



# Interactions with Patients Including Benchmarking on Patient Services Compliance

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# Speakers

INDUSTRY EXPERT PANEL

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## Stefanie Doebler

Of Counsel

*Covington & Burling LLP*

## Chapman Richardson

Global Head, Data Consumerization

*Sanofi*

## Sarah Whipple

Vice President, Legal & Chief  
Compliance Officer

*Akebia Therapeutics, Inc.*

# Patient Services

## TYPES OF PROGRAMS

Pharmaceutical and biopharmaceutical manufacturers have been receiving greater attention and scrutiny from the government and other entities regarding their interactions with patients through their patient services programs.

### **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

# 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

Anti-Kickback Statue

False Claims Act

HIPAA / Data Privacy

FDCA / Off-Label

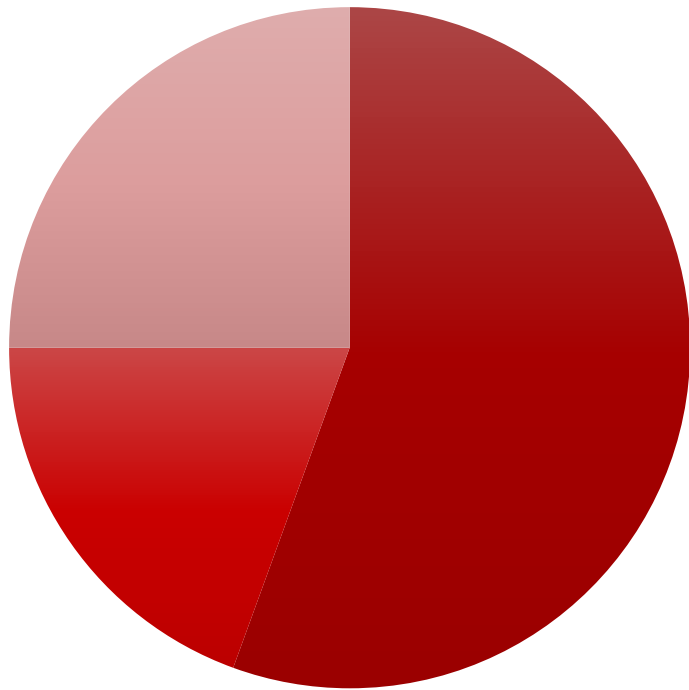
Adverse Events Reporting

# Survey Results

## ORGANIZATION OVERVIEW

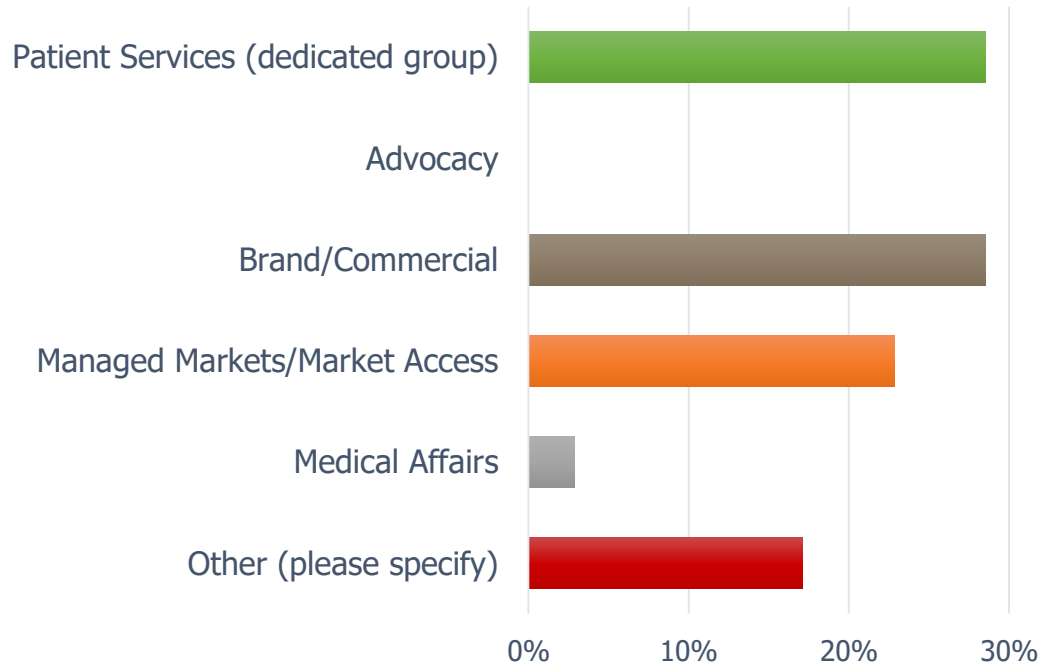


### What is the size of your organization?



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

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



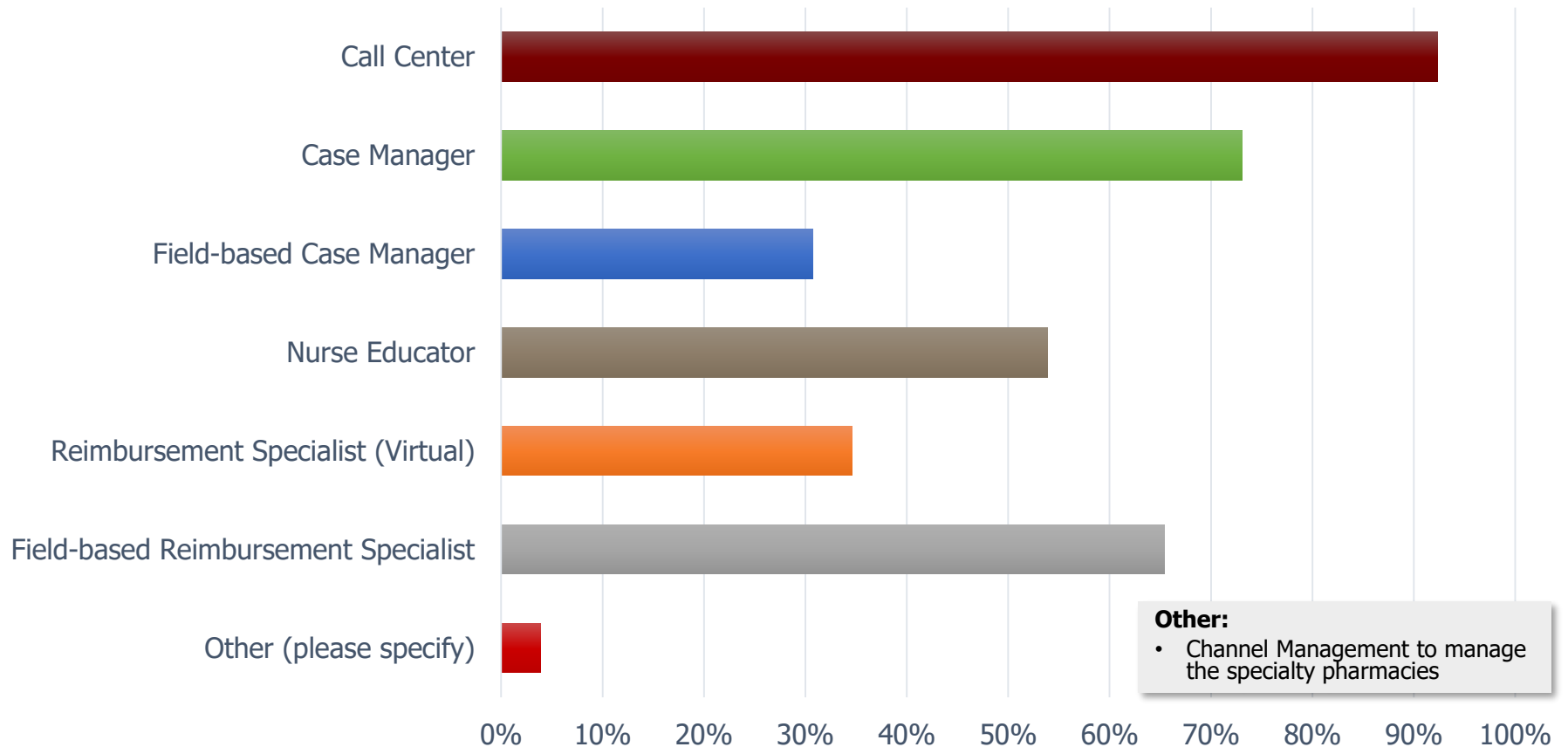
#### Other:

- Both Patient Services and Brand/Commercial
- Both Brand/Commercial and Managed Markets/Market Access
- Corporate Responsibility
- No dedicated patient service team

