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# Real World of Conflict of Interest (COI)

**HFMA / NEHIA Joint Program**

**2021 In-Person Compliance & Internal Audit Conference**

**Mystic Marriott Hotel & Spa – Groton, CT**

Thursday, December 2<sup>nd</sup> 2021



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**Tanya White**

Director, System Compliance Operations  
Office of Privacy and Corporate Compliance (OPCC)



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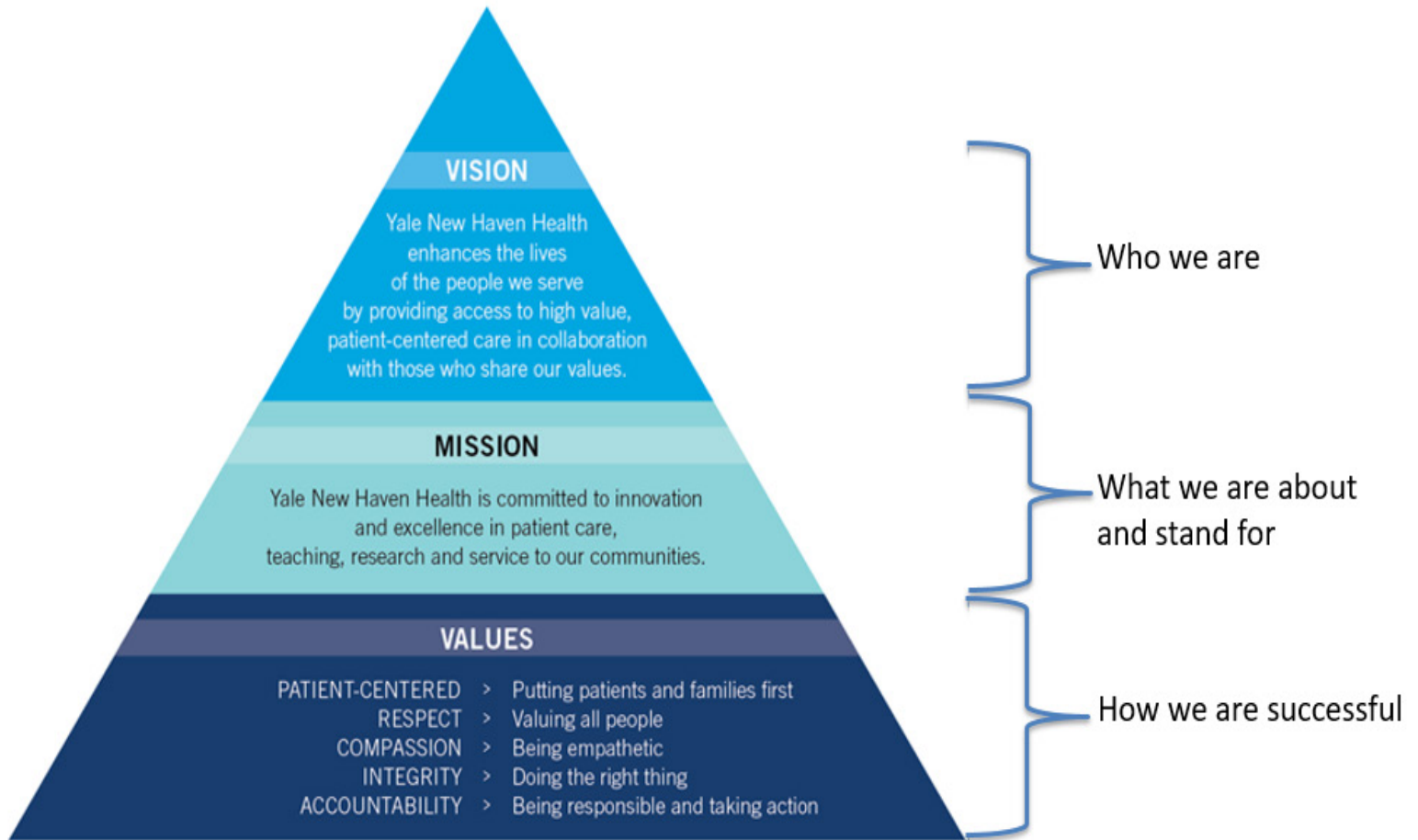
Compliance and Privacy Specialist  
Office of Privacy and Corporate Compliance (OPCC)

