



# **Giving in the Era of Prosecutorial Scrutiny: Navigating the Murky Waters of Patient Support Programs**

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Any examples provided are hypotheticals and should not be attributed to any individual company.

# Speakers

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# Patient Services

## PROGRAM MODELS

Pharmaceutical and biopharmaceutical manufacturers have been receiving more attention, legal scrutiny and activity from government and other entities regarding the following components of their patient support services.

### Patient Support Program

- Support provided to commercially insured patients in the form of:
  - Benefits investigation
  - Prior authorization and appeal support
  - Patient education

### Patient Assistance Programs

- Free product or co-pay assistance to uninsured or underinsured patients

### Independent Charitable Copay Foundations

- Donations to foundations that provides co-pay assistance to gov't insured patients

# Industry Landscape

## PAPS AND INDEPENDENT CHARITIES

### Aegerion

Pleads guilty to violating AKS by funding PAP which defrayed patient's copay obligations and violating HIPAA



### Jazz

Sets aside settlement money for DOJ probe into charity donations



### Lundbeck

Settles to resolve investigation of donations to independent copay assistance charities



2017

2018



### Celgene

Settles lawsuit alleging the company violated AKS through financing and steering charities to its drug



### United Therapeutics

Settles and enters into CIA for violating False Claims Act through donations to charity to pay for copays to direct patients towards its drug



### Pfizer

Settles to resolve claims, in violation of False Claims Act, that the company used a foundation to pay copays of Medicare patients

# Industry Landscape

## NURSE EDUCATORS

### Settlement

2015

**Novartis** entered into a settlement with DOJ to resolve claims that it had paid kickbacks to specialty pharmacies. One issue in the settlement was nurse-led adherence programs designed to increase refills. Nurses allegedly minimized side effects of drug.

### Example Allegations

2017

**Novo Nordisk** settled REMS violation allegations. Government declined to intervene in qui tam suit alleging the company ran a “white-coat marketing scheme” using diabetes educators who functioned as sales representatives.

Qui tam complaint - **Otsuka** regarding nurses who acted like sales reps, identified patients, provided free reimbursement support services to HCPs and targeted high-prescribing HCPs.

Qui tam complaint - **AstraZeneca**'s use of nurses who acted like sales reps, were used instead of sales reps because they could gain access, and provided free reimbursement support.

Qui tam complaints - **Gilead, Eli Lilly, Bayer** and **Amgen** for paying nurse educators to recommend and induce prescriptions of products.

2018

CA Dept. of Insurance - **AbbVie** for nurses who acted like sales reps, minimized side effects, went to patients homes and provided free reimbursement support to HCPs.

# White Coat Marketing

OIG GUIDANCE

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## **What is it? Does the government take notice?**

White coat marketing is the use of Healthcare Professionals to be involved in marketing or sales activity.

It has recently come under fire as the subject of several qui tam suits.

## **Why is it a problem?**

According to the OIG, white coat marketing receives increased scrutiny under the AKS because patients rely so heavily on the word of physicians, they may have “difficulty distinguishing between professional medical advice and a commercial sales pitch.” HCPs are “in an exceptional position of public trust, [and] may exert undue influence when recommending health care-related items or services—especially when marketing to their patients.”

*OIG Advisory Opinion No. 11-08, 2011*

# Product Support Services

## OIG GUIDANCE



### BAD

- Marketing/selling tool & unbalanced info re: risks
- Touted as a benefit/substitute for services
- Violates privacy laws
- Medical advice
- Provided based on volume/value of Rx's
- Lack of transparency (role w/ drug company)
- Reimbursement guarantees
- Completing medical info for physician office and not keeping office informed

### MEDIUM

- Using people w/ direct contact with patients

### GOOD

- Balanced, necessary info for appropriate & safe use of product
- No independent value & tailored to product
- Does not violate privacy laws
- No provision of medical advice
- Provided to all offices/patients equally
- Transparency
- Services provided after Rx
- Keeping physicians' office informed & requiring medical info to be provided by physician office & physician signature



# Risk Mitigation

## CONSIDERATIONS

Operational controls are critical to mitigating risks associated with patient services programs.

### Patient Support Services

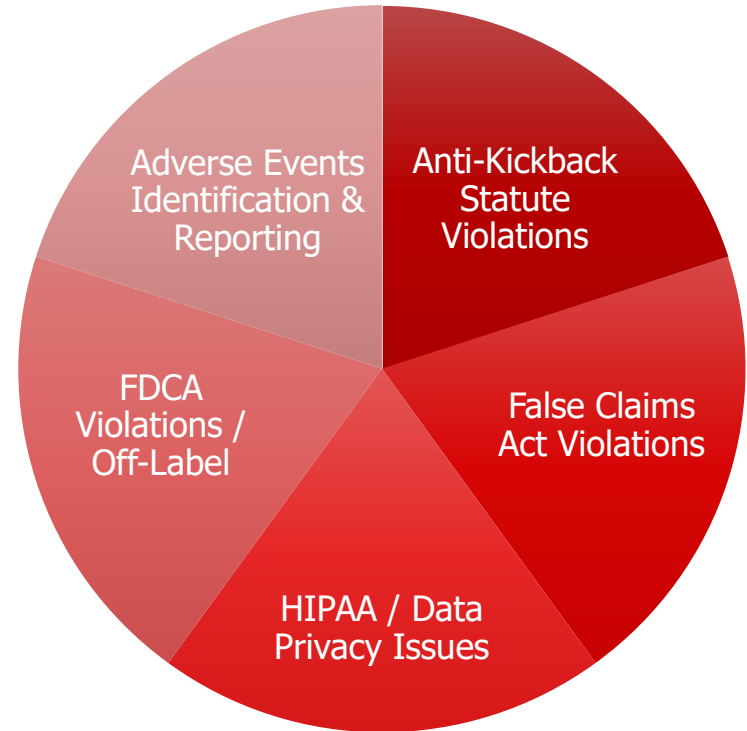
- Purpose and types of services provided
- Appropriateness of HCP and Patient interactions
- Privacy laws
- Relationship with sales
- Balanced information provided
- Monitoring & auditing of services and Hubs/specialty pharmacies