# Survey Results

## TEAM STRUCTURE AND SERVICES

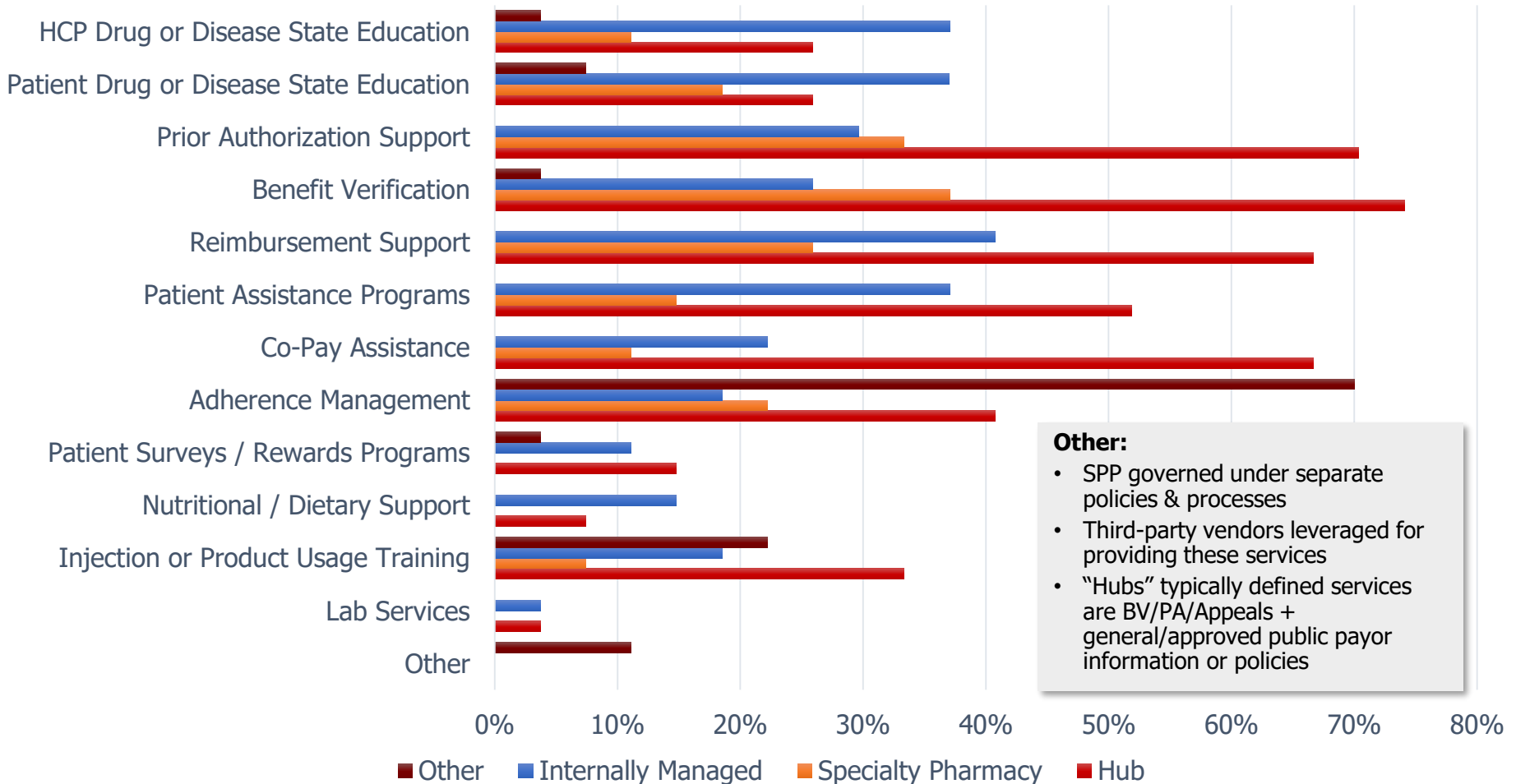
### Which of the following types of individuals/groups does your Patient Services team include?



# Survey Results

## TEAM STRUCTURE AND SERVICES

### Which of the following services does your Patient Services Team provide and how are they managed?





# Funding to Independent Charities

NEW SETTLEMENTS AND CORPORATE INTEGRITY AGREEMENTS

## Jazz, Lundbeck, and Alexion

Agrees to pay a total of \$122.6M to resolve allegations that they each violated the False Claims Acts by illegally paying the Medicare or Civilian Health and Medical Program (ChampVA) copays for their own products through purportedly independent foundations as conduits. Jazz and Lundbeck also entered a CIA with the OIG.

## US WorldMeds

Agrees to pay \$17.5M to resolve allegations that they violated the False Claims Act by paying kickbacks to patients and physicians to improperly induce prescriptions of its drugs Apokyn and Myobloc. US WorldMeds also entered into a CIA.

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## Astellas and Amgen

Agrees to pay a total of \$125.75M to resolve False Claims Act allegations that they each paid illegal kickbacks to Medicare patients using copay assistance foundations as conduits. Both companies also entered into a CIA.