# Agenda

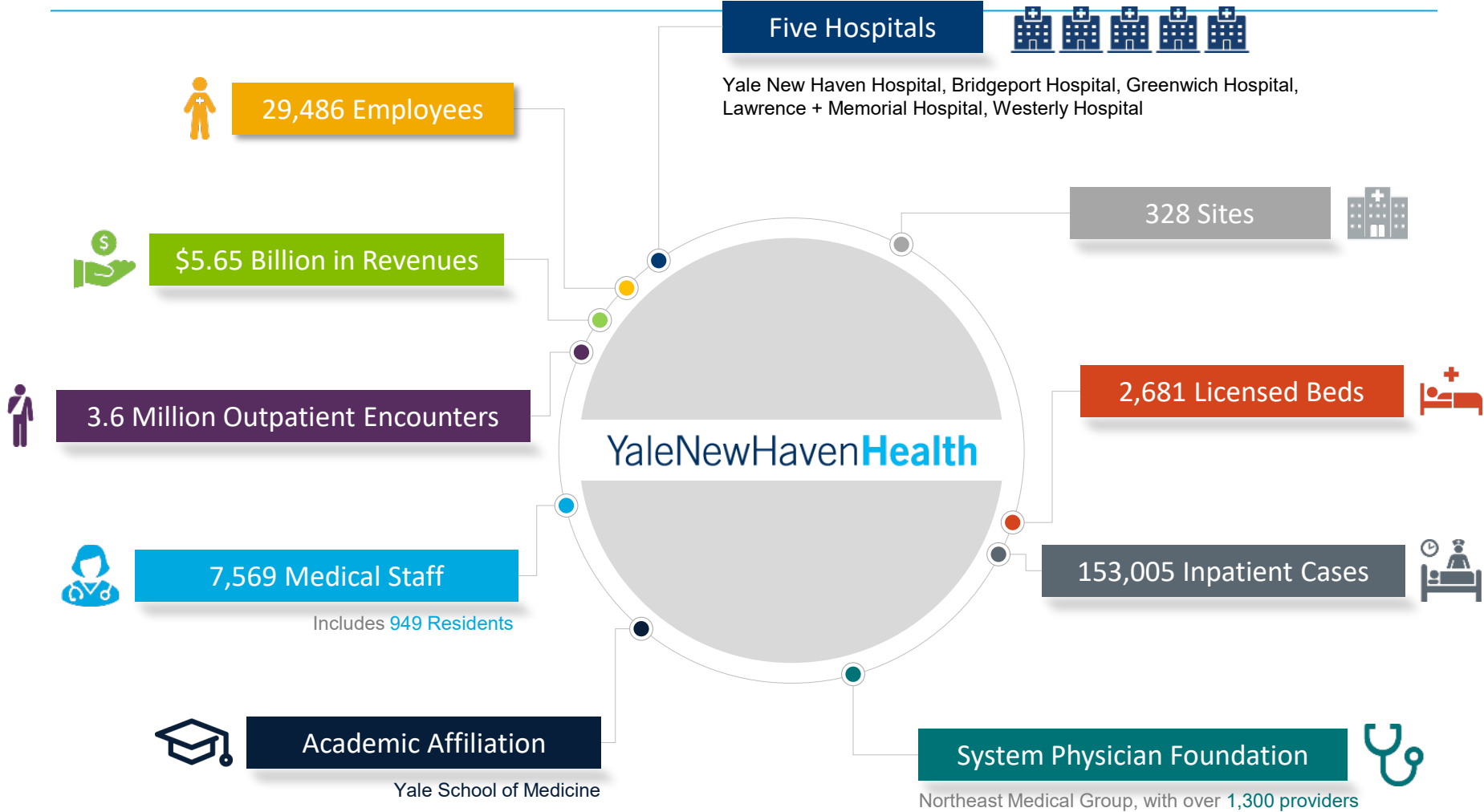
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- About Yale New Haven Health System
- Conflict of Interest (COI)
- CMS Open Payments & OIG Special Fraud Alert
- Hypothetical “Real World” COI Scenarios
- Questions/Comments

# VISION, MISSION AND VALUES



# Yale New Haven Health System (YNHHS) / Snapshot



# Our Scope

**Assigned Users:** 4,150 individuals

## Who We Survey at YNHHS?

- Employed medical staff members
- Medical Staff Members with an administrative role
- Key Executives
- Directors and Above
- Employees with grant writing responsibility
- Prospective NEMG physician hires
- Trustees and Board Members
- Members of the following Committees:
  - Pharmacy & Therapeutics (P&T)
  - Formulary Integration (FIC)
  - Clinical Governance (CGC)
- Individuals in the following Departments:
  - Pharmacy
  - Development Office
  - Legal & Risk Services Department
  - Supply Chain
  - Office of Privacy & Corporate Compliance
  - Center for Emergency Preparedness and Healthcare Solutions (CEPHS)
  - Center for Outcomes Research and Evaluation (CORE)
  - Grants Resource Office

## Conflict of Interest Policies:

- Covered Individuals
- Trustees

# COI Refresher

Do you see a conflict of interest?

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*"Try this—I just bought a hundred shares."*

What are types of conflicts are you managing?