### Patient Assistance Programs

- Coverage for off-label uses of product
- Measures to exclude Medicare/Medicaid patients

### Independent Charities

- Organizational structure that makes funding decisions
- Exchange of information and data



# Risk Mitigation

## MONITORING & AUDITING



### **Recorded Calls**

Record calls with patient services representatives and audit by management and Compliance



### **Call Notes/Email Audits**

Text analytics/other monitoring of call notes & email audits for issues relating to improper interactions with patient support groups or misuse of independent charities



### **Processes & Controls**

Grants/donations processes devoid of commercial influence, proper monitoring of data flows to and from independent charities and within company



### **Contracts**

Review existing contracts between patient service HUBs and Patient Assistance Programs (PAPs), ensure services are being provided for FMV, ensure contracts with charities have proper legal requirements



### **In-Person Monitoring**

Conduct in-person monitoring of field and virtual personnel to ensure policies are being followed



### **Reimbursement Support**

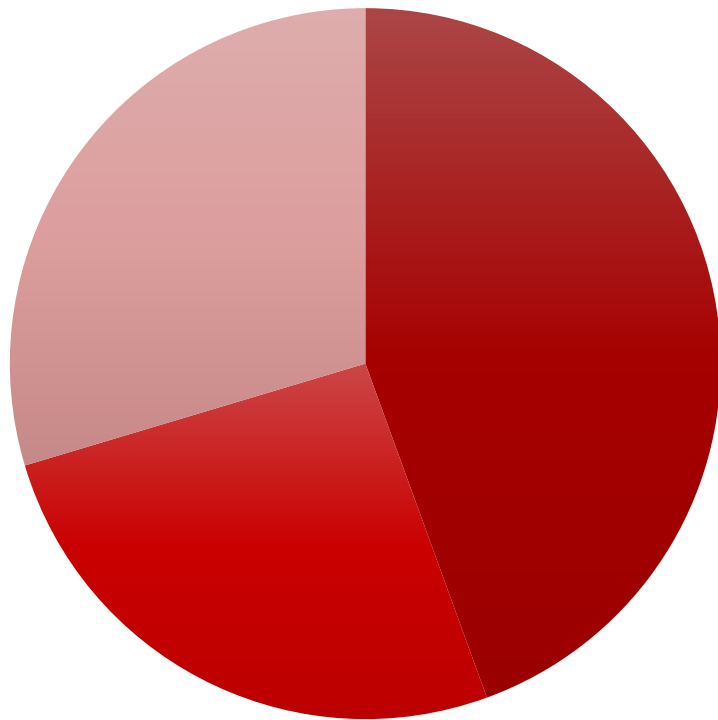
Conduct routine audits of vendors or employees providing insurance and other reimbursement support to ensure compliance with laws & policies

# Survey Results

## ORGANIZATION OVERVIEW



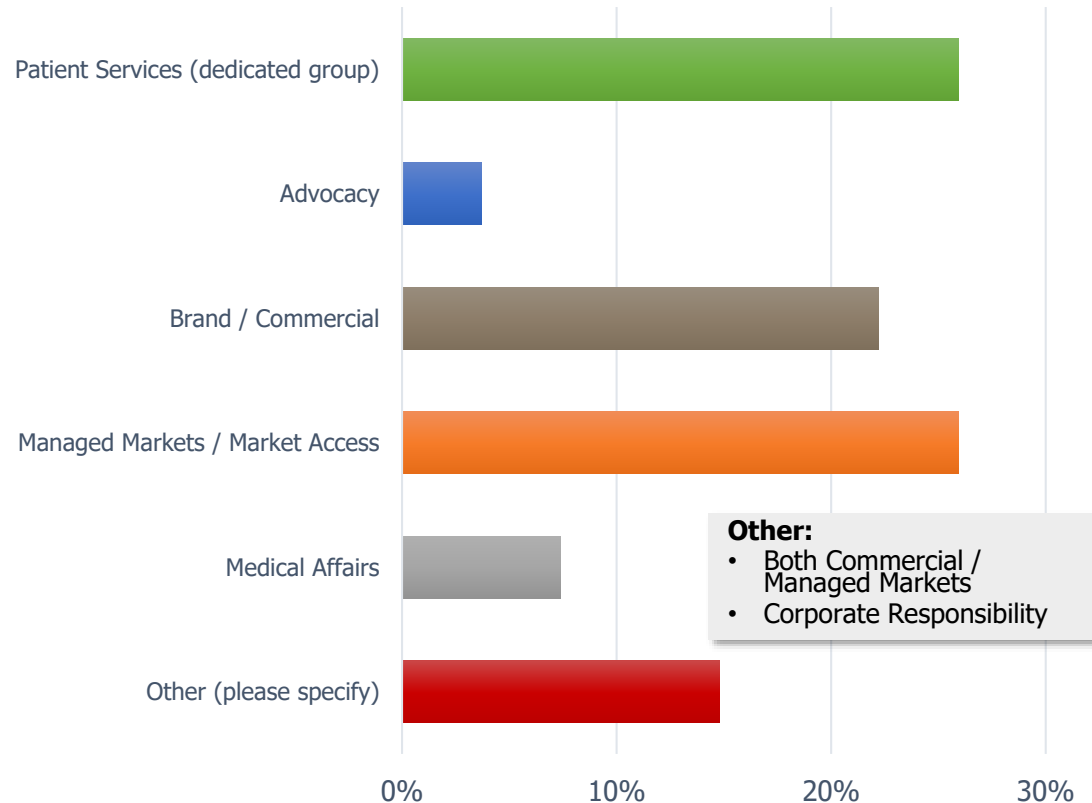
### What is the size of your organization?



