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Patient Services Compliance Survey

Trends and Insights into this Highly Scrutinized Area

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Summary: Patient services programs and the associated risks across the life sciences industry vary in shape and style, especially as the government is beginning to heavily investigate the activities conducted by manufacturers in this area. This article highlights some of the differences in the industry as seen through an annual patient services compliance survey conducted by Helio Health Group.

Government scrutiny has historically focused on the life science industry's interactions with Healthcare Professionals ("HCPs"). However, over the past several years, regulators have taken an interest in examining the manufacturer's interactions with patients and the assistance programs provided by them. With several Corporate Integrity Agreements ("CIAs") and government investigations focused on the relationship between life sciences organizations and patients, this has become a critical area of concern for compliance professionals.

Patient services programs differ in the types of activities conducted and the patient populations served. They can be generally classified into one of three categories:

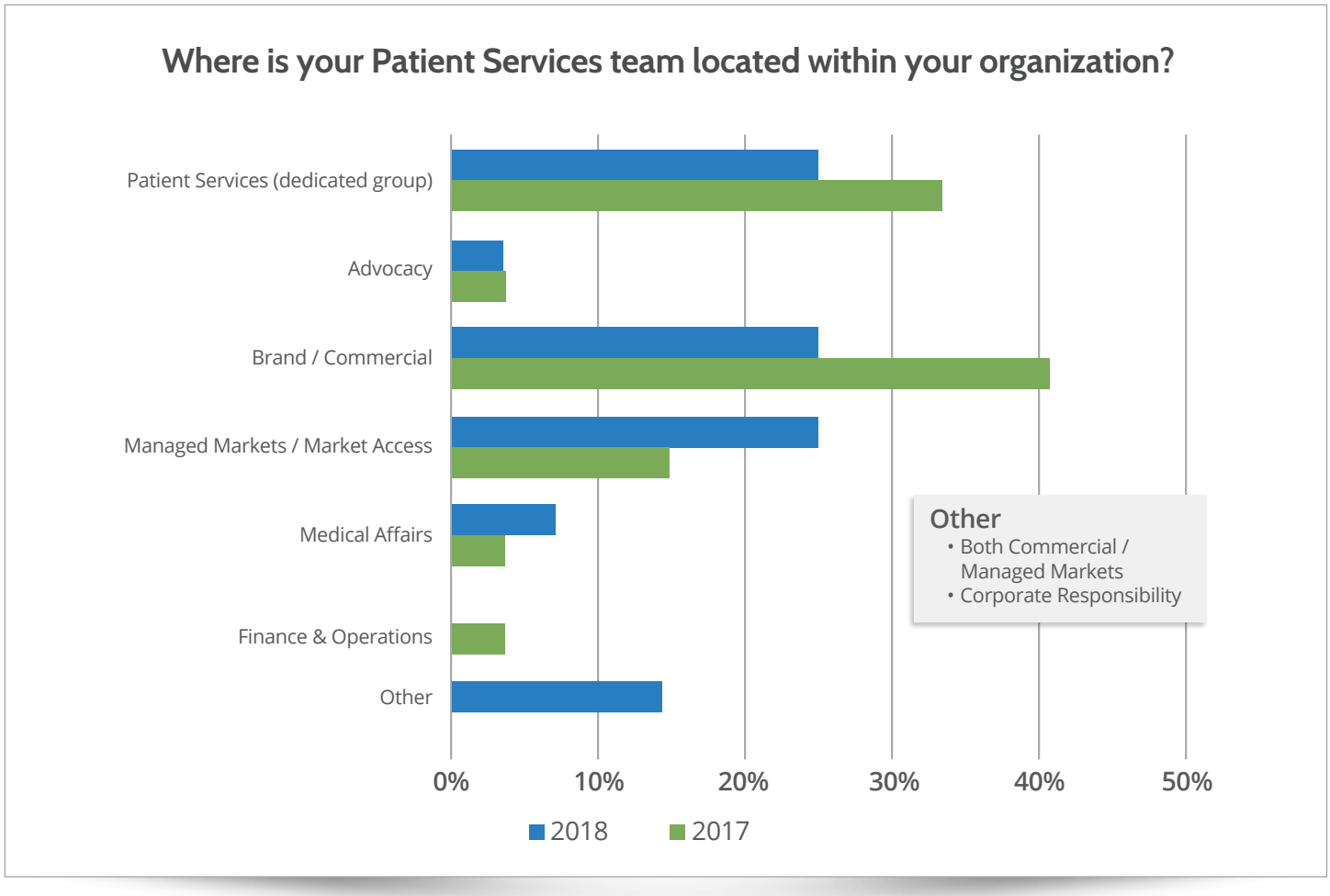
- Patient Support Programs ("PSPs"),
- Patient Assistance Programs ("PAPs"), and
- Independent Charities and/or Charitable Copay Foundations.