# CMS Open Payments

2020

[What are the different payment types?](#)

Total US Dollar Value

**\$9.12 Billion**

Total Records Published

**6.38 Million**

## Payments by Type

### General Payments

Amount \$2.03 Billion	Payments 5.78 Million	Disputed Amount \$2.34 Million	Disputed Payments 351
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### Research Payments

Amount \$5.97 Billion	Payments 589,362	Disputed Amount \$5.78 Million	Disputed Payments 81
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### Ownership or Investment Interest

Amount \$1.12 Billion	Payments 3,291	Disputed Amount \$0.00	Disputed Payments 0
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## Payments by Entity

Entity Type	Number of Entities	General Payments	Research Payments	Ownership or Investment Interest
Physicians	487,152	\$1.55 Billion	\$73.16 Million*	\$1.12 Billion
Teaching Hospitals	1,213	\$479.26 Million	\$1.47 Billion	N/A**
Companies	1,621	\$2.03 Billion	\$5.97 Billion	\$1.12 Billion

## Open Payments Program Expansion – What to Know

Did you know that in 2021 Open Payments expanded to include five additional provider types? Beginning on January 1, 2021 reporting entities are now required to collect data about payments made to physicians and teaching hospitals as well physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives. Program Year 2021 data will be reported to CMS and published in calendar year 2022.



# OIG Special Fraud Alert (Nov 2020)

## Fraud & Abuse related to Speaker Programs

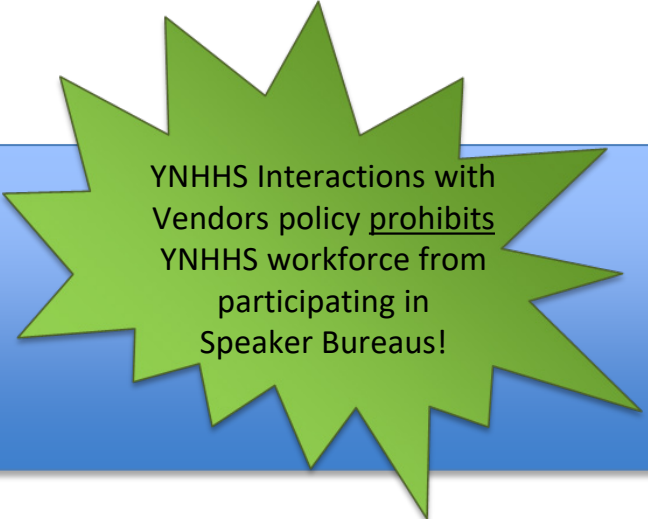
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- **Majority of investigated and resolved fraud cases identified drug and device companies:**
  - Selected high-prescribing HCPs to be speakers and rewarded them with lucrative speaker deals
  - Conditioned speaker remuneration on sales targets
  - Held speaker programs at high-end restaurants, entertainment venues or during recreational events or otherwise in a manner not conducive to an educational presentation
  - Invited an audience of HCP attendees who had previously attended the same program or HCPs friends, significant others, or family members who did not have a legitimate reason to attend the program

### Discussion Topic:

Do you allow your employees to participate in Speaker Bureaus?

Do you prohibit any other industry interactions?



YNHHS Interactions with Vendors policy prohibits YNHHS workforce from participating in Speaker Bureaus!

# The Risk is Real!

## 51 Months in Federal Prison

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### Department of Justice

U.S. Attorney's Office – District of Rhode Island

U.S. Attorneys » District of Rhode Island » News

#### Department of Justice

U.S. Attorney's Office

District of Rhode Island

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FOR IMMEDIATE RELEASE

Friday, March 9, 2018

### **Doctor Sentenced for Healthcare Fraud, Accepting Kickbacks to Prescribe Highly Addictive Version of Fentanyl**

PROVIDENCE, RI – Dr. Jerrold N. Rosenberg, 63 of Warren, the operator of a now-defunct pain management practice in Rhode Island, was sentenced today to 51 months in federal prison for committing healthcare fraud and for conspiring to solicit and receive kickbacks in return for prescribing the drug Subsys, a fast-acting, powerful, and highly-addictive version of the opioid drug Fentanyl.

