



REVIEW: 4th Annual Patient Services Program Compliance Survey

**Virtual Twenty-First Annual PCF Pharmaceutical
and Medical Device Ethics and Compliance Congress**



Disclaimer

The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the presenters' employers.

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

Panelists

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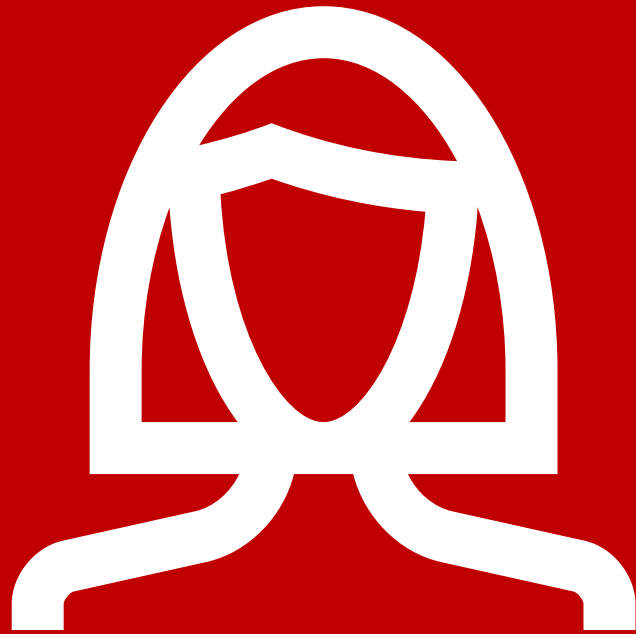
Introduction

For the fourth consecutive year, Helio Health Group collected insights from compliance professionals around the industry with respect to Patient Services Programs (“PSPs”), a still-evolving element of life sciences companies’ strategies that continues to bear potential risks stemming from the increasingly complex commercial and financial relationships across payer, provider, and patient organizations. Since 2017, Helio’s annual patient services compliance survey has provided a year-to-year perspective of industry benchmarks for controlling the risks associated with expanding patient access to therapeutics through PSPs.

The 2020 edition of Helio’s survey highlights the evolving aspects of patient services program compliance driven by a year of new developments in Federal and State enforcement activity accompanied by an unparalleled level of digital disruption throughout the life sciences sector as a whole. The results also offer a look into companies’ responses to the increased monitoring burden of patient services programs in the context of 2020’s dramatic shift to digital work environments.

Organizational Structure

What is the size of your organization?



46%

Small (Lower than Top 50 Biopharma)

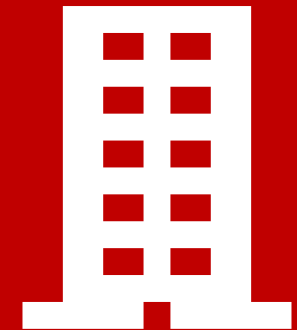


25%

Medium (Top 50 to 20 Biopharma)

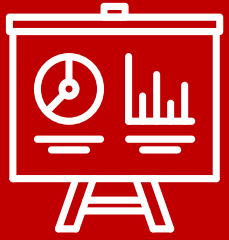
29%

Large (Top 20 Biopharma)



Organizational Structure

Where is your Patient Services team located within your organization?



33%

Managed Markets



29%

Patient Services
(Dedicated group)

13%

Brand / Commercial



4%

Advocacy



8%

Medical Affairs

13% Other

Does your Company have an individual in Compliance or Legal who is involved/responsible for Patient Services activities/approvals?

63%



Yes, Legal & Compliance
Dedicated Resource

33%



Yes, Legal Review Only

4%



Yes, Other

Patient Assistance Programs

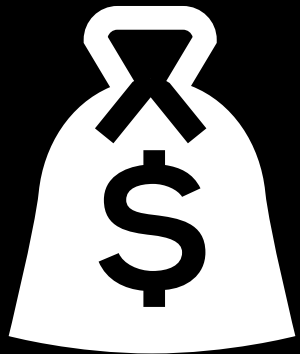
Patient Assistance Programs

Does your Company provide patient assistance program(s)?

87% Yes

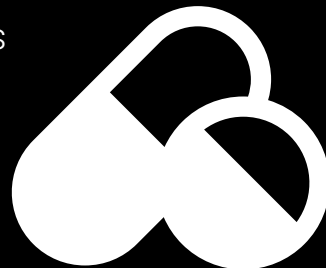
13% No

If applicable, select all that apply:



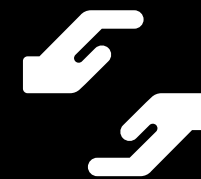
95%

Co-payment Cards/Vouchers



85%

Free Drug



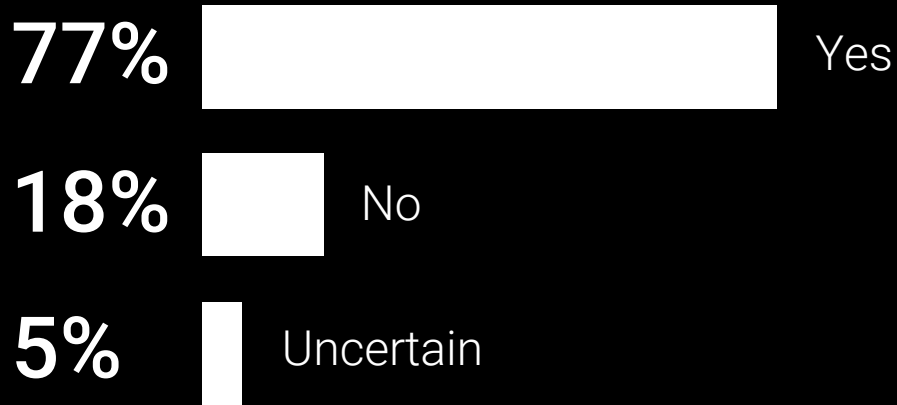
60%

Bridge/Gap Program

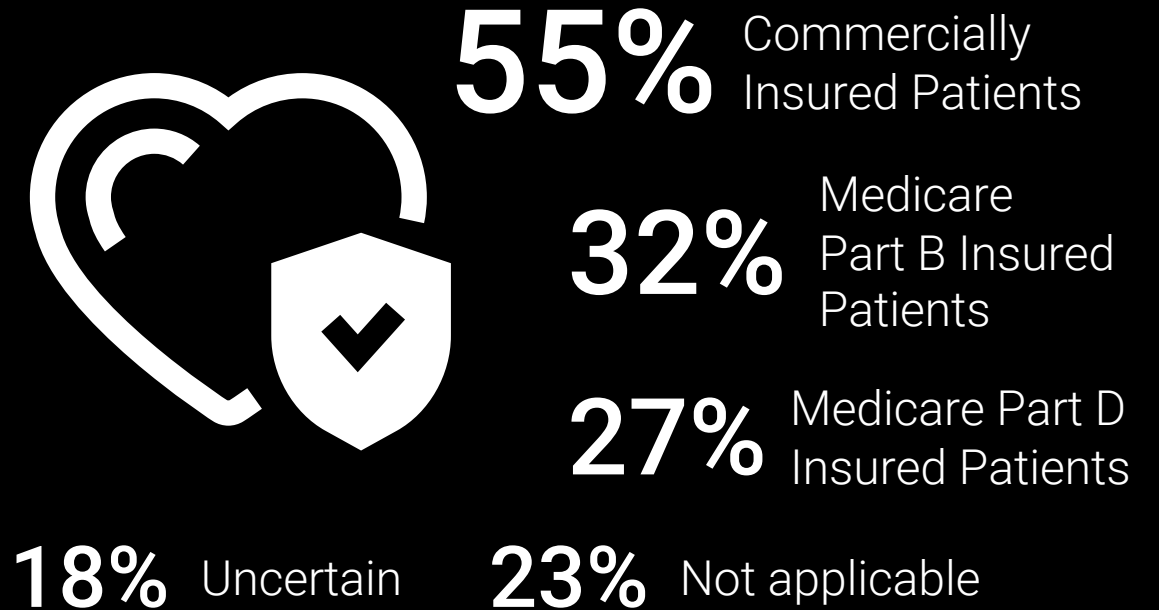
5% Uncertain

Patient Assistance Programs

If applicable, do you have policies and/or procedures for the operation of or participation in the PAP?

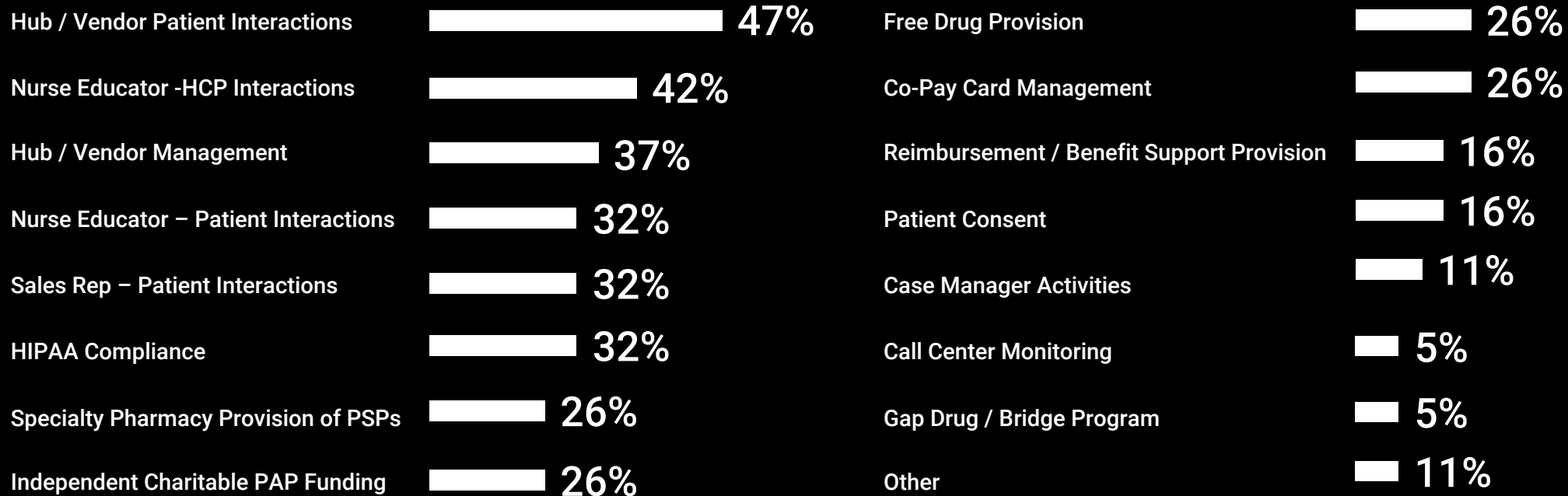


Does your Company provide free drug to the following? Select all that apply.



Patient Assistance Programs

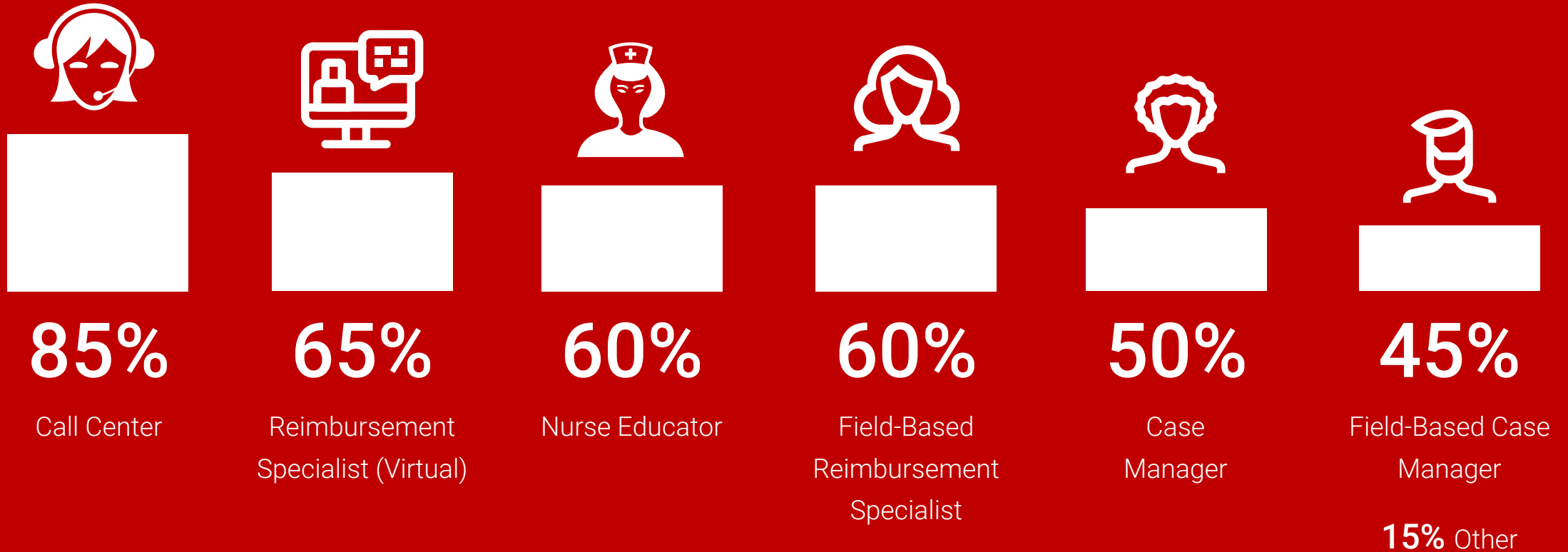
What is your biggest concern regarding patient services and compliance?
Select all that apply.