PSPs are designed to provide support to patients in various forms including patient education, product support, benefits investigation and other reimbursement support. PAPs, managed internally by a manufacturer or through a third party, are created by life science companies to provide free product or co-pay assistance to commercially insured patients. Manufacturers also provide donations to independent charities and charitable foundations, to which they are otherwise unaffiliated. Independent charities and charitable foundations can provide co-pay assistance and other financial assistance to government or commercially insured patients at the foundation's discretion.

The risks associated with each of the activities described depend on the design and management of the program. Applicable laws that come into play with patient programs include the Anti-Kickback Statute ("AKS"), False Claims Act ("FCA"), Beneficiary Inducement Law, Federal Food, Drug, and Cosmetic Act ("FFDCA") and Health Insurance Portability and Accountability Act ("HIPAA"). Helio's annual patient services compliance survey aims to understand how the industry is developing and managing their patient services programs and associated risks.

Trends Between 2017 and 2018

In 2017, the survey focused on compliance concerns relevant to establishing patient services programs. With the increase in government activity in pursuit of violations of the AKS, FCA, and HIPAA related to patient services, the 2018 survey focused on monitoring and controls specific to areas where compliance challenges are emerging. The 2017 survey was completed by 27 compliance professionals and the 2018 survey by 28 compliance professionals across small, mid-size (top 21-50) and large (top 20) pharmaceutical and biologic companies.[2] The following highlights key trends observed between 2017 and 2018:



Organizational shift of reporting structure: Companies moved their patient services teams out of brand/commercial functions and into managed markets/market access, medical affairs, a dedicated patient services group, or other functional areas such as corporate responsibility.

Composition of the Patient Services team: It is important to understand the makeup of the company's team and their roles. Certain roles may have increased risks in their interactions with patient services groups. In other situations, it may be important to separate roles to avoid providing inappropriate support to patients or HCPs.

