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FEATURE

Helio's Seventh Annual Patient Services Compliance Survey

Surprising Developments in 2023

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Summary: The landscape of Patient Support Services and Patient Assistance Programs has noticeably changed, revealing an increase in risk. The latest Helio Health Group survey highlights these trends and reveals the pressures that are reducing funding for patient assistance programs and a corresponding decrease in compliance safeguards.

Healthcare insurance in America is marked by its high cost and the large number of people underinsured and unable to absorb these high costs.[2] For example, from 2000 to 2017, there was a 76% increase in the amount Americans spent on prescription medications.[3] According to the Patient Access Network ("PAN") Foundation, one of the largest U.S. charitable organizations, whose mission is to provide "financial assistance that helps people afford their prescription medications,"[4] 54% of low-income patients skipped or reduced doses of their medication before receiving assistance because they could not afford the cost of their full prescribed dose.[5] Moreover, 93% of patients and 80% of healthcare providers believe that patient assistance programs ("PAPs") make patients more likely to take their medications as prescribed.[6] Therefore, providers and patients recognize the crucial role of PAPs in increasing medication regimen compliance and reducing financial stress.[7]

The Importance of PAPs

In general, Americans incur higher prescription drug costs than citizens in any other country.[8] In addition, the U.S. health insurance system, including both government (i.e., Medicare Part D) and private insurers, instituted copayments, coinsurance, and deductibles, requiring patients to personally experience some of the pressure of high drug costs.[9] Although these arrangements were intended to increase patient appreciation of treatment costs and actively engage in efforts to contain those costs, they also have the unintended consequence of forcing some patients to limit or forego treatment altogether, ultimately increasing healthcare costs in the long term.

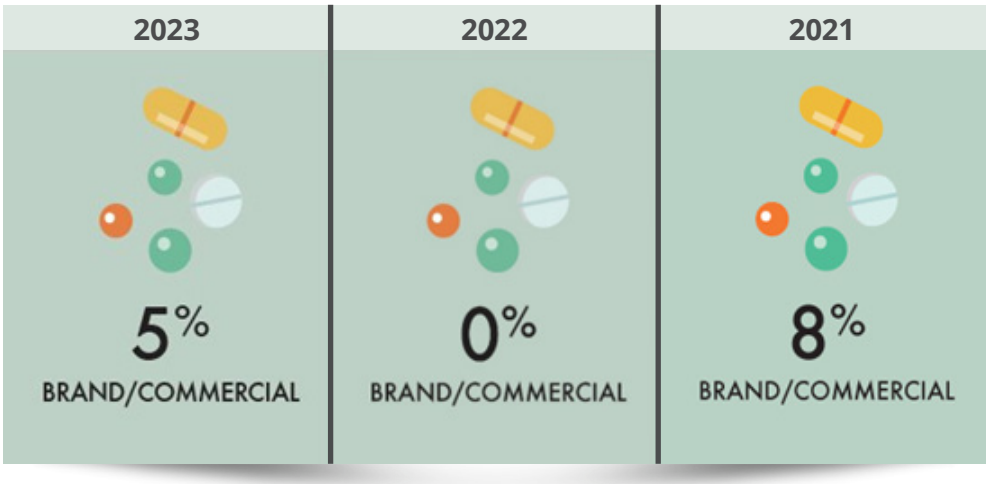
Consequently, PAPs help bridge the widening coverage gap.[10] They do so by providing copay assistance, coupons, and other cost-reduction methods, which decrease the burden of prescription costs for patients and consequently reduce patient's vulnerability to cost pressure when choosing medication.

PAP supporters say these programs provide critical assistance to patients who cannot afford their medications.[11] Critics argue that PAPs interfere with market forces, encouraging healthcare providers to prescribe and patients to choose overpriced medications.[12] These critics also assert that PAPs constitute a kickback for patients to choose these expensive medicines at the government's expense. As a result, government regulators have adopted a strict no-tolerance approach to PAPs covering federal healthcare beneficiaries' out-of-pocket costs.[13]

Survey Highlights

Helio's latest patient support services ("PSSs") survey reveals some surprising changes in commercial influence over these programs and a corresponding decrease in program monitoring and auditing. Moreover, the trend of reduced industry support for charitable programs continues despite their value in improving patient health and quality of life. Some of the issues observed in this survey are not new, and others reflect continuing government enforcement activities involving charitable

FIGURE 1: *Percent of Companies with Patient Services within Commercial*



programs. Nevertheless, the landscape is changing and will impact how life science companies plan and deliver patient support services.

Increasing Commercial Influence

When Helio fielded its first PSS survey in 2017, we asked how patient services functions were positioned within life science companies. The placement of these functions with a company reveals much about the perception, perceived risks, and influences on patient services. In 2017, 37% of respondents reported placing the patient services team within their organization's brand or commercial operations. Thus, placing patient services within the commercial part of the organization was the most common approach.