■ Small ■ Mid-Size ■ Large (Top 20 Pharma)

The results include information from 27 respondents.

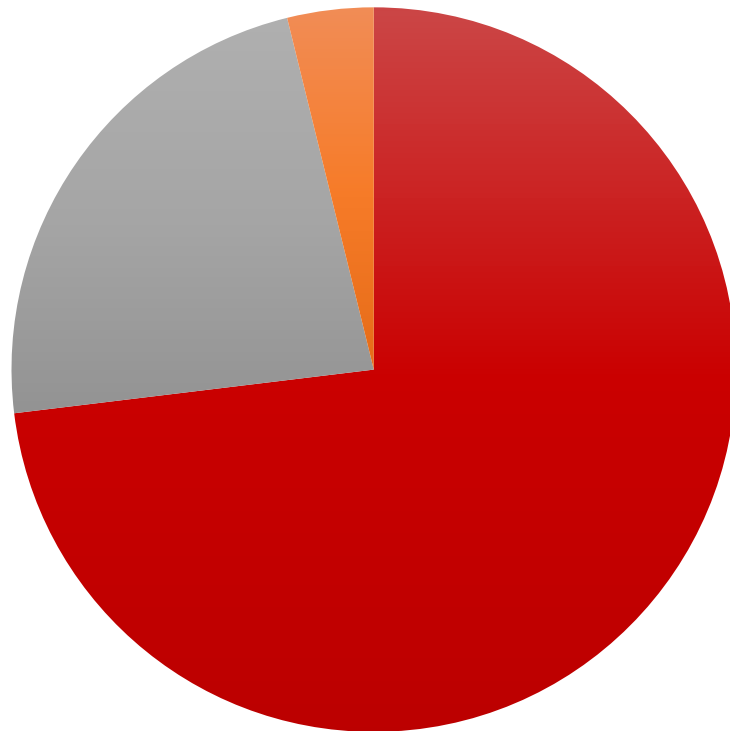
### Where is your Patient Services team located within your organization?



# Survey Results

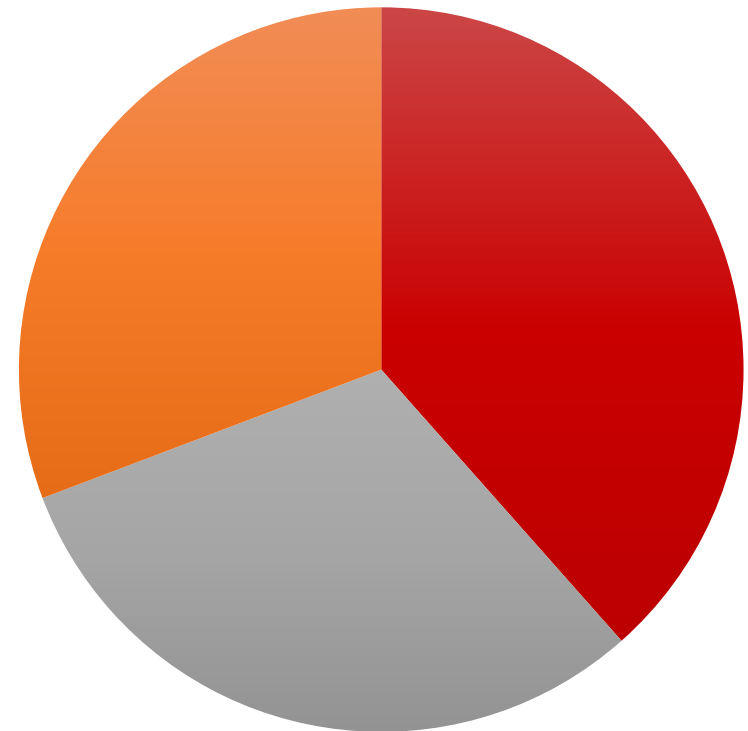
## FUNDING TO INDEPENDENT CHARITIES

**Does your company provide funding to independent charities or independent co-pay foundations?**



■ Yes ■ No ■ Uncertain

**Has your funding process changed in the past 1-2 years due to the ongoing environment of regulations, investigations and CIAs focused on this type of funding?**