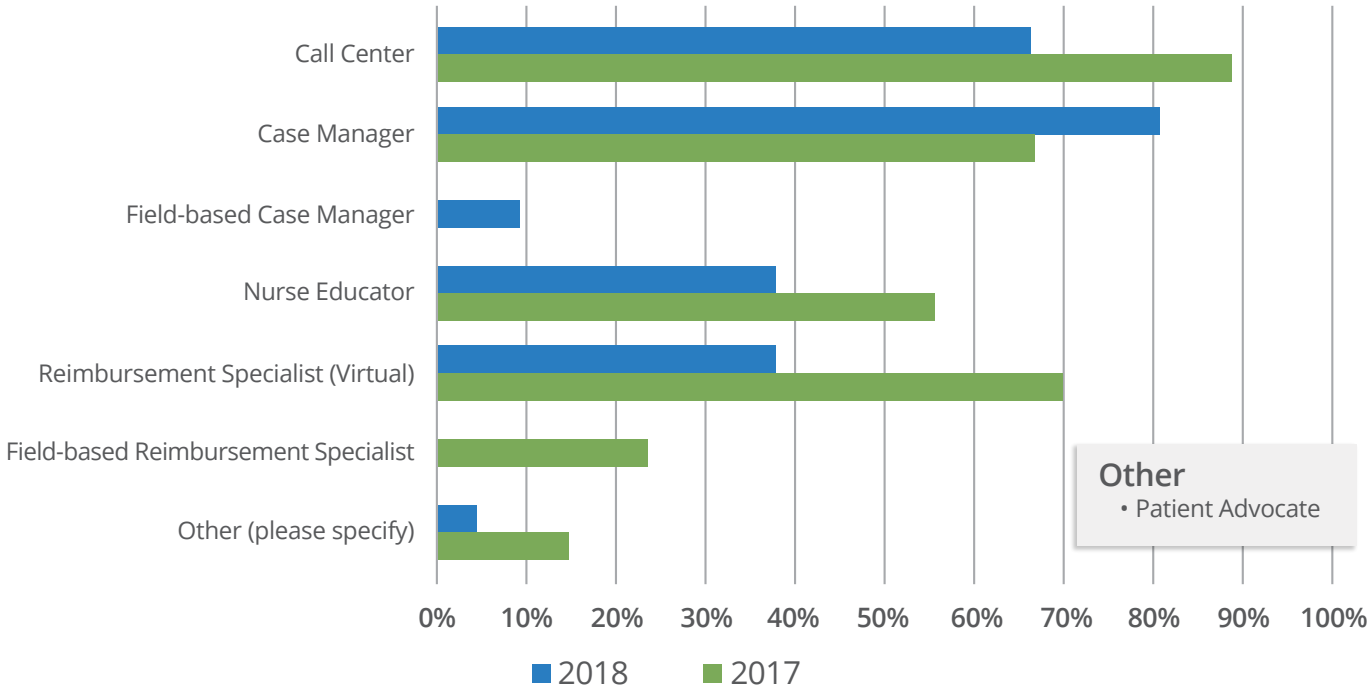
Decline in reimbursement specialists: In 2017, 70% of participants noted the existence of reimbursement specialists on their patient services team, but only 38% had them in 2018.

Increase in data privacy management: In 2017, 46% of respondents stated their companies deployed a data privacy management program - that increased to 63% in 2018. Furthermore, privacy considerations are depicted through certain changes such as who in the organization has access to patient data, and what components of data they can access.