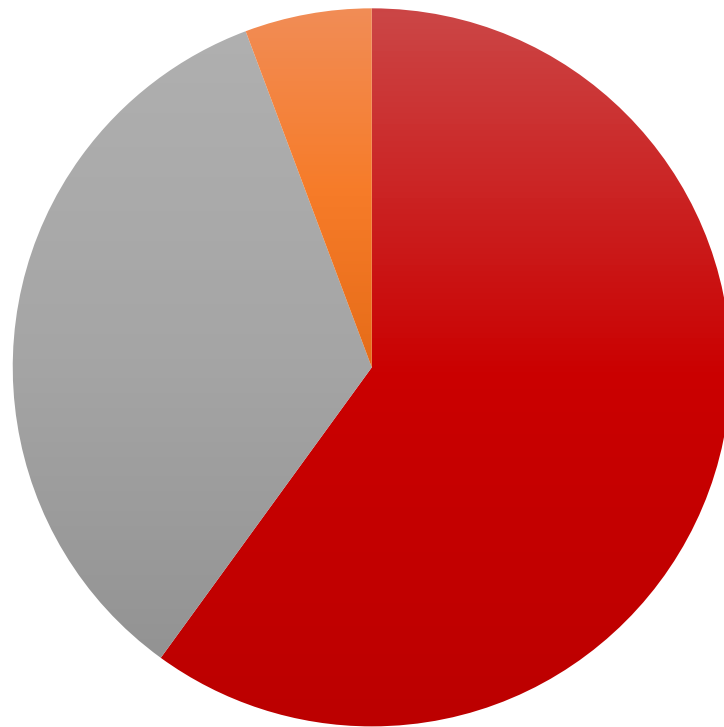
## Chronic Disease Fund (Good Days) & Patient Access Network Foundation

Agrees to pay a total of \$6M to resolve allegations that they were used as a conduit to pay kickbacks to Medicare patients. Both foundations also entered into a CIA.