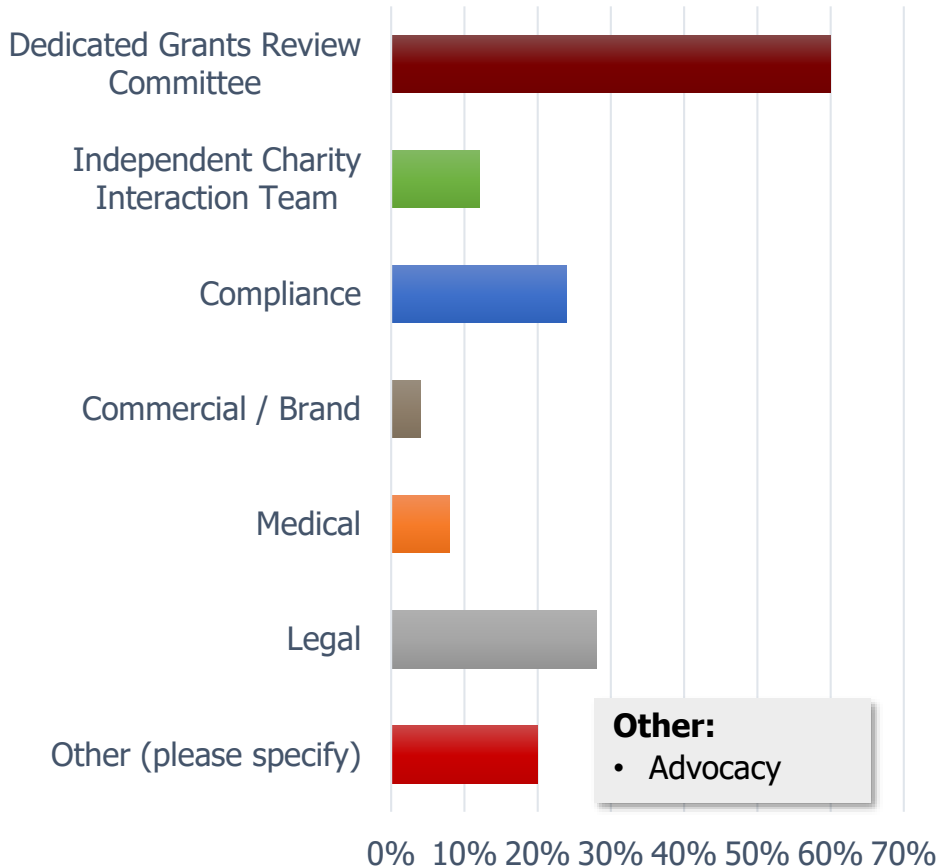


■ Yes ■ No ■ Uncertain

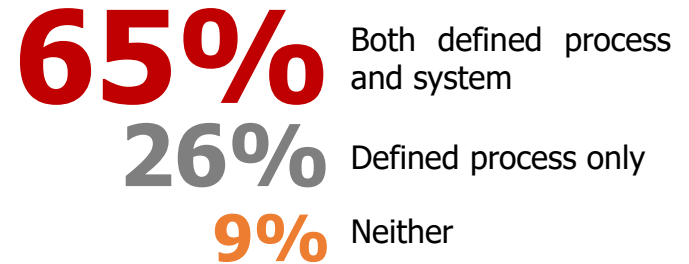
# Survey Results

## FUNDING TO INDEPENDENT CHARITIES

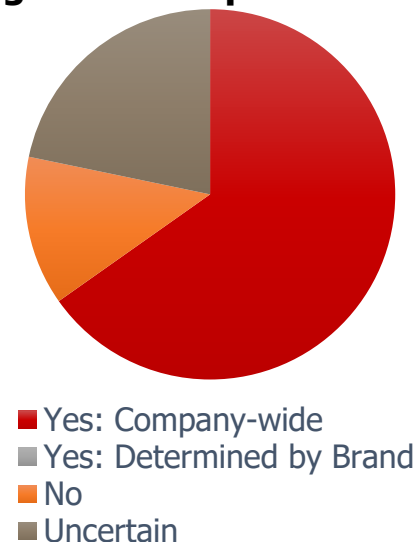
### What department/function is responsible for reviewing and approving funding requests?