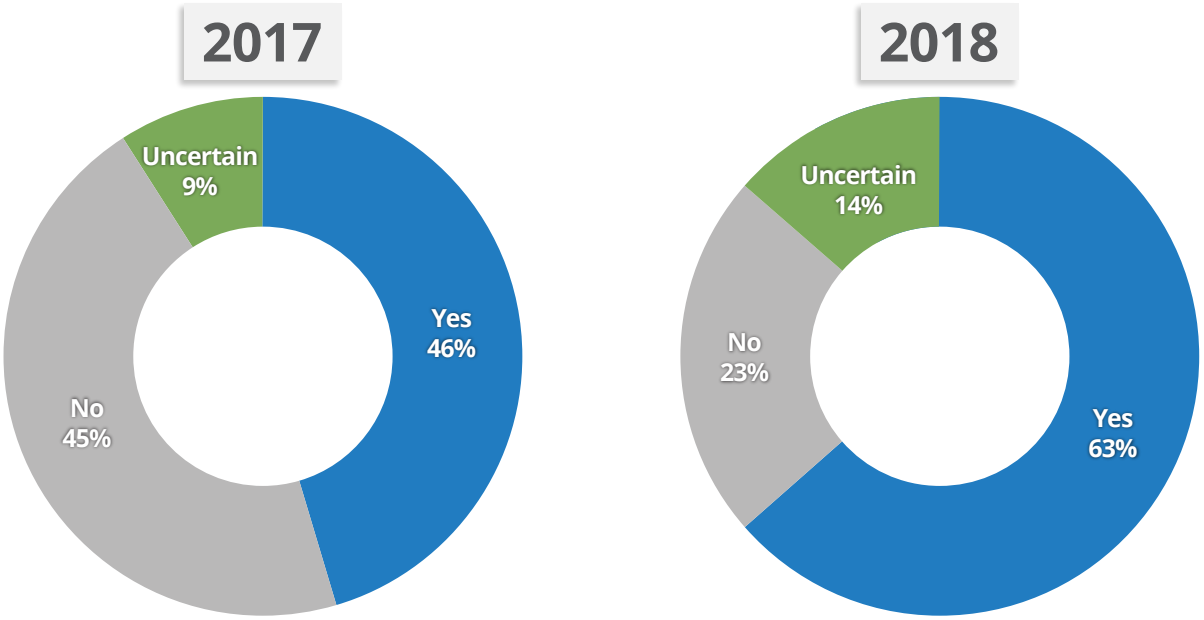
In 2017, 30% of the respondents stated that brand/commercial management had access to patient data while only 9% said they had access in the 2018 survey. This is mirrored in the 41% of respondents who indicated that their reimbursement specialists had access to patient information in 2017 but only 27% indicated they had access in 2018. Lastly, the survey indicates that many manufacturers now provide patient data to a third-party vendor and do not share the information internally (from 37% in 2017 to 59% in 2018.)