# Survey Results

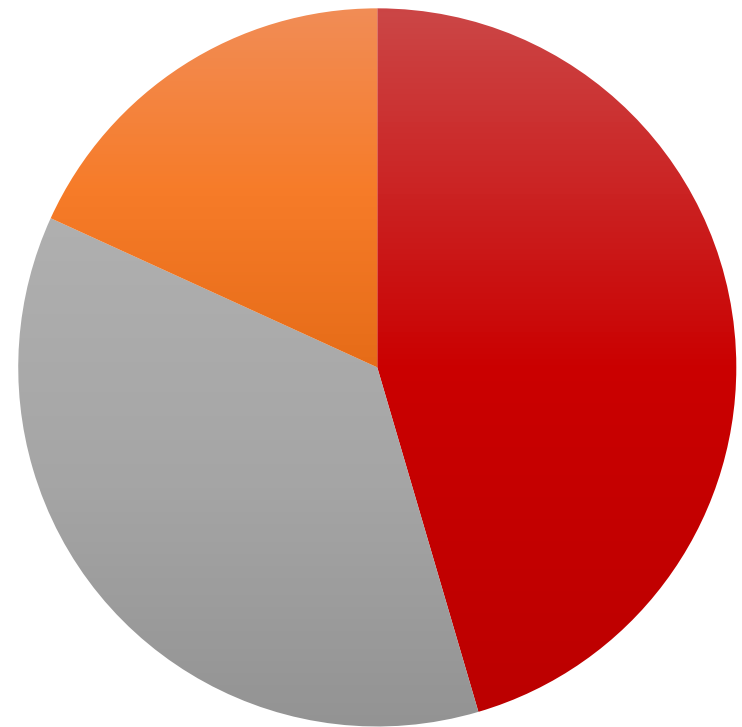
## FUNDING TO INDEPENDENT CHARITIES

**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?**

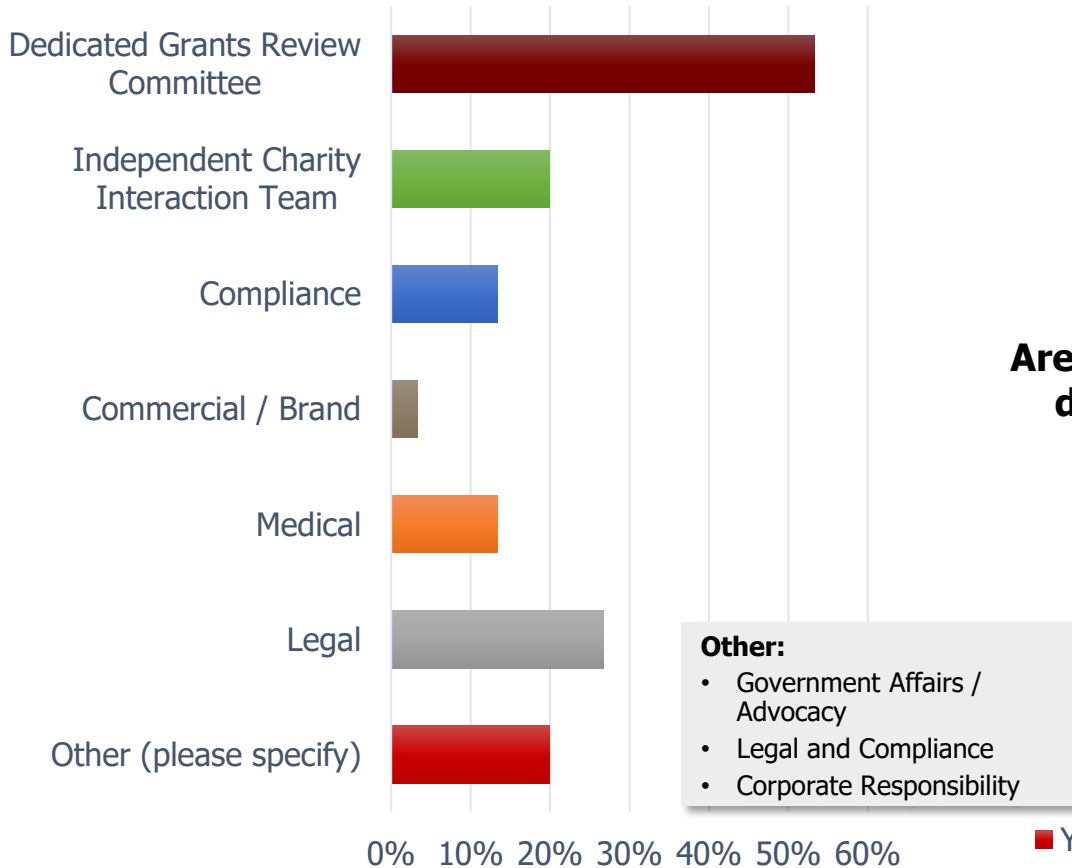


■ Yes ■ No ■ Uncertain

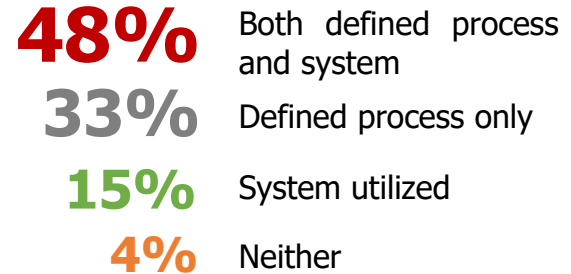
# Survey Results

## FUNDING TO INDEPENDENT CHARITIES

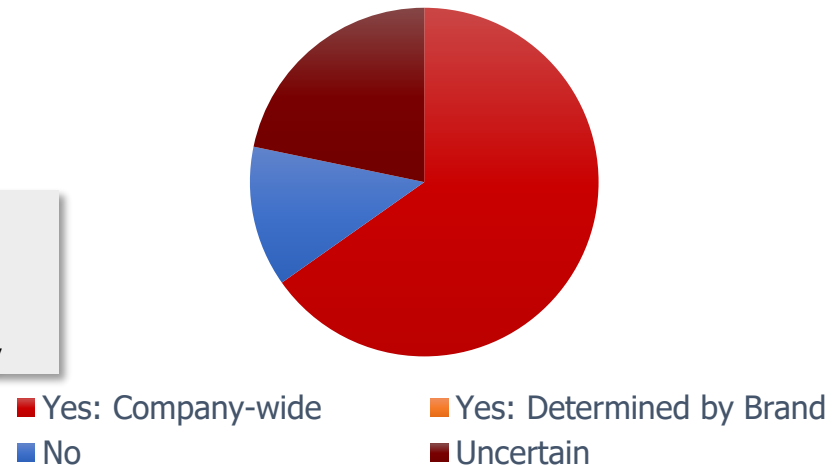
### What department/function is responsible for reviewing and approving funding requests?