After 2017, the placement of patient services functions within companies noticeably shifted with a clear preference for decreasing the entanglement of commercial functions with patient services. We noted it in the 2021 survey.[14] By 2022, the shift was complete, and no company reported that their patient services team was part of the commercial function.[15]

The change directly corresponds to the three-period (2017-2020) of increased government enforcement efforts by the U.S. Department of Justice ("DOJ") that resulted in more than six pharmaceutical companies settling allegations that they violated the Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") in connection with supporting independent charitable patient assistance programs ("ICPAPs").[16] Thus, it is likely that these changes were driven in part by the government's efforts to increase awareness and concern about the compliance risks associated with overt commercial influence on patient support services.

Helio's survey data supports this observation. In 2017, 37 percent of companies had their patient services team within the commercial function, decreasing to 28 percent in 2018. This remained steady in 2019 at 29 percent but dropped sharply to 13 percent in 2020 and decreased further to 8 percent in 2021. By 2022, this figure hit 0, indicating that companies made a concerted effort over five years to reduce the perception that patient services are a commercial tool (Figure 1).

Reversing the Trend

The 2022 report that zero patient support teams were incorporated into larger commercial departments lasted only a short time. In 2023, there was a small yet noticeable uptick in companies reincorporating patient services into the commercial sphere (+5%).

Further, Helio introduced a new question in 2022 about whether patient services still reported to the commercial function,

FIGURE 2: *Percent of Companies with Patient Services Reporting to Commercial*

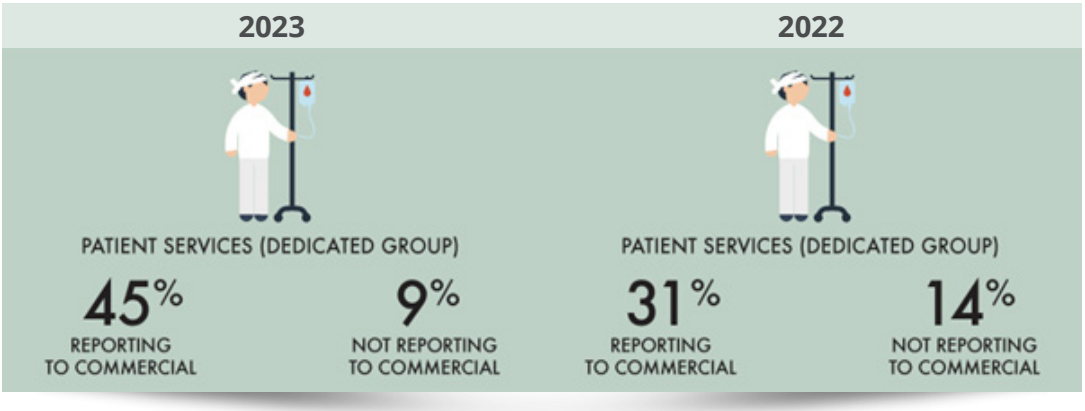
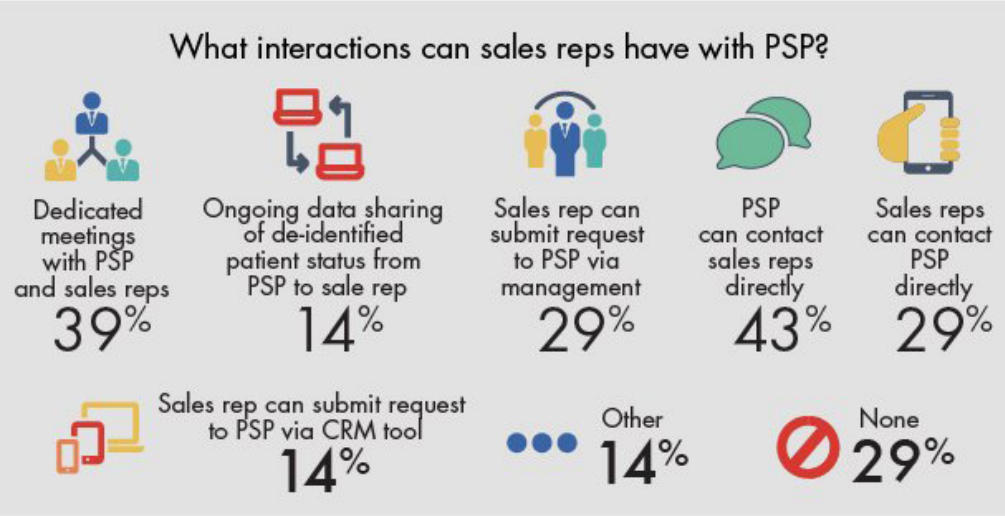


FIGURE 3: *Interactions Between Field Sales Organizations and PSS Functions*



even if organizationally it had been separated from the commercial function. Responses to this question demonstrated that partitioning patient services and commercial functions was less thorough than previously believed. In 2022, 31 percent of patient services teams *reported* to the commercial function despite stating that patient services were no longer part of the commercial department (Figure 2).

Between 2022 and 2023, the survey results revealed a 13 percent increase in patient services teams reporting to the commercial function. By 2023, nearly half of the patient services teams reported into commercial. The initial belief that the industry was developing a self-imposed firewall of separation between patient services and commercial functions is crumbling.

Field Sales & PSS Team Interactions