Increased monitoring initiatives: Monitoring has increased significantly in several patient support groups. Of note, more manufacturers are monitoring hubs and third-party vendors – an increase from 37% to 47%.

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



Does your company deploy a data privacy management



Monitoring of patient services can pose its own challenges including privacy issues as well as managing the sensitive nature of these interactions with patients. While the industry is use to monitoring traditional interactions with HCPs (e.g., ride along, live monitoring of speaker programs and advisory boards) this has not been the case for patient support services. Respondents who did conduct increased monitoring also noted that they monitor phone calls and conduct in-person observations of patient support specific activities.

Differences Between Small and Large Manufacturers

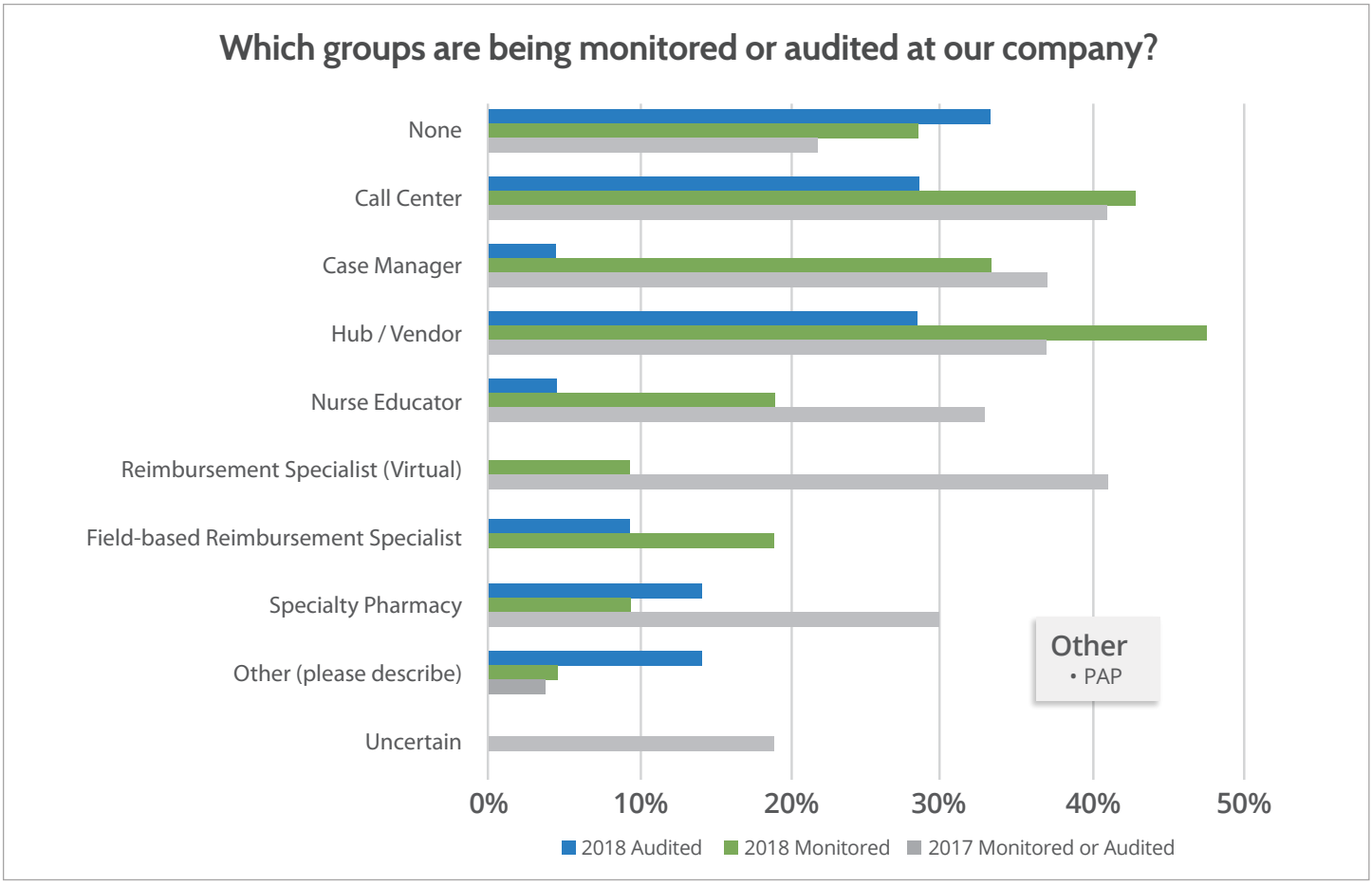
The following highlights key differences from the survey in 2018 seen between small and large pharmaceutical companies:

Placement of patient services team: While 25% of both small and large manufacturers and 33% of mid-size manufacturers stated their patient services team sits within brand/commercial, 38% of large and 33% of mid-size manufacturer respondents said their team is located within the managed markets/market access group as opposed to only 8% for small manufacturers.

In addition, 33% of small manufacturers and 25% of large manufacturers stated that their patient services team has their own dedicated group while only 11% of mid-size manufacturers have the patient services team in its own group. The location of the patient services team at smaller pharmaceutical companies may often be based on the limited options of functional areas and the multiple roles that many employees manage at a smaller company.

More donations provided by large manufacturers: Funding to independent charities or co-pay foundations is provided at 88% of the large and mid-size manufacturers who responded, whereas only 46% of the small manufacturers stated that they provided donations.

Access to patient data: 71% of mid-size and 33% of large manufacturer respondents said reimbursement specialists



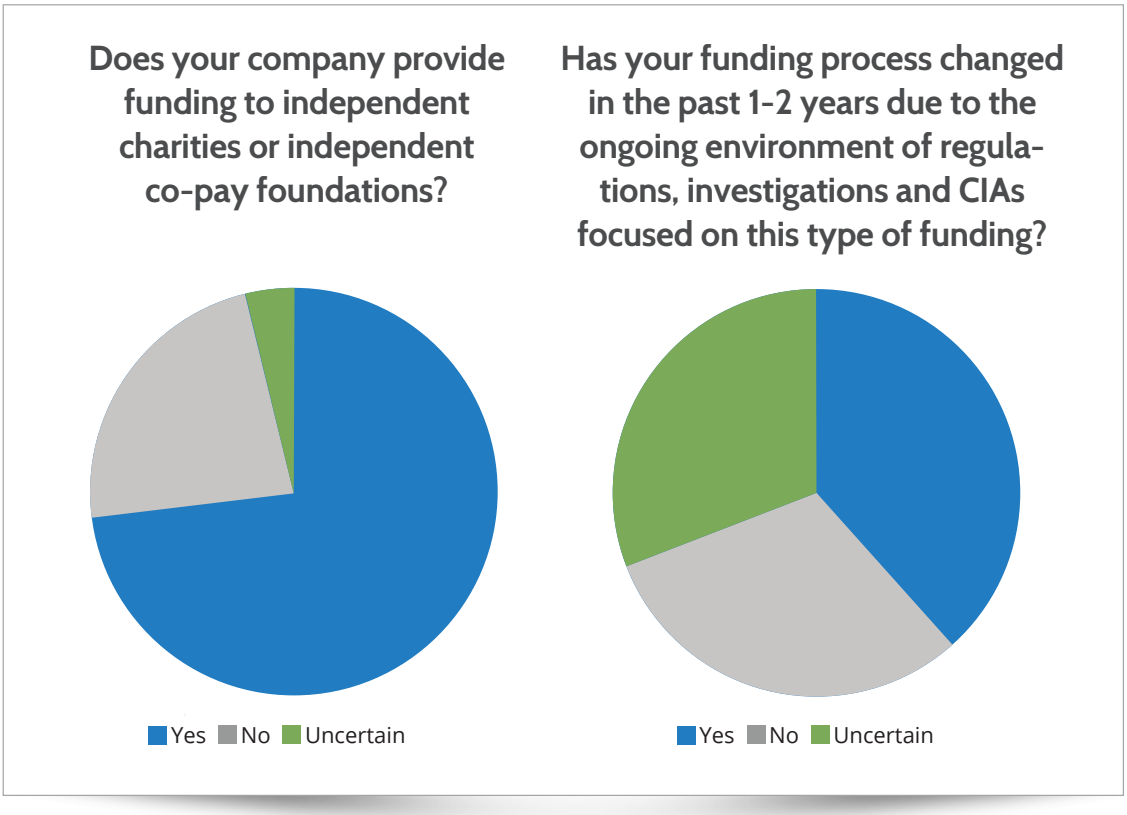
have access to patient information but at small manufacturers, no reimbursement specialists had access. 42% of mid-size and 50% of the small manufacturer respondents said case managers had access to patient information and 20% said their sales representatives had access as well, whereas the large and mid-size manufacturer respondents' sales representatives did not have access to patient data and information.

Donations to Independent Charities and PAPs

The government has increased its scrutiny of donations made by pharmaceutical manufacturers to independent charities as demonstrated by the number of increased investigations and settlements with various manufacturers over the last two years. In many cases, the Department of Justice ("DOJ") alleged that manufacturers violated the FCA through their donations to independent charities that provide co-pay assistance to direct patients toward their drug or to knowingly assist with the co-pays of government insured patients. "Under the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering or paying, directly or indirectly, any remuneration—which includes money or any other thing of value— to induce patients [covered by federal healthcare programs] to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations."