### 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?



# Patient Data Privacy

## CONSIDERATIONS

- Use of Patient Data
- Storage of Patient Data
- Data Privacy Regulations
  - HIPAA
  - GDPR
  - State Specific Privacy Laws
    - California Consumer Protection Act

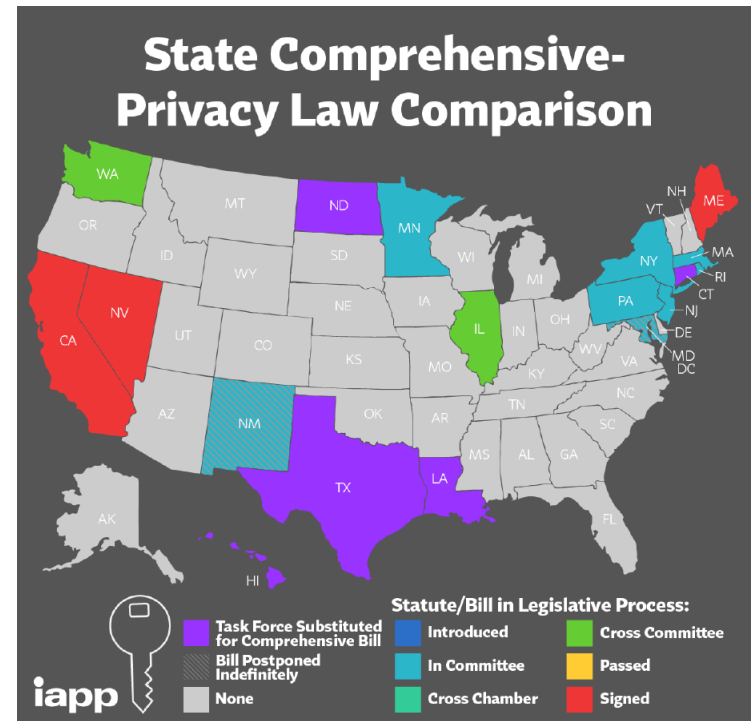
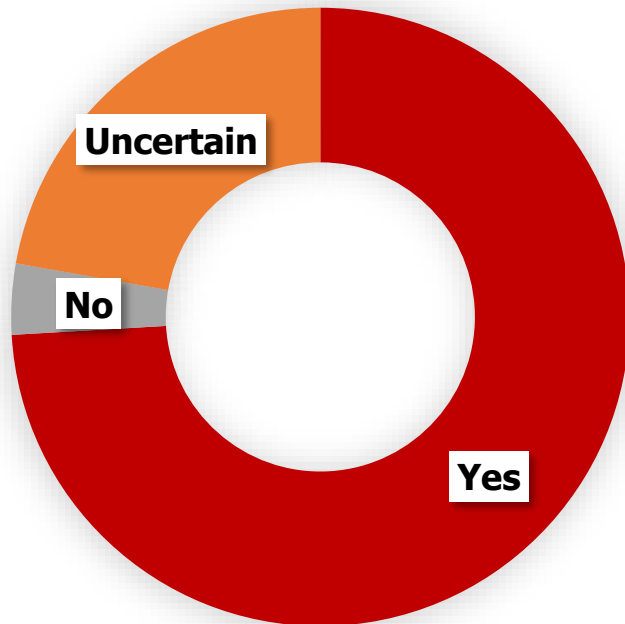