Team Structure and Services

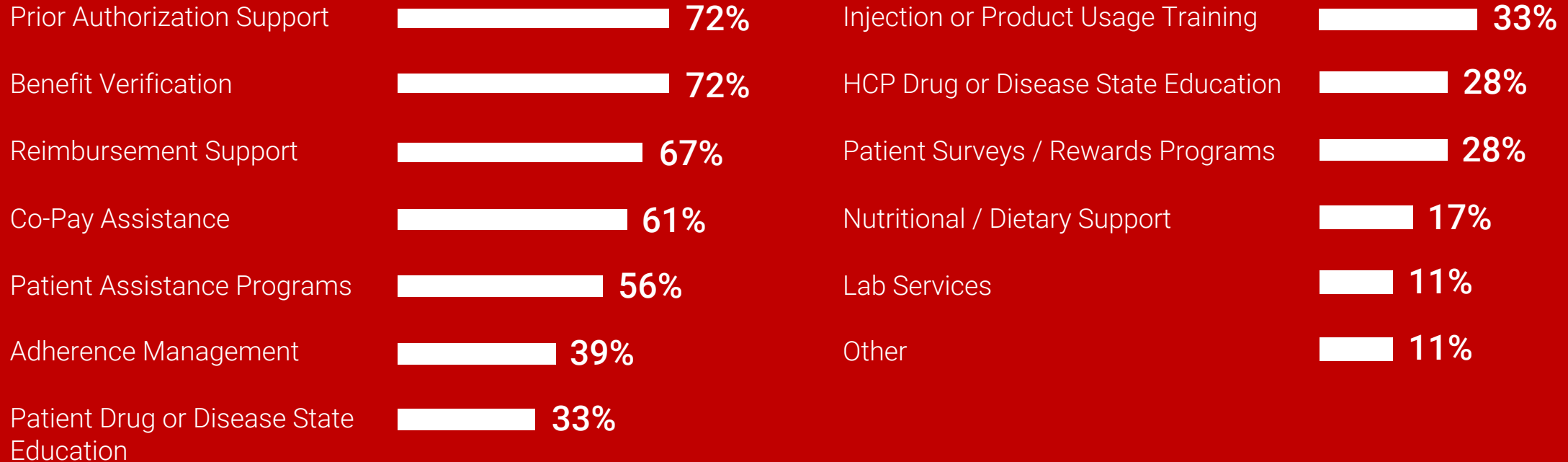
Team Structure and Services

Which of the following types of individuals/groups does your Patient Services team include? Select all that apply.



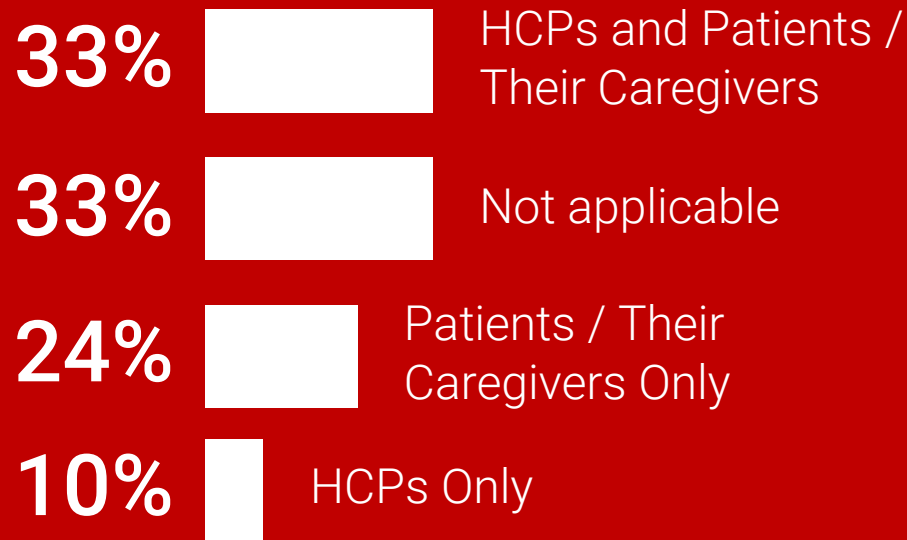
Team Structure and Services

Which of the following services does your Patient Services Team provide through a HUB? Select all that apply.



Team Structure and Services

If you have nurse educators, whom do your Patient Services nurse educators interact/support?

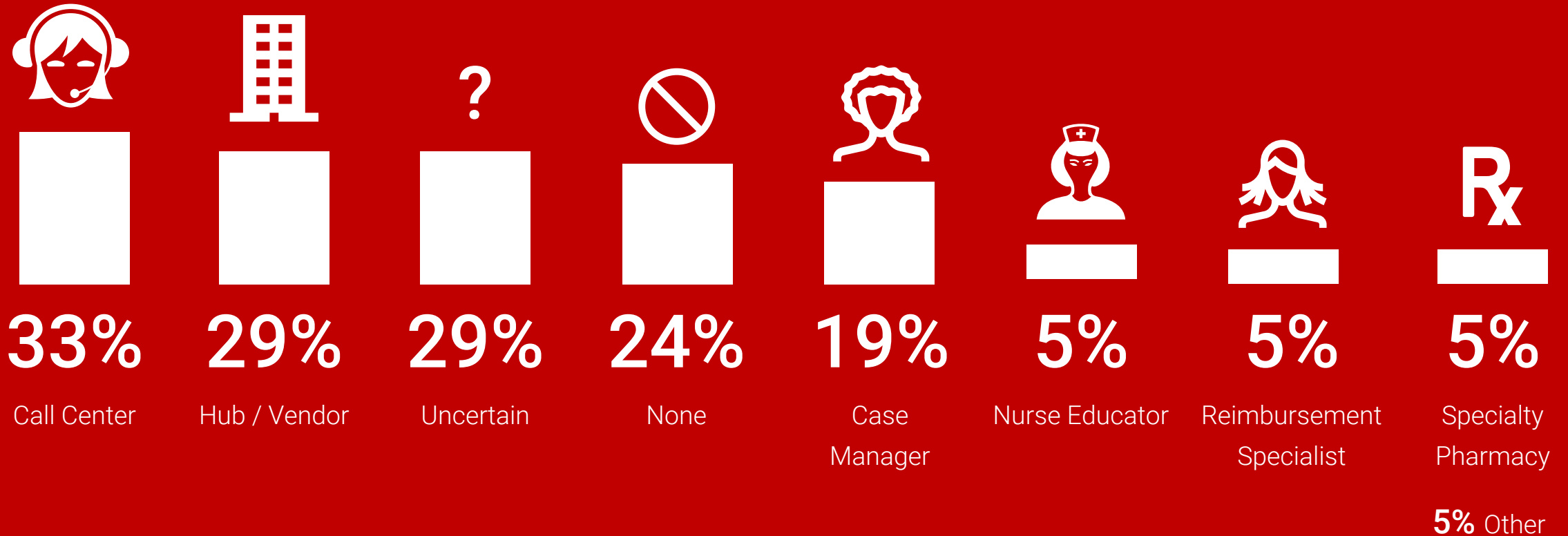


If you have nurse educators, which of the following resources do they use? Select all that apply.