### Is there a clearly defined process and/or system utilized for reviewing and approving funding requests?



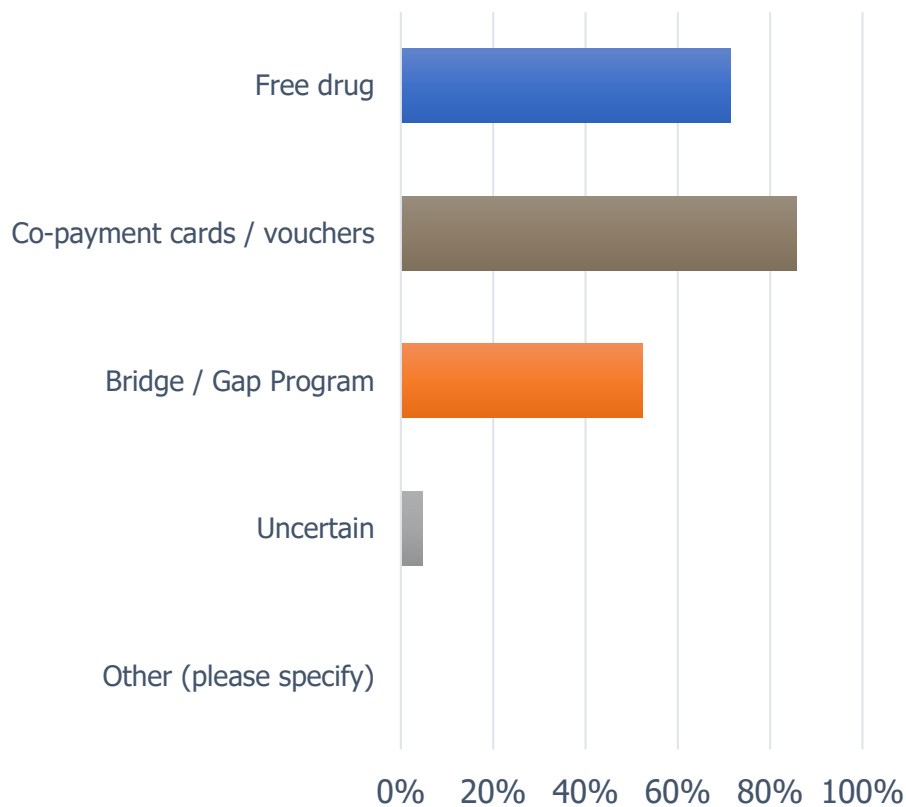
### Are there specific and defined criteria for donating to an independent charity?