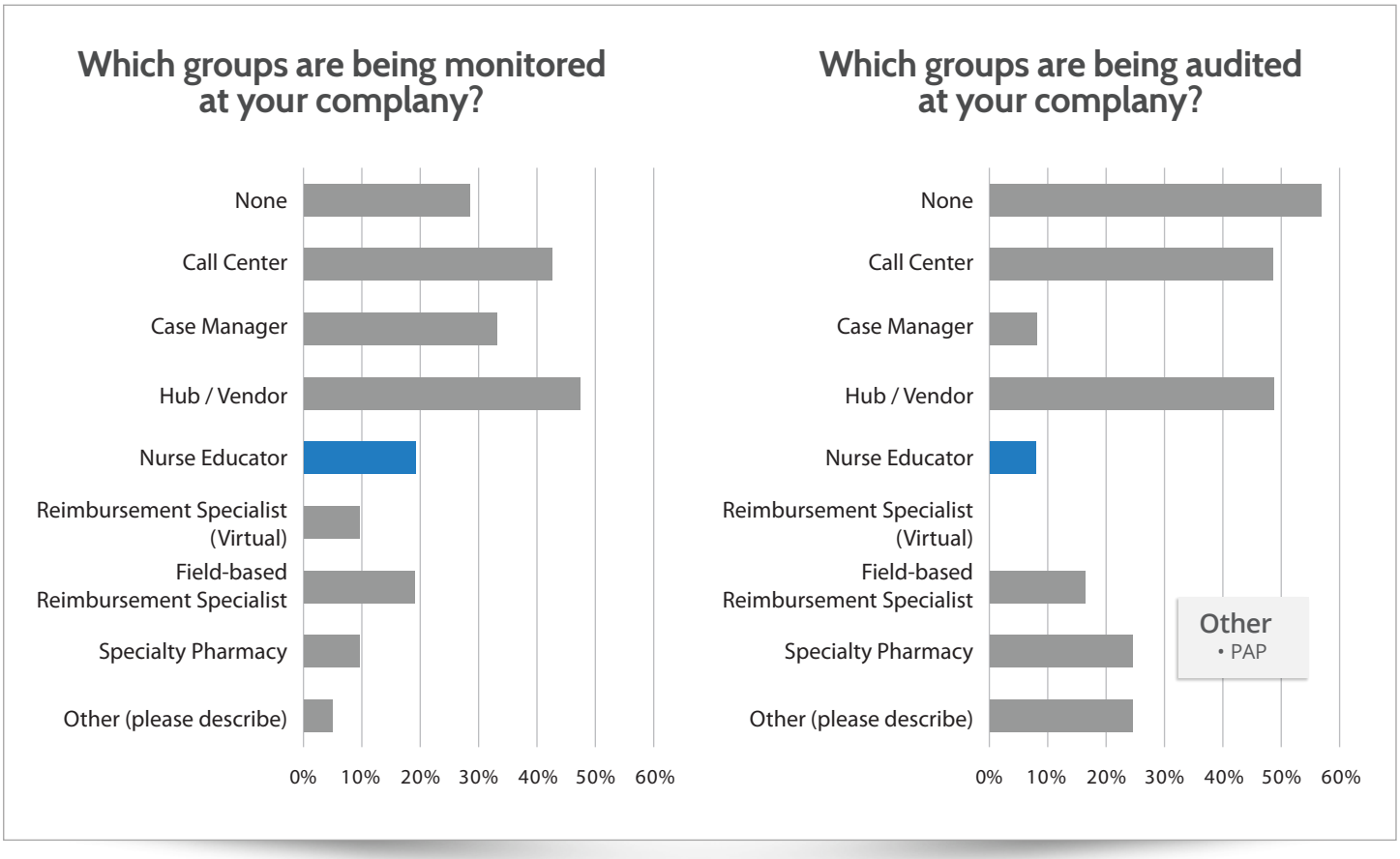
In Helio's survey, 73% of the participants stated that their company provided funding to independent charities or independent co-pay foundations. Additionally, 38% said their funding process had changed in the past year due to the ongoing environment of regulations, investigations and corporate integrity agreements focused on this type of funding.

When donating to an independent charity, pharmaceutical manufacturers must consider the criteria and parameters under which the donation is made. In the United Therapeutics ("UT") settlement, "the government alleged that UT routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug, and that this data was used by UT to decide how much to donate to the foundation."[4] Nearly half of the survey respondents stated they did not have, or were uncertain if they had, specific and defined company-wide criteria for donations.



Nurse Educators

The utilization of nurse educators, often called clinical educators, clinical specialists, patient educators, and field nurses, is becoming increasingly common in pharmaceutical manufacturers. These nurse educators serve to educate both providers and patients on disease states and products. Of the companies surveyed, 38% have nurse educators on their patient services team. 19% respondents stated that their



nurse educators interacted and/or supported patients and their caregivers only, whereas 9% stated their nurse educators interacted with providers only. 24% said they interacted with both patients and providers.

When building a nurse educator program, manufacturers must consider the types of services the nurses are conducting and the types of interactions that they may have with providers and/or patients at critical points in the patient journey (i.e., pre or post-prescription). Additionally, manufacturers must consider the reporting structure and compensation of the nurse educators. If the nurse educators report into commercial, manufacturers may want to consider how performance is tracked and what the nurses are trained on. There is a potential for risk if objectives resemble those of sales objectives (e.g., number of HCP touchpoints, number of prescriptions). Roles and rules around interactions with other field facing employees (e.g., patient support team, sales representative, MSLs, etc.) should be clearly defined by the company to prevent additional risk.