Image source: <https://iapp.org/resources/article/state-comparison-table/>

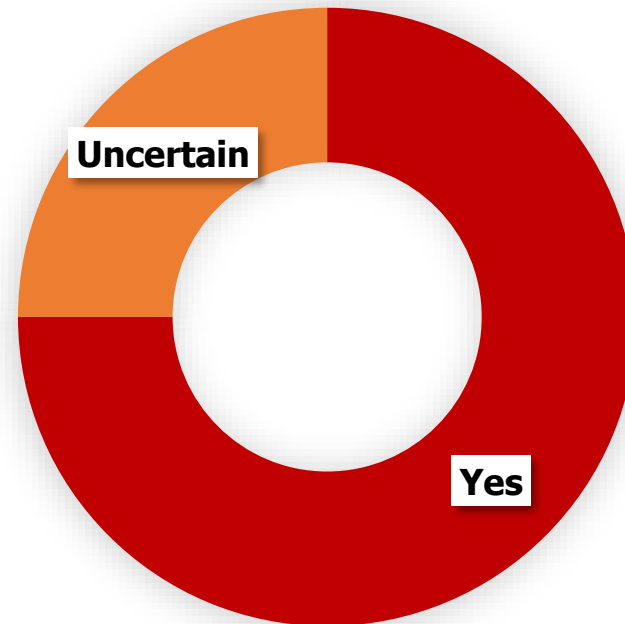
# Survey Results

## DATA PRIVACY

**Does your company deploy a data privacy management program?**



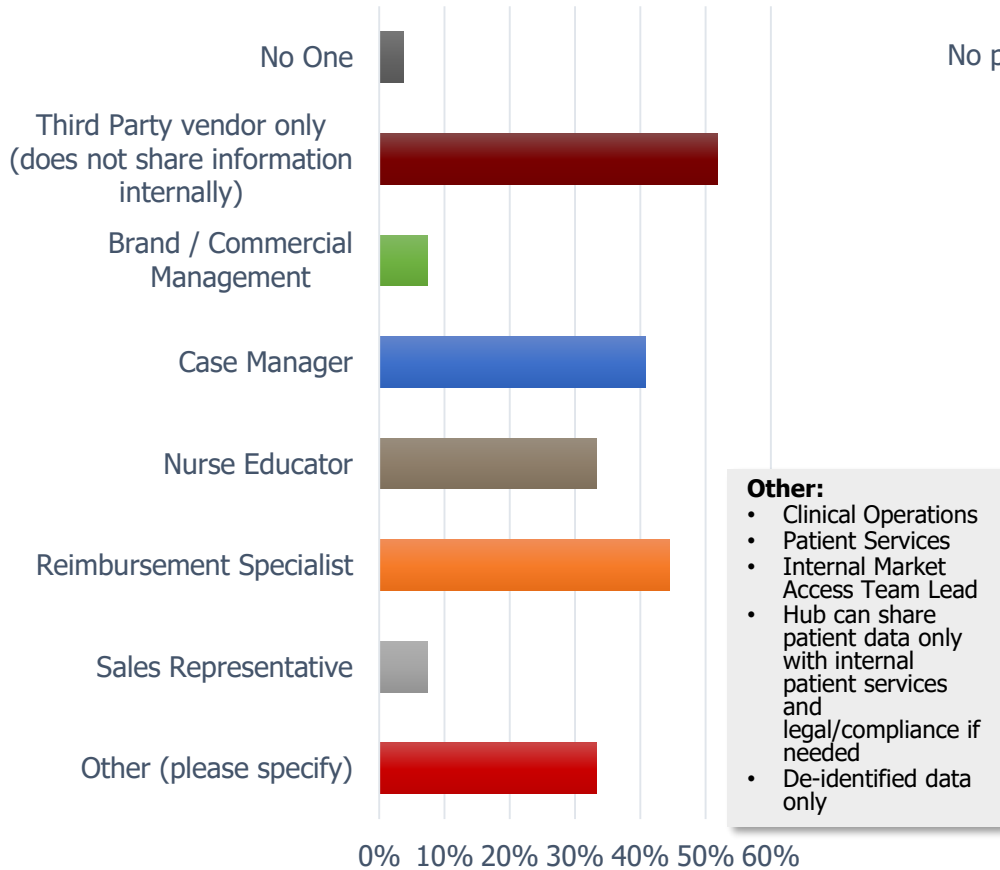
**Is your patient services platform HIPAA compliant?**