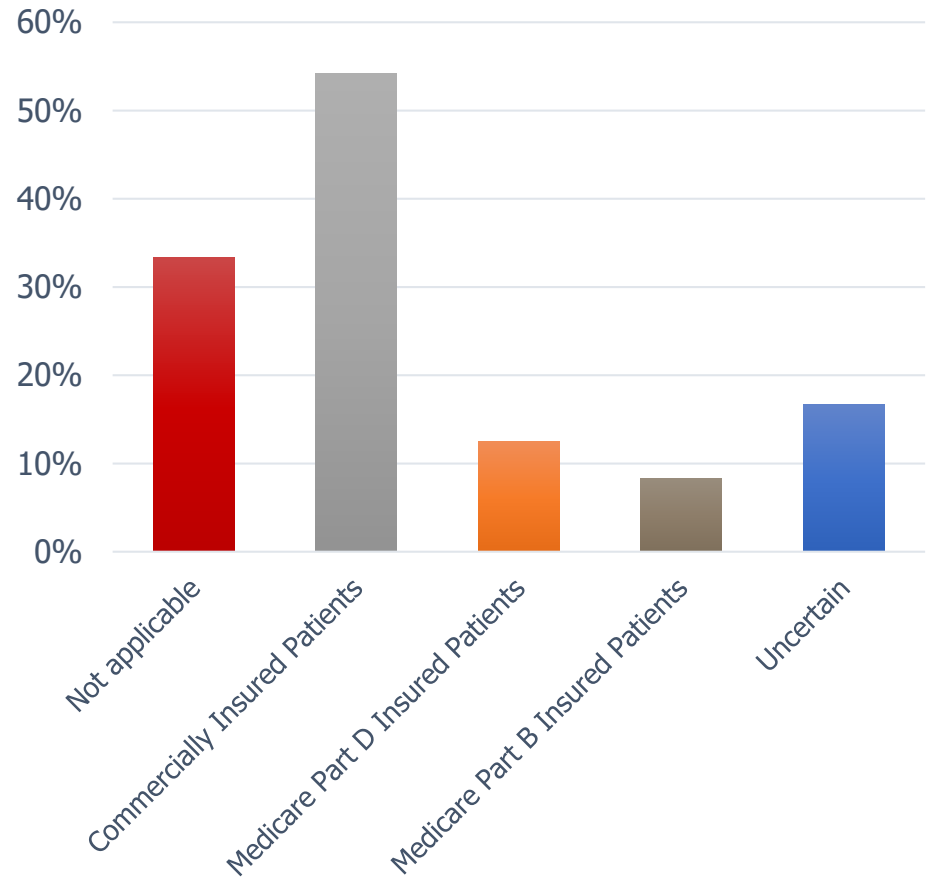
# Survey Results

## PATIENT ASSISTANCE PROGRAMS

### What does your company provide?



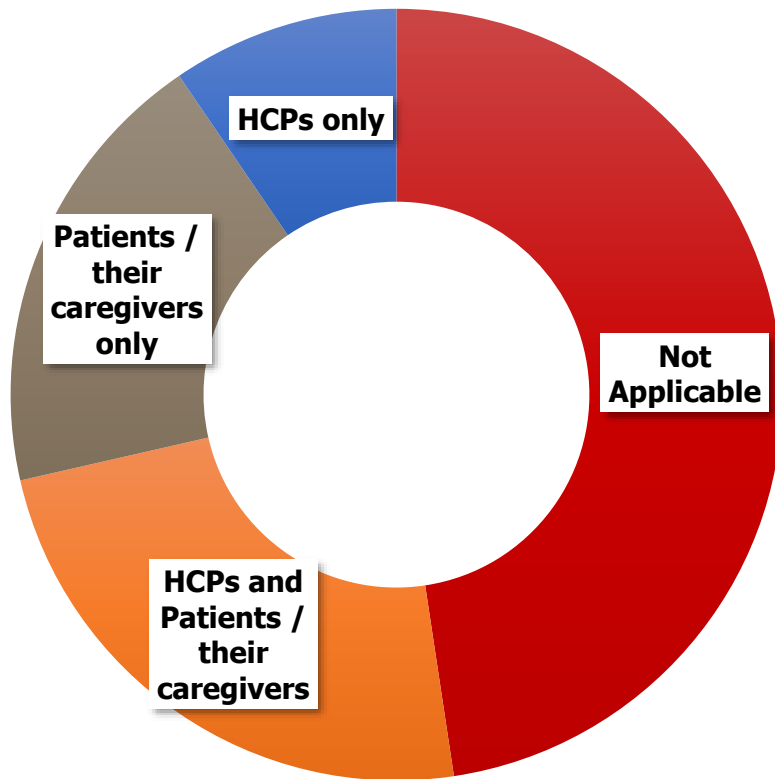
### Does your company provide free drug to the following?



# Survey Results

## TEAM STRUCTURE AND SERVICES: NURSE EDUCATORS

**Whom do your Patient Services nurse educators interact/support?**



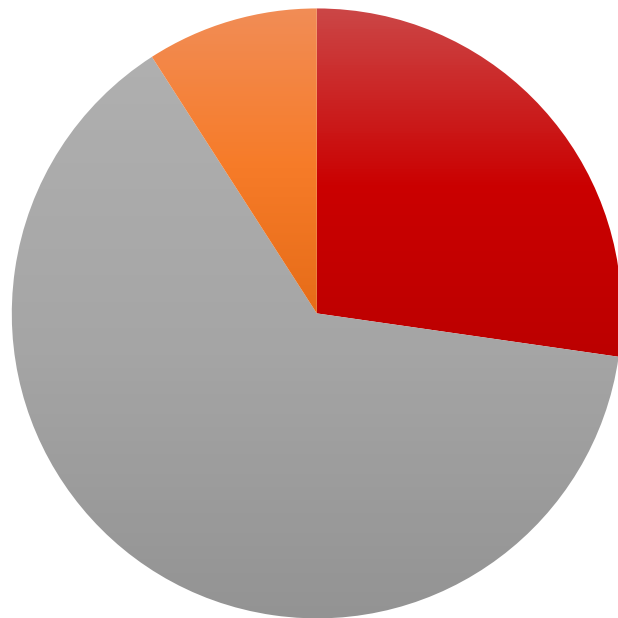
**Which of the following resources do the nurse educators use?**