Team Structure and Services

Are you recording calls of your nurse educators or other patient services team members?

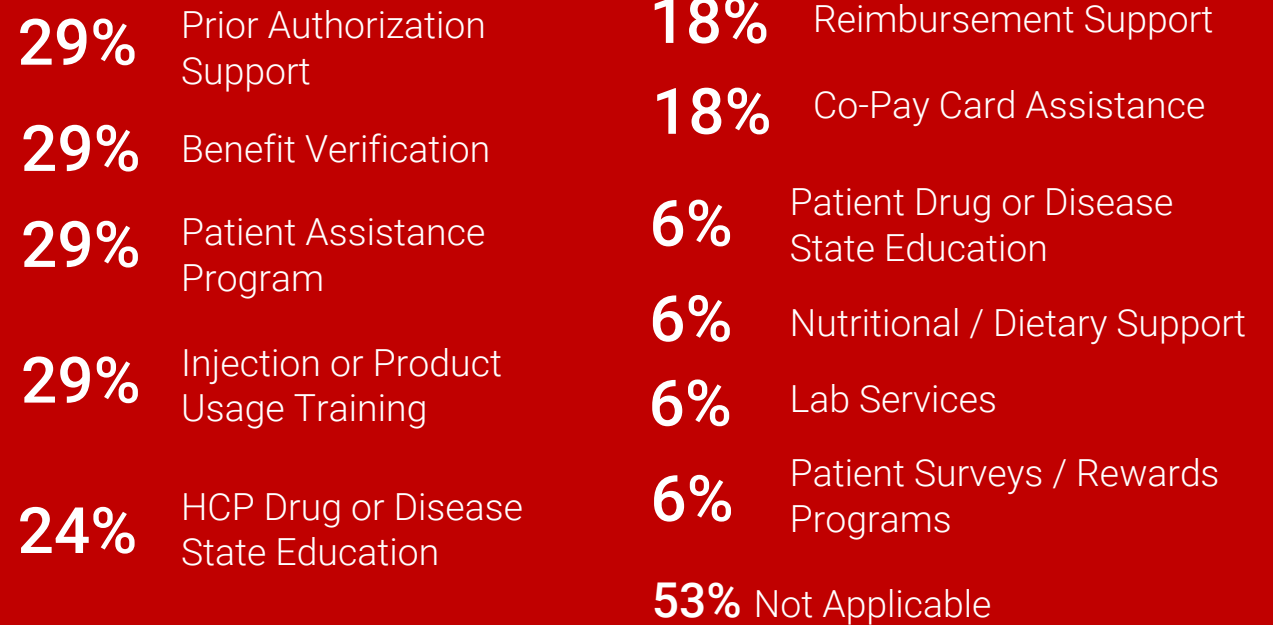


Team Structure and Services

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

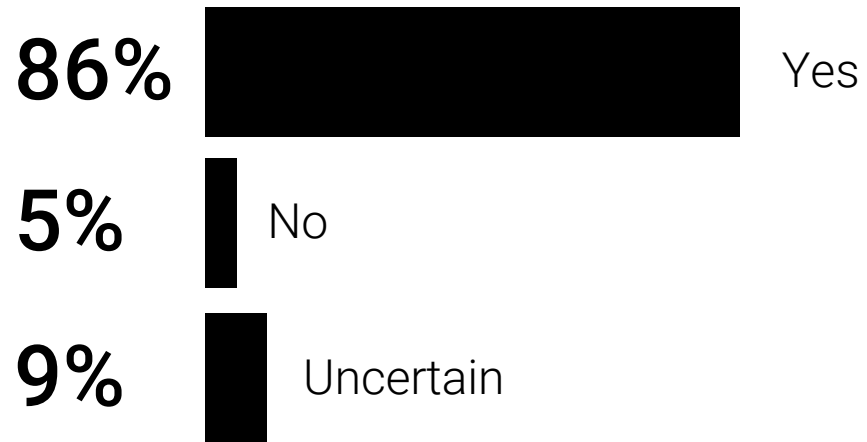


If applicable, which of the following Patient Services do you provide to patients using your product for an unapproved indication? Select all that apply.

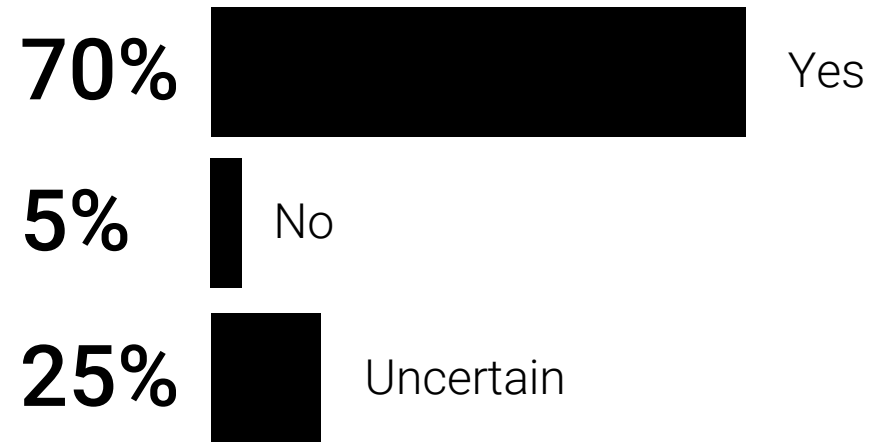


Data Privacy

Does your Company deploy a data privacy management program?