In September of 2018, California's insurance commissioner filed a lawsuit against AbbVie alleging that AbbVie violated the Insurance Frauds Prevention Act ("IFPA") through illegal kickbacks. The lawsuit alleged that at no cost to the providers, "AbbVie nurses provide patient care, pharmacy and insurance authorization assistance, open enrollment resources, paperwork help, advice on insurance products, and other services, all of which provide a substantial value, so long as the doctors prescribe AbbVie's drug instead of selecting another course of treatment."[5]

Additionally, there have been numerous *qui tam* lawsuits against multiple pharmaceutical manufacturers under the False Claims Act stating that manufacturers utilized nurse educators to increase the number of prescriptions and provide kickbacks to physicians via services.[6] However, on December 17, 2018, the DOJ filed motions to dismiss 11 of the *qui tam* complaints by National Healthcare Analysis Group ("NHCA") that were allegedly "created for the sole purpose of filing suits under the federal False Claims Act".[7]

While the cases subject to dismissal remain ongoing and if manufacturers should still consider the OIG framework[8] of allowable patient education and reimbursement support activities when designing and delineating the roles of nurse educators. One area where manufacturers can focus their attention is on the lack of monitoring and auditing within the nurse educator group (see chart above). In our survey, few respondents noted monitoring nurse educators and their activities; however, we think that trend will change in 2019 and beyond.

Conclusion

The appropriateness of interactions and activities related to patient assistance programs should be a top priority of manufacturers. Donations to independent charities and the utilization of nurse educators continue to be heavily scrutinized. Manufacturers should establish compliance processes to complement the ongoing operations of patient services programs. When structured correctly, these initiatives are not kickbacks – in fact, these programs are extremely beneficial to advocates, caregivers, and especially patients. The continuation of these programs is crucial for affected populations and our society as a whole; therefore, it is critical that life sciences organizations implement compliance controls to encourage the continuation of appropriate behavior and ensure the longevity and effectiveness of these programs.

References

1 *Helio Health Group is a management consulting and data science-focused firm that specializes in providing consulting services across compliance and patient services areas of life sciences organizations.*

2 *See Pharm Exec's Top 50 Companies 2018, Pharmaceutical Executive (Jun. 1, 2018), available at: http://www.pharmexec.com/pharm-execs-top-50-companies-2018.*

3 *See Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks, United States Department of Justice, Office of Public Affairs (Dec. 6, 2018), available at: https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying.*

4 *See Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks, United States Department of Justice, Office of Public Affairs (Dec. 20, 2017), available at: https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability; see also K. Wildoner, When Good Intentions Go Astray – United Therapeutics Settles AKS Suit, 4.2 LIFE SCIENCE COMPLIANCE UPDATE 7 (Feb. 2018).*

5 *See State of California v. AbbVie Inc., Sept. 18, 2018, available at: https://www.insurance.ca.gov/0400-news/0100-press-releases/2018/upload/nr111-2018AbbiVieComplaint091818.pdf; see also N. Fiorentino, Turning Up the Heat on Nurse Educator Programs, 5.2 Policy & Medicine Compliance Update (Feb. 2019).*

6 *See Ed Silverman, Caregivers or marketers? Nurses paid by drug companies facing scrutiny as whistleblower lawsuits mount, STAT (Oct. 2, 2018), available at: https://www.statnews.com/2018/10/02/nurse-educators-humira-whistleblower-lawsuits/*

7 *See P. David Yates, DOJ: A Company Created to File Lawsuits Has Wasted 1,500 Hours of The Government's Time, Forbes (Dec. 19, 2018), available at: https://www.forbes.com/sites/legalnewsline/2018/12/19/doj-a-company-created-to-file-lawsuits-has-wasted-1500-hours-of-the-governments-time/amp/; see also N. Fiorentino, Turning Up the Heat on Nurse Educator Programs, 5.2 Policy & Medicine Compliance Update (Feb. 2019).*

8 *See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (2003).*

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