# Survey Results

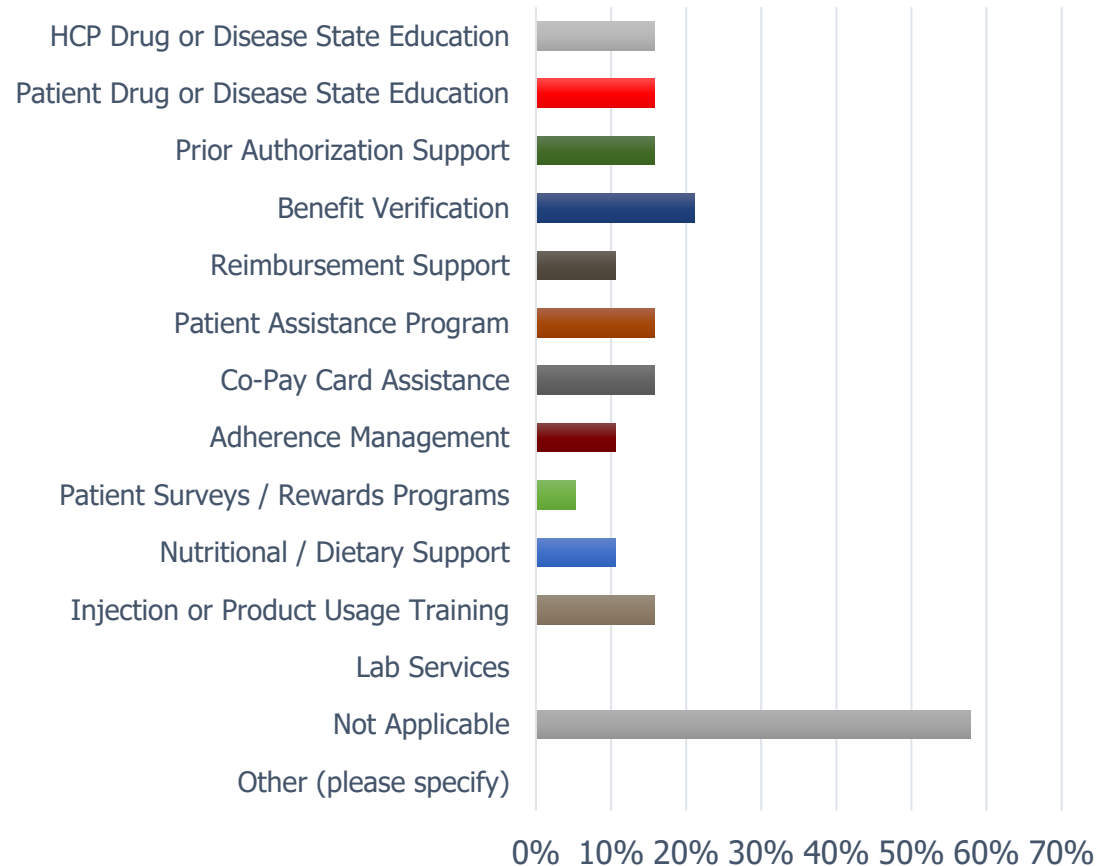
## TEAM STRUCTURE AND SERVICES: UNAPPROVED INDICATION

**Do you provide any Patient Services to patients using your product for an unapproved indication?**



■ Yes ■ No ■ Uncertain

**Which of the following Patient Services do you provide to patients using your product for an unapproved indication?**



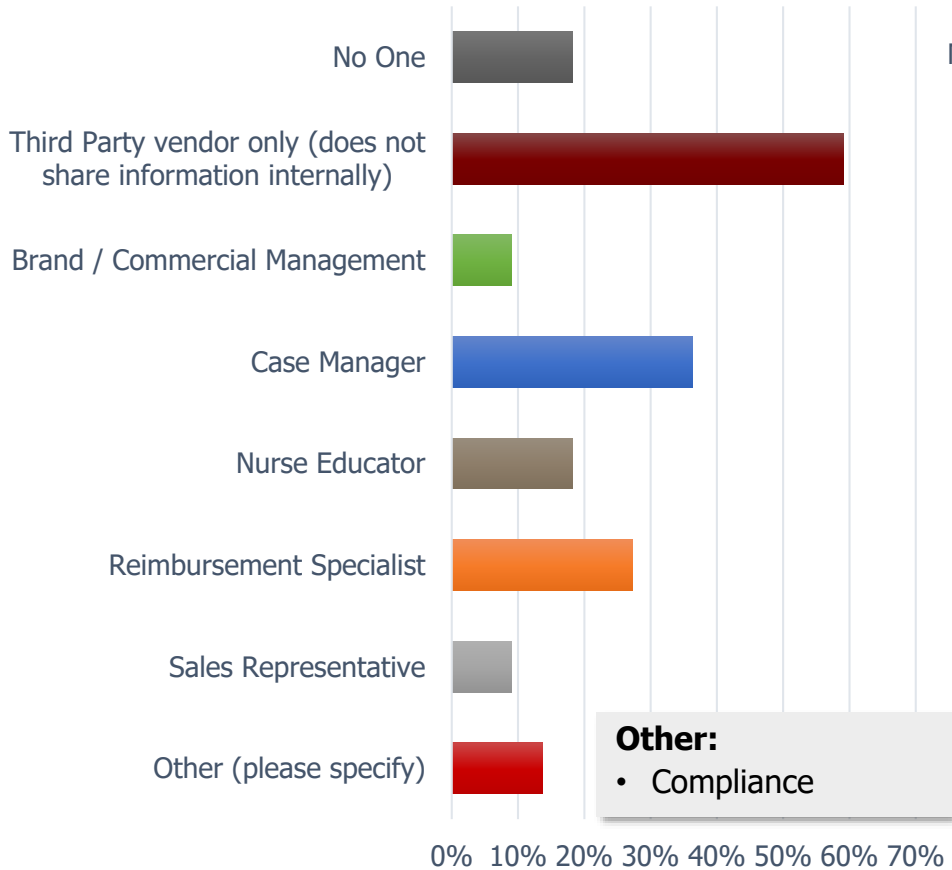