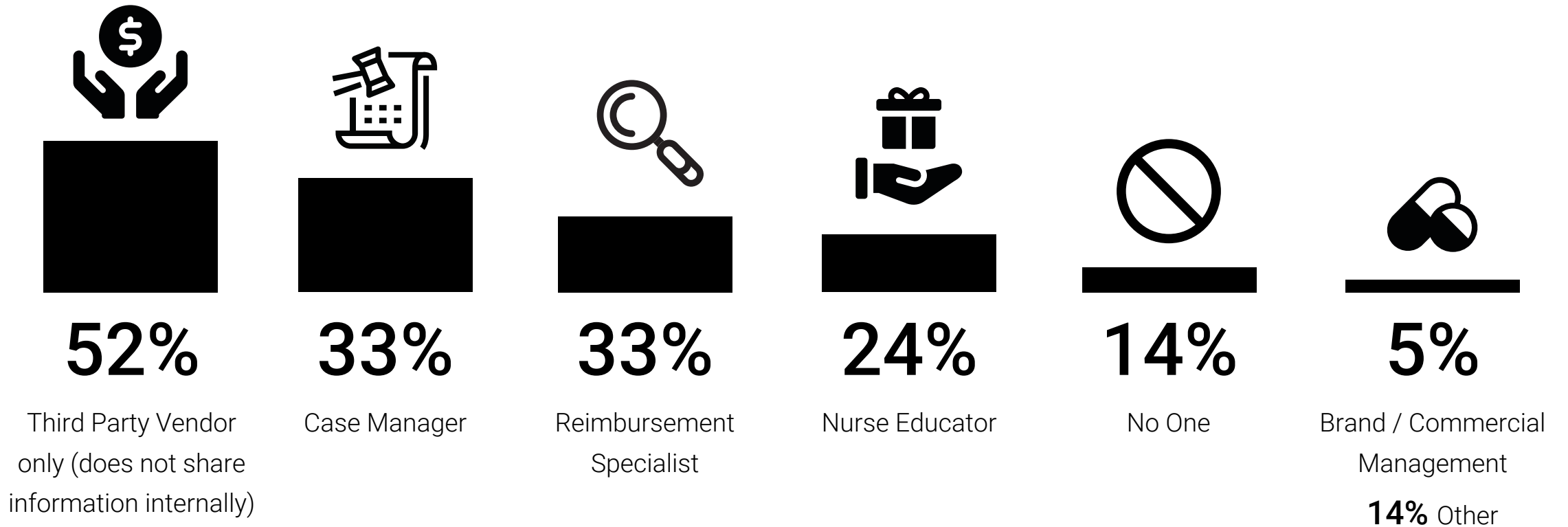


Is your patient services platform HIPAA compliant?

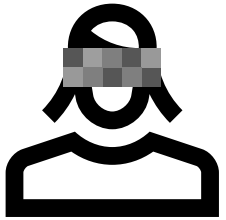


Who in your organization has access to patient data or information?

Select all that apply.



What specific components of patient data are shared between functional areas? Select all that apply.



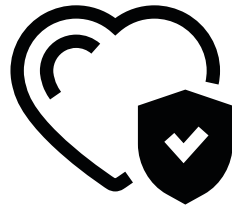
80%

Only de-identified patient information



15%

No patient information is shared



10%

Insurance Information



5%

Patient Address



5%

Drug Shipment




5%

Co-Payment Assistance


15% Other


What kind of patient data consent does your Company capture? Select all that apply.


Broad consent covering all potential use cases  50%

Revocable consent that can be rescinded at any time by the patient  39%

Targeted consent only covering the initial use case at point of capture  39%

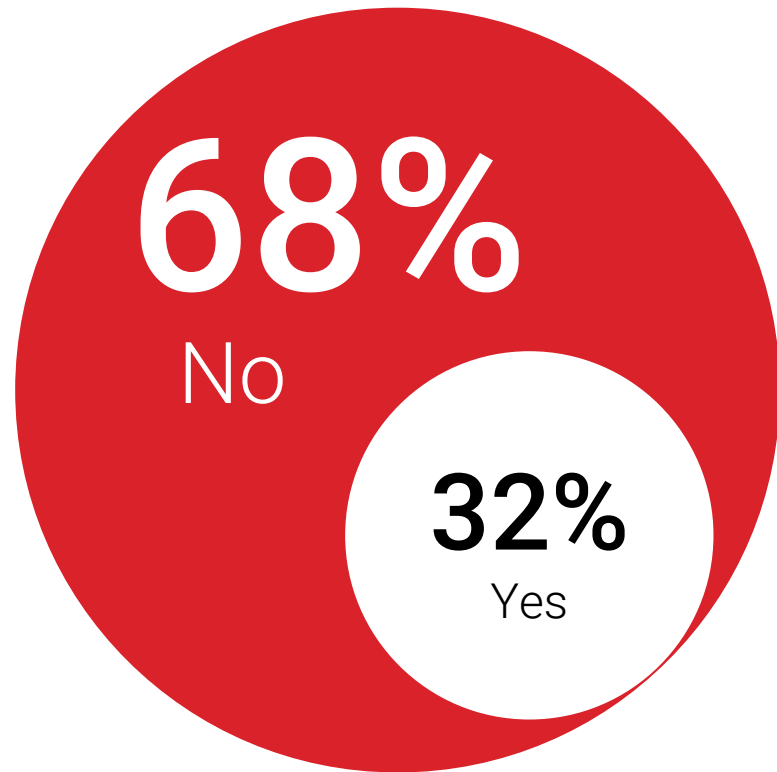
Patient customizable consent allowing for individual patient preferences  22%

Time constrained consent that forces an expiration date for data usage  22%

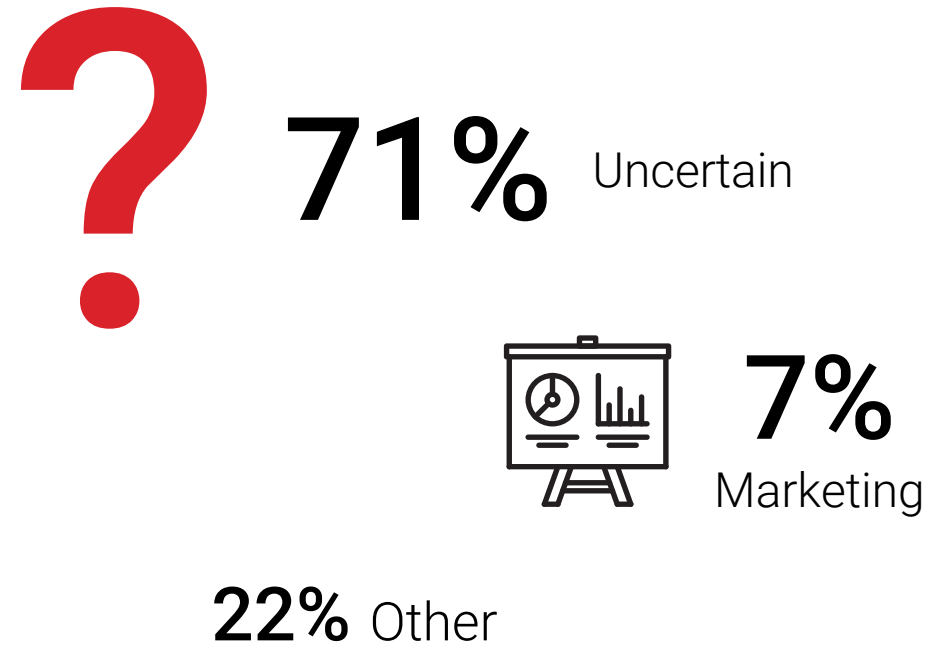
Consent that follows respective patient data wherever it moves throughout your organization  11%

Data Privacy

Has your Company developed Electronic Health Record (EHR) tools for use by HCP practices to facilitate diagnosis or prescription of your product?

