendor's products

Policies:

- Vendor Gifts, Meals, Other Business Courtesies and Consulting Payments
- Medical Vendor Gifts and Meals to Healthcare Professionals

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Vendor Relations – Meals

Q: A drug representative who visits my practice wants to drop off pizza for our monthly staff meeting. They will bring written materials on the company's new drugs and leave them with the pizza. Is this okay?

A: No – this is an example of “dine and dash” and is not permitted.

Requirements for meals from vendors:

- No more than once per quarter per vendor
- Vendor means company/manufacturer, not individual product or representative
- Meals must be associated with an educational program
- Vendor must provide the educational program (not “dine and dash”)
- Meals may not be lavish

Pharmaceutical vendors report all \$10+ gifts/meals to physicians through CMS Open Payments – this is a public reporting program.

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Vendor Relations – Gifts

A skilled nursing facility representative sent a large basket of food items as a gift to my office for the holidays. Can we accept it?

Requirements for gifts from vendors:

- Value:
 - May not exceed \$150 per calendar year per healthcare professional
 - Perishable/consumable gifts (gift baskets, flowers, non-meal foods) valued at more than \$150 may be accepted by a UH entity or department (not an individual) but must be reasonable, appropriate, and of modest value per recipient
 - Gifts must benefit patients or be of nominal value
- How often:
 - May not be offered more than quarterly
 - Gifts cannot be accepted if a contract is being negotiated, reviewed, or renewed
- Gifts that are never accepted:
 - Cash, cash equivalents, stocks, bonds, gift cards/certificates
 - Preprinted prescription pads
 - Entries into promotional raffles, lotteries, or contests

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Vendor Relations – Promotional & Educational Material

A vendor visits my office and wants to leave promotional brochures and patient educational materials at my practice. Is this permitted?

- Vendor may only provide this material if it's requested by UH
- Vendor may never leave materials in any areas of UH facilities – patient areas, common space, billboard posting space (i.e. waiting room, front desk, patient hallway in practice, etc.)

What about vendor-branded educational material that might be useful to patients?

- Licensed UH clinical professional must review and approve all educational material before it is given to patients
- Vendor may never provide material directly to patients/family

UH System Policy CE-11: Medical Vendor Gifts and Meals to Healthcare Professionals

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Vendor Relations – Promotional & Educational Material

Q: A new vendor wants to visit my office to demonstrate a new healthcare gadget or provide samples of a brand new drug. Can we try out this new gadget at our office?

A: No.

Your practice may not accept or dispense samples for any medication that is not approved by the UH formulary.

Any new devices or equipment go through proper channels with Supply Chain for approval.

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Take Aways

- Perform a Risk Assessment
- Know your environment
- Know your vendors
 - Procurement
 - Maintenance
 - Termination
- Department Buy in
- Scalability

- Final Thought: Develop Relationships

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Questions?

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Conflicts of Interest

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What is a Conflict of Interest (COI)?

- A conflict of interest is a situation when there are concerns or interests that compete or may appear to compete with one another.

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What is our policy on COI?

- When UH employees are acting for UH or engaging in an activity affecting UH, the employees act with loyalty to UH
- UH employees disclose potential conflicts of interest
- The Compliance and Ethics Department will help the employee provide more information about the potential conflict
- UH employees may not accept engagements that are adverse to UH
- UH employees and affiliated physicians cannot have a supervisory relationship with a family member or close personal/romantic relationship.
- [UH Policy CE-8: Conflicts of Interest](#)

What are some examples of potential COI?

- Financial interest with a vendor
- Financial interest with a competitor
- Board or committee membership
- Isolated business transactions
- Outside employment
- Business courtesies
- Hiring of relatives

What do we do when there is a potential conflict?

- Any potential conflict of interest (COI) should be reported to Compliance and Ethics
- Contact the Compliance and Ethics Department
- Compliance will review the situation
- UH Policy will be explained
- If necessary, guidelines will be put in place to manage the conflict
- The employee's manager is responsible for oversight