*“Rosenberg admitted that, between 2012 and 2015, **he conspired with Insys officials to receive kickbacks, in the form of purported speaker fees, from the manufacturer of the spray. Rosenberg admitted that he accepted these payments, which totaled over \$188,000. Rosenberg admitted that the speaking fees he received from Insys were a significant motivating factor in his decision to prescribe Subsys to his patients.**”*

# The Risk is Real!

## \$678 Million Settlement

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### Department of Justice

U.S. Attorney's Office – Southern District of New York

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FOR IMMEDIATE RELEASE

Wednesday, July 1, 2020

### **Acting Manhattan U.S. Attorney Announces \$678 Million Settlement Of Fraud Lawsuit Against Novartis Pharmaceuticals For Operating Sham Speaker Programs Through Which It Paid Over \$100 Million To Doctors To Unlawfully Induce Them To Prescribe Novartis Drugs**

**Novartis Admits to Certain Conduct Alleged in the Lawsuit and Agrees to Strict Limitations on Its Ability to Conduct Future Speaker Programs**

Ø Programs = \$\$ to Physicians

Education was NOT Provided

Provided Exorbitant Meals/Top Shelf Alcohol

Selected High-Volume Prescribers

CIA Now Permits Novartis to ONLY Hold Virtual Events, Due to Misconduct

# Hypothetical “Real World” COI Scenario

## COI Case #1

- You receive an anonymous hotline call that 250 employees showed up to a department retreat with a customized t-shirt. The caller overheard that the Director’s brother owns the t-shirt company and talked the Vice President into using their company.
- When you review the Director’s COI form, she did not disclose this familial relationship.

## Discussion Topics

- What are your next steps?
- Does your organization have a documented purchasing process?
- Does the purchase amount matter?
- What type of Management Plan do you provide this employee?

# Hypothetical “Real World” COI Scenario

## COI Case #2

- You are reviewing your annual COI forms and a full-time, employed Key Executive and APRN discloses the following:
  - Part owner of a for-profit company which specializes in therapy solutions and programs.
  - Employee devotes 75 days/year and receives a 6-figure annual compensation.
  - Speaks at a conference for a medical device company
  - This company is a vendor for your organization.

## Discussion Topics

- What other information do you need?
- Can this conflict be managed?
- Any secondary commitment concerns?

# Hypothetical “Real World” COI Scenario

## COI Case #3

- A practice manager at one of the physician practices sends you an email that a physician was requesting that one of the Physician Assistants in the practice to refer her patients to his ambulatory surgery center, which is located down the street. The practice manager shares that he has received calls from patients asking for the ambulatory surgery center’s phone number.
- You review the physician’s disclosure and noticed the only disclosure is for consulting services with a pharmaceutical company.

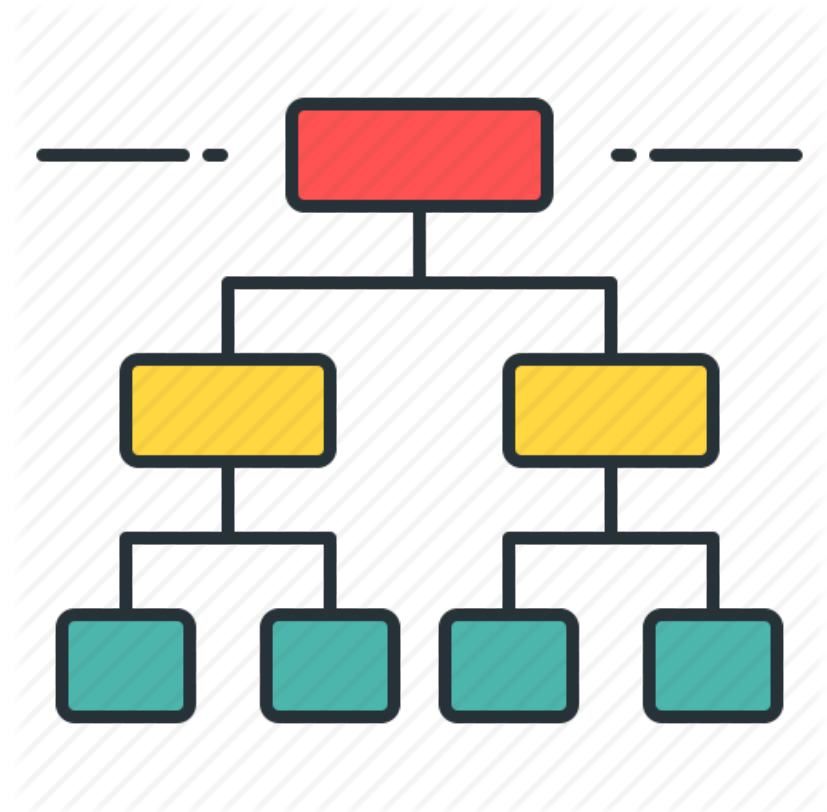
## Discussion Topics

- What other information do you need?
- When do you involve legal in your risk assessment?
- Do you allow employees to start a competing business?
- Does it make a difference if the employee is a physician or not?



# COI Decision Trees

- Role-based mapping approach, intended to create consistency in both the review and management of like disclosures
- The Covered Individual (CI) COI Committee's purpose is to review complex situations and provide advice and consultation to Compliance





# Questions / Open Forum

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