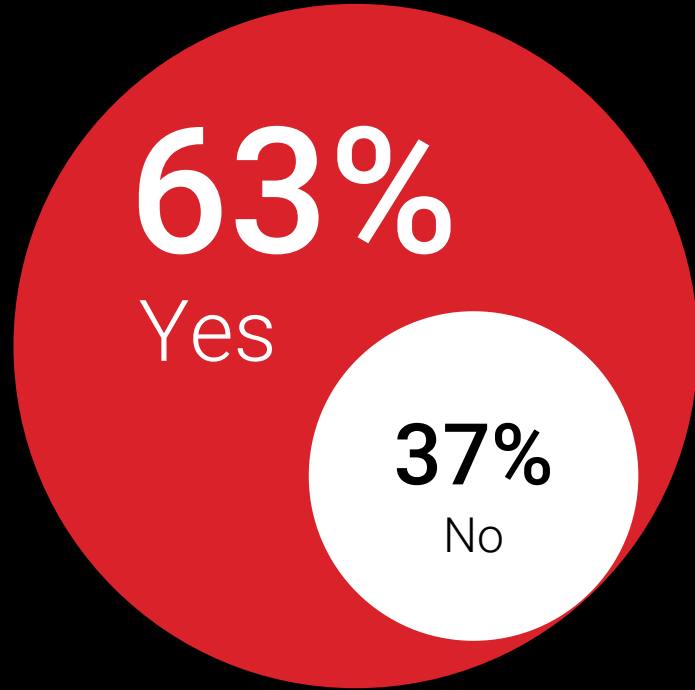


If applicable, who was involved in the development of the EHR tool?

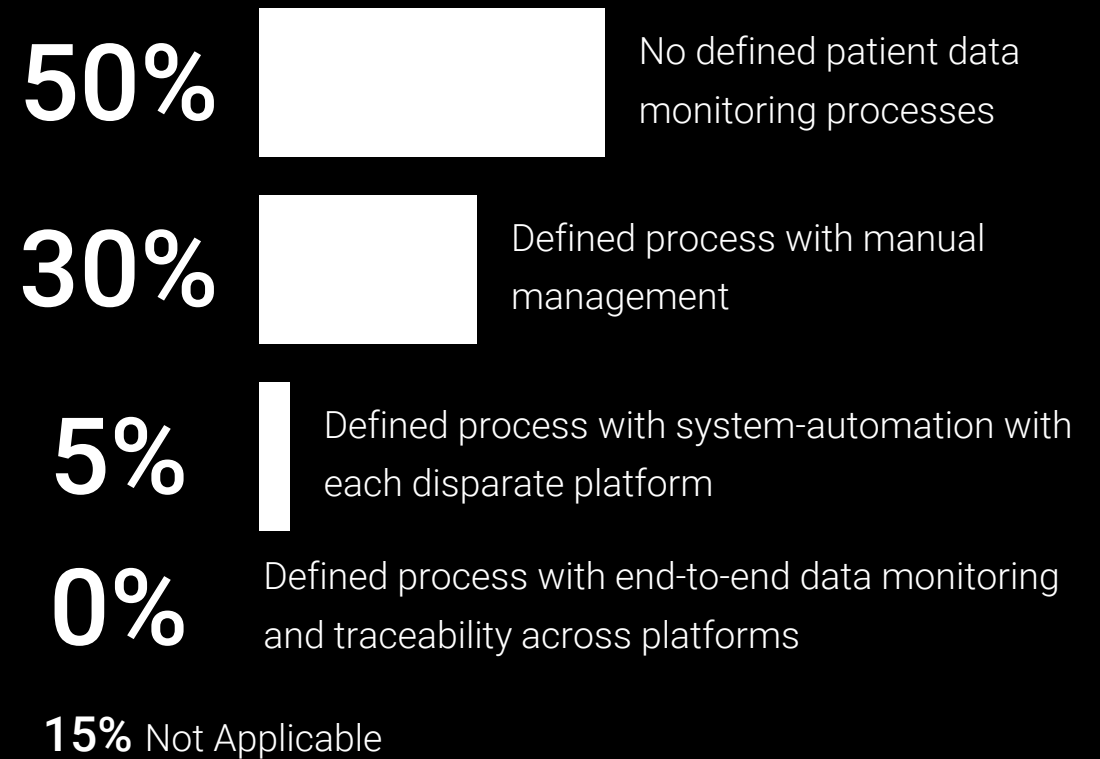


Monitoring and Auditing

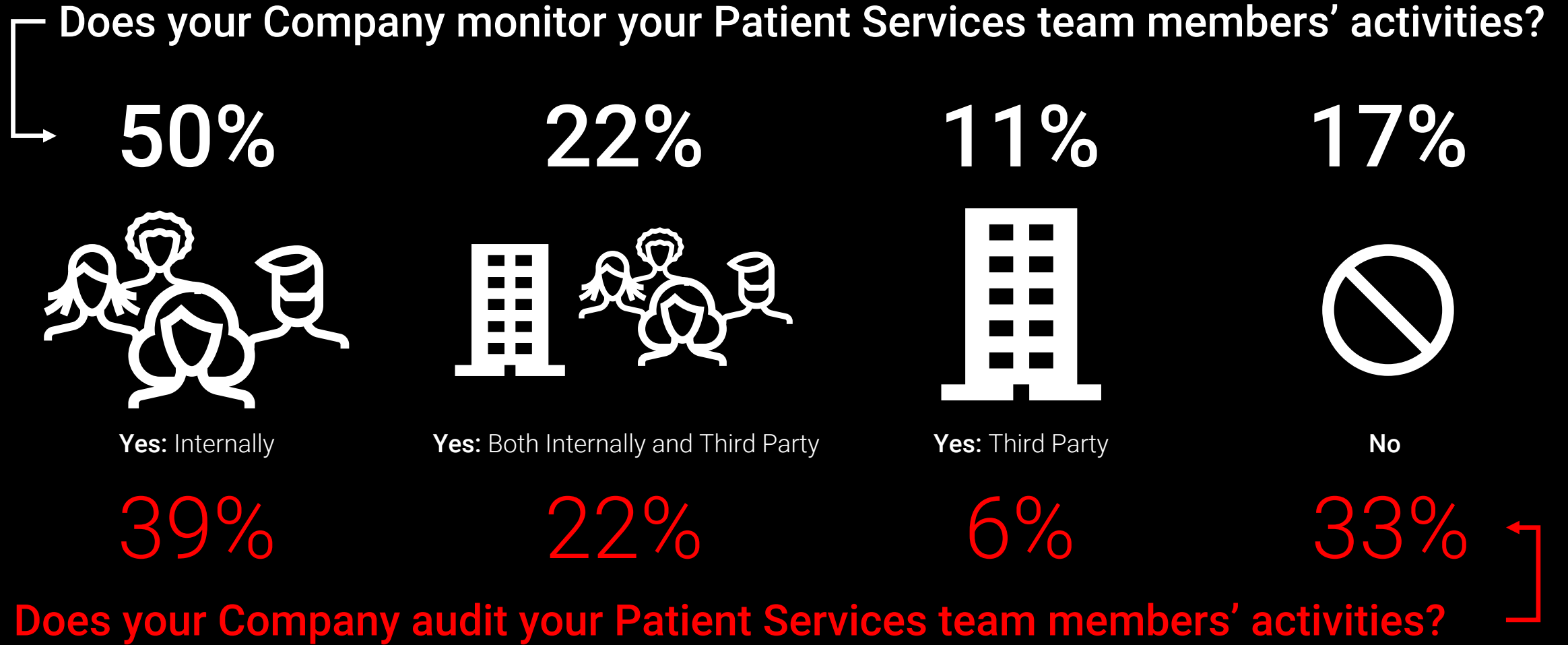
Does your Company monitor patient data usage to ensure compliance with regulations and consent?