# Survey Results

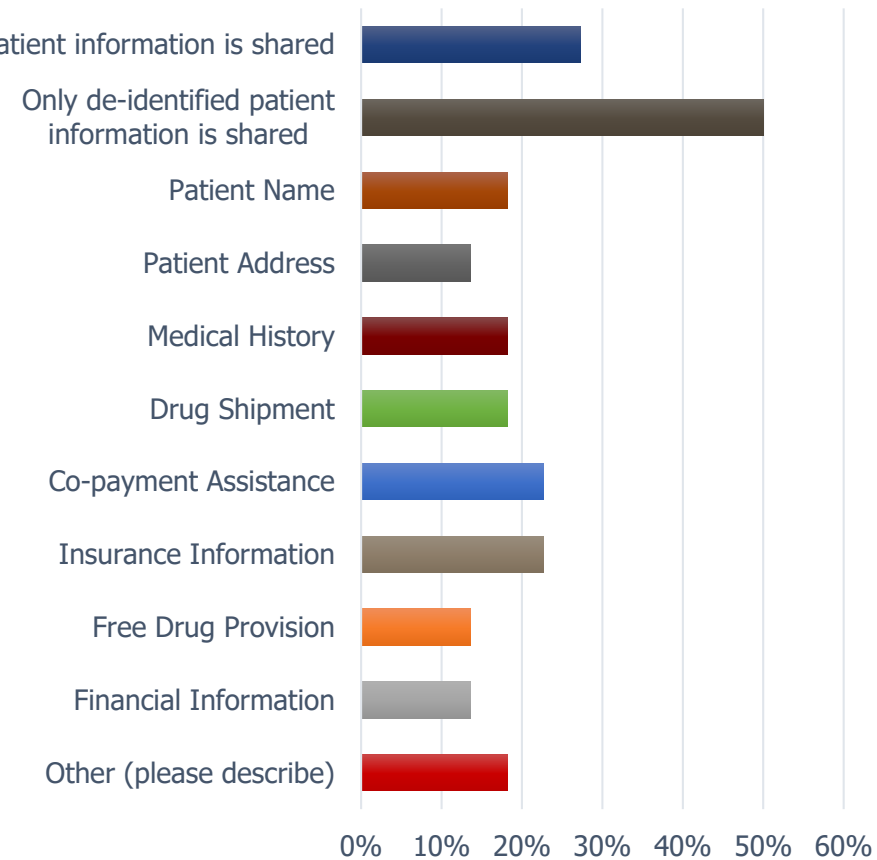
## DATA PRIVACY



### Who in your organization has access to patient data or information?



### What specific components of patient data are shared between functional areas?

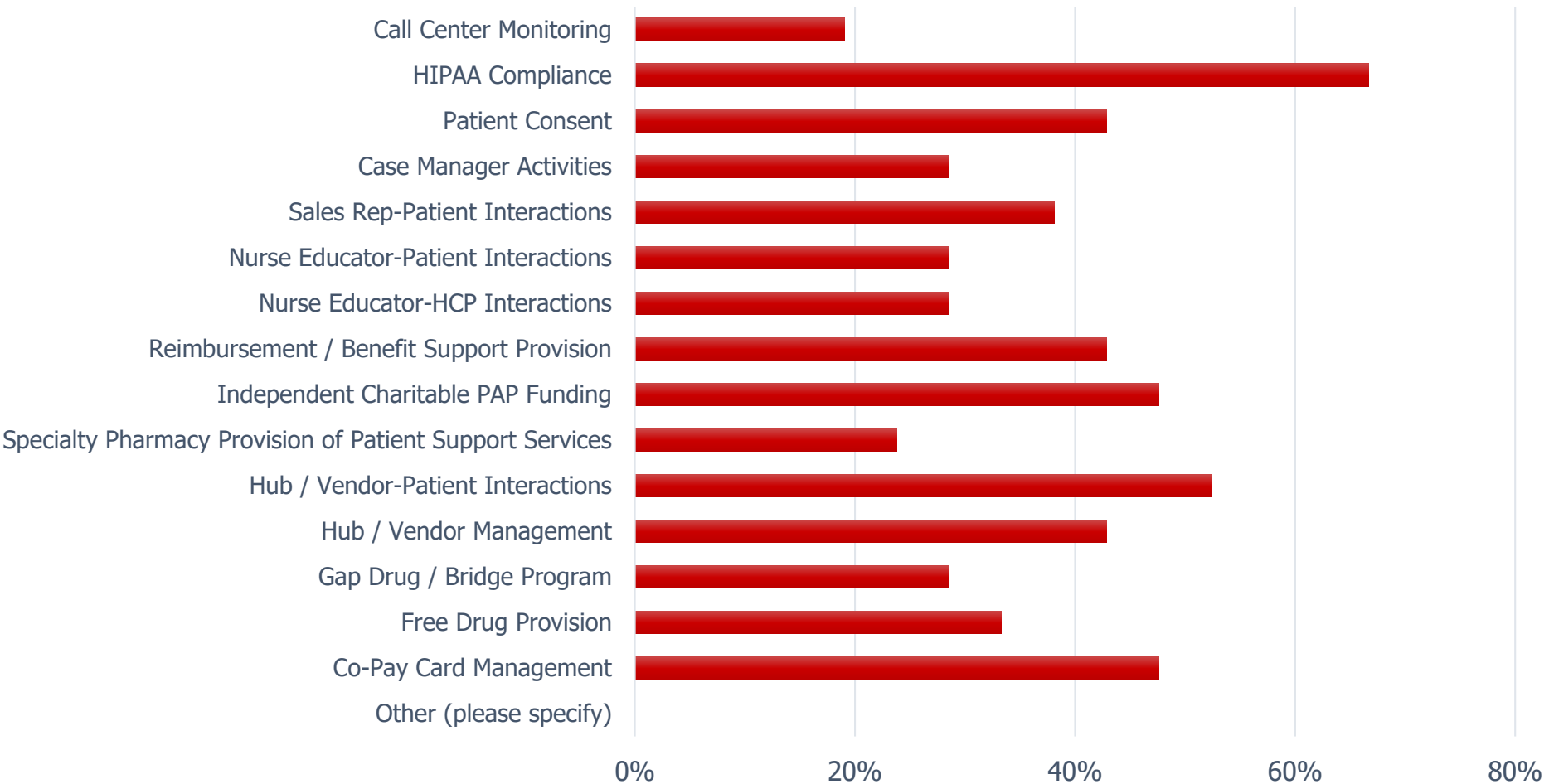


# Survey Results

## COMPLIANCE CONCERNS



### What is your biggest concern regarding patient services and compliance?



# Q&A

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