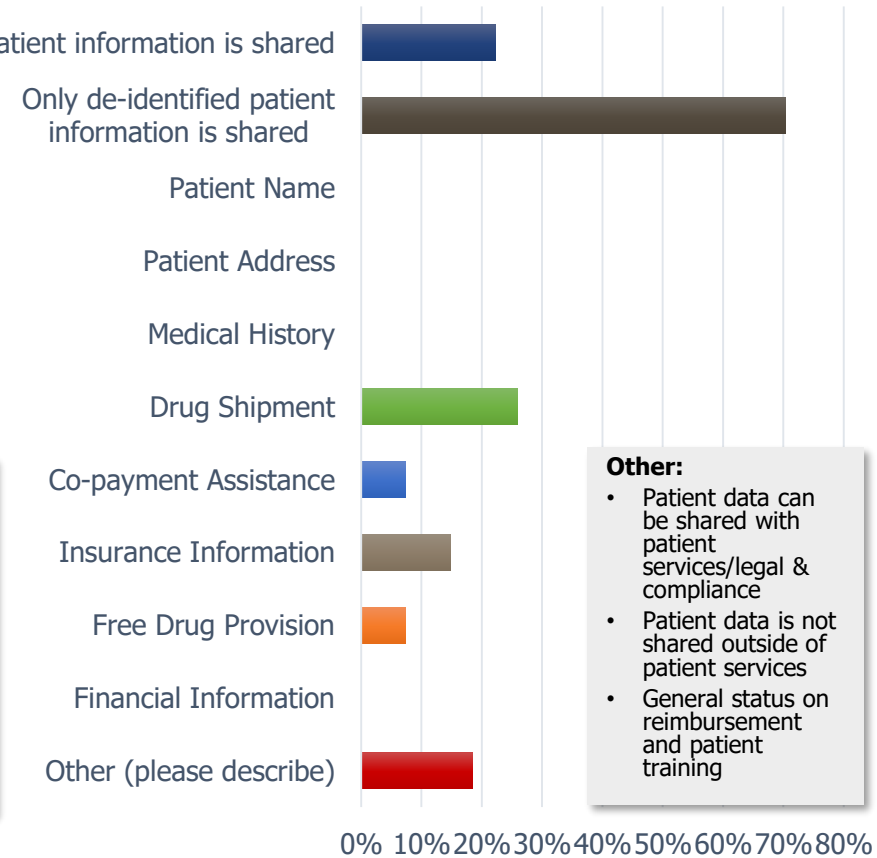
# Survey Results

## DATA PRIVACY

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



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

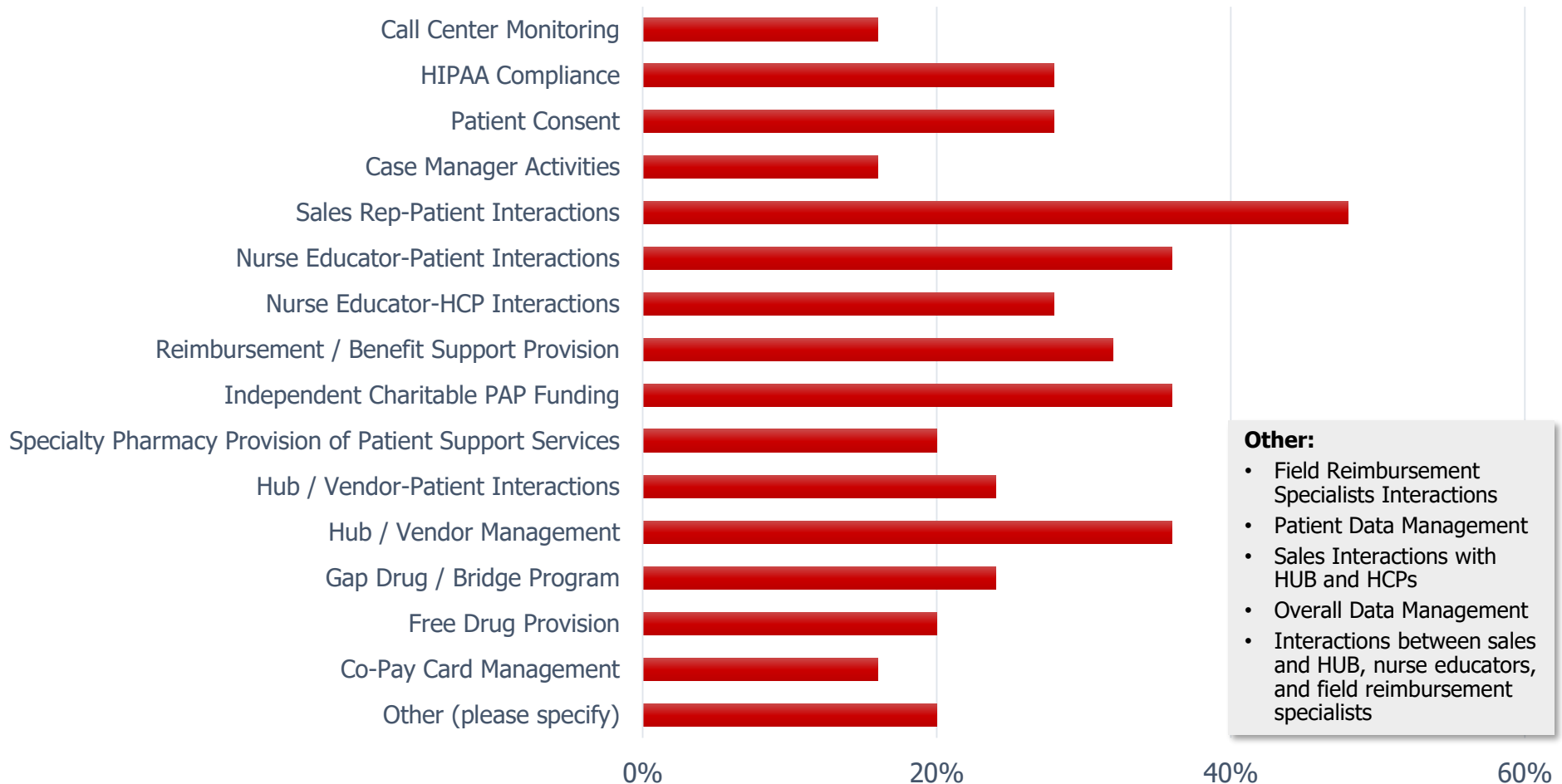


# Survey Results

## COMPLIANCE CONCERNS



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



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