How mature is your Company at monitoring patient data usage?

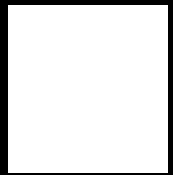


Monitoring and Auditing



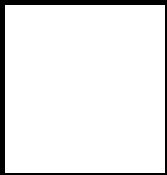
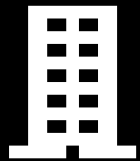
Monitoring and Auditing

Which groups are being monitored at your Company? Select all that apply.



56%

Call Center



56%

Hub / Vendor



56%

Reimbursement
Specialist
(Virtual)



44%

Nurse
Educator



38%

Case
Manager



31%

Field-Based
Reimbursement
Specialist



25%

Specialty
Pharmacy



6%

None

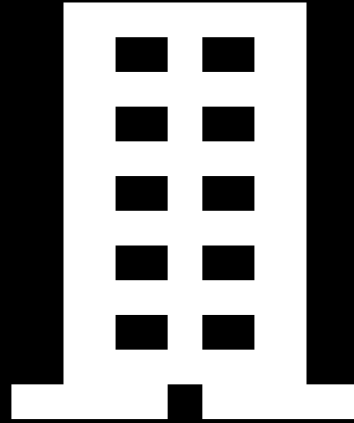
6% Other

Team Structure and Services

Who manages your Patient Assistance Program's co-payment card program?

68%

Third Party (External)



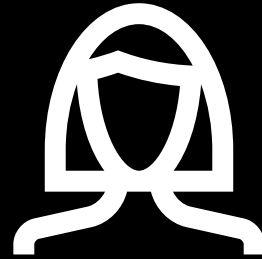
42%

Third Party (External)

Who manages your Patient Assistance Program's provision of free drug?

16%

Internally



26%

Internally

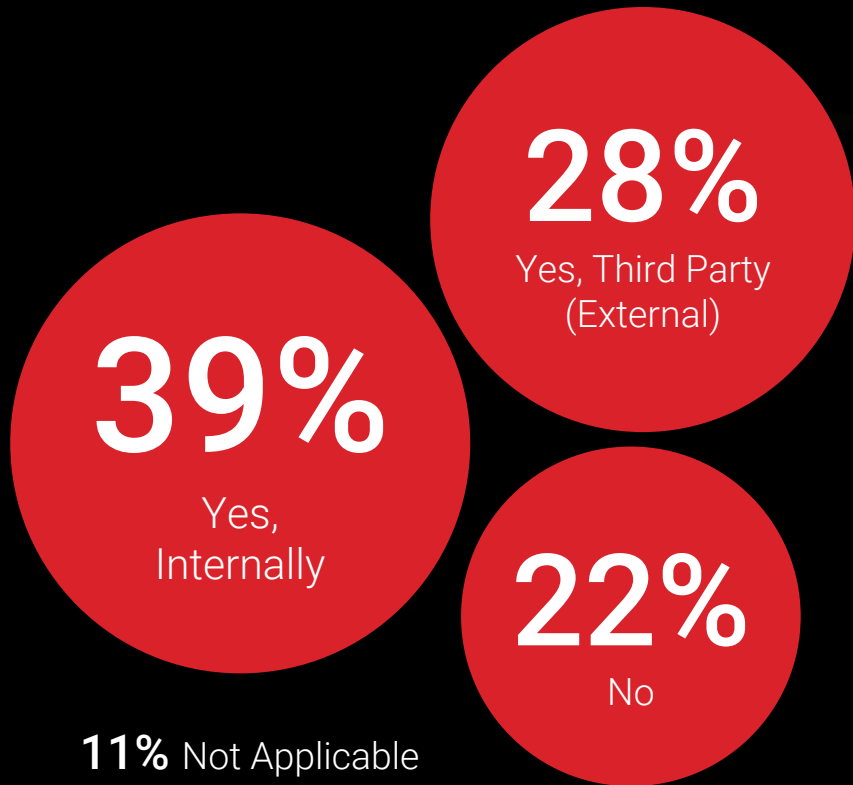
16%

Not Applicable

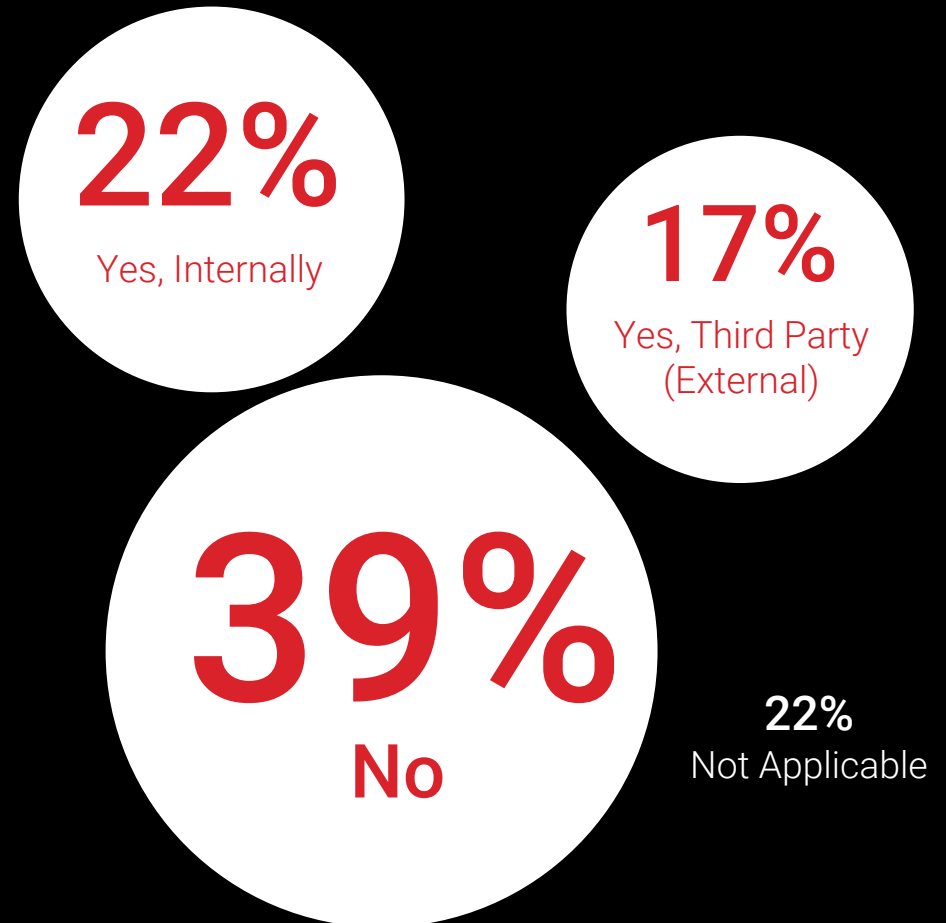
32%

Monitoring and Auditing

Does your Company monitor your provision of co-payment cards?

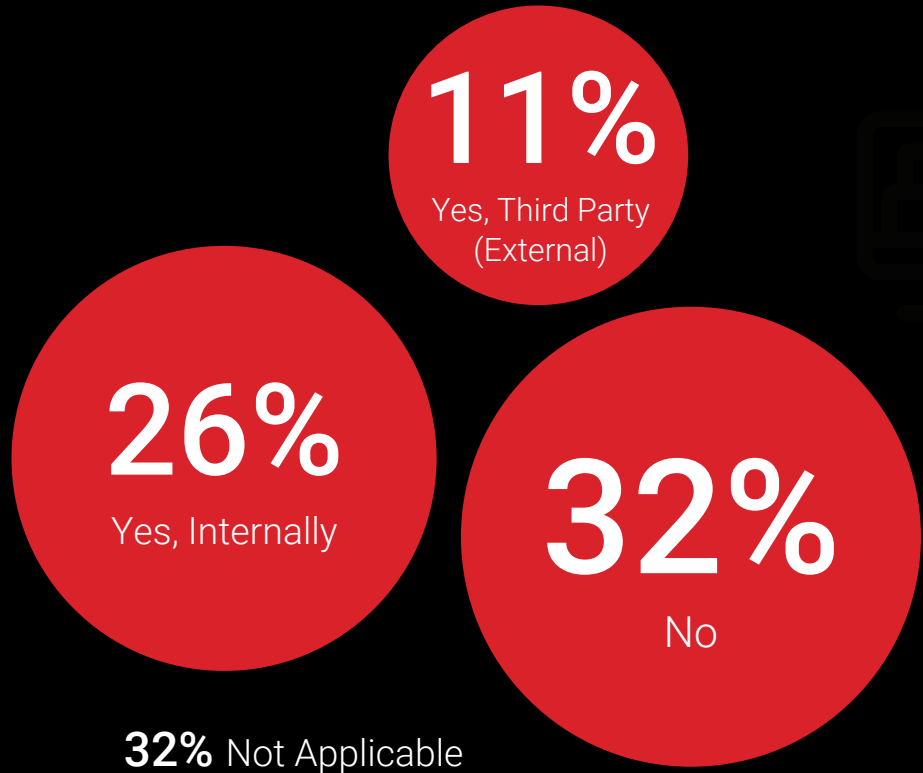


Does your Company audit your provision of co-payment cards?

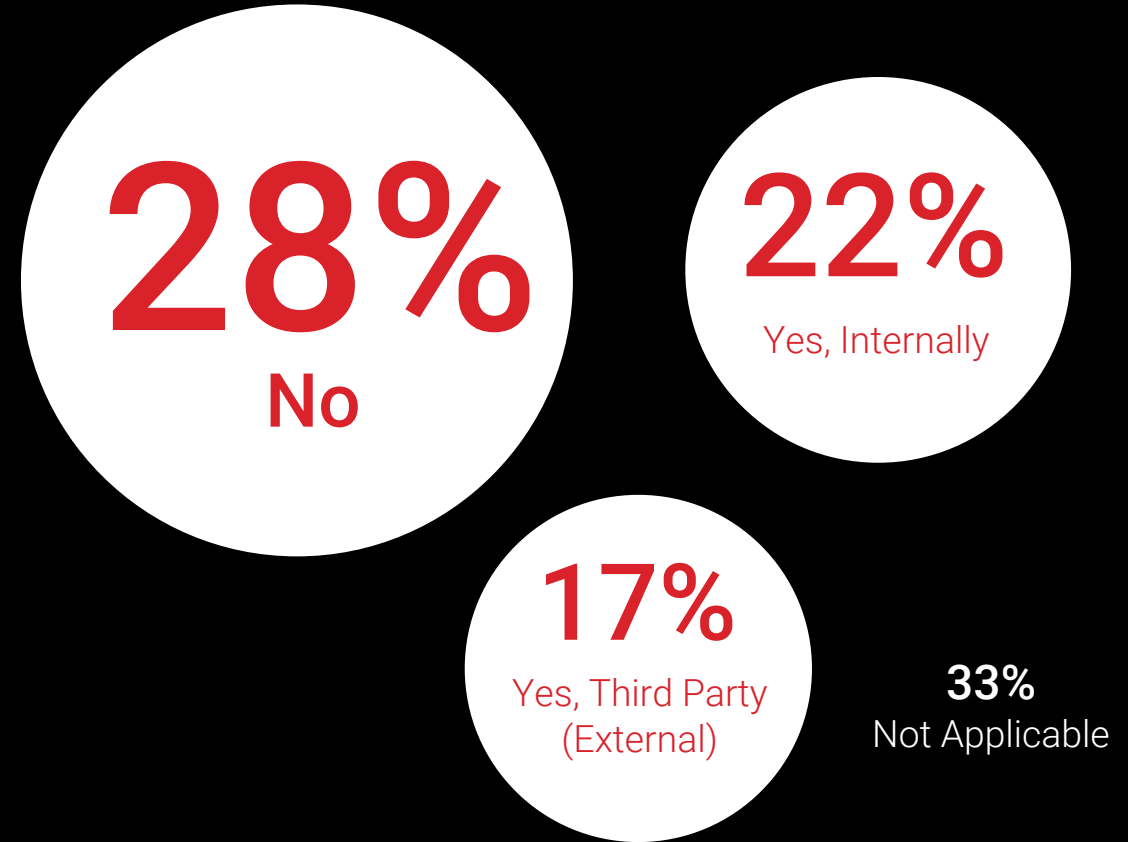


Monitoring and Auditing

Does your Company monitor your provision of free drug?



Does your Company audit your provision of free drug?



Closing Thoughts

- Patient Services Programs continue to be a “moving target” for Compliance leaders
 - Life sciences companies are still trying to find the right balance of resources, technology, and internal controls to allocate to the emerging risk areas in Patient Services Programs
- The shift to digital workspaces and virtual meeting platforms has accelerated the pace at which life sciences companies are being forced to modify their compliance controls in this space.
- Patient services programs are not going to disappear any time soon.
 - The time for Compliance leaders to assess and fortify their program’s readiness to handle the growing volume of risk and government scrutiny related to Patient Services Programs is *now*.

Contact Us: Full Survey Results

Full results of Helio Health Group's 2020 Patient Services Compliance Survey can be obtained by contacting:

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A thorough analysis covering the evolution of Patient Services compliance challenges and year-over-year trends from Helio's 2017-2020 surveys will be published in the December 2020 edition of *Policy & Medicine Compliance Update* (www.complianceupdate.policymed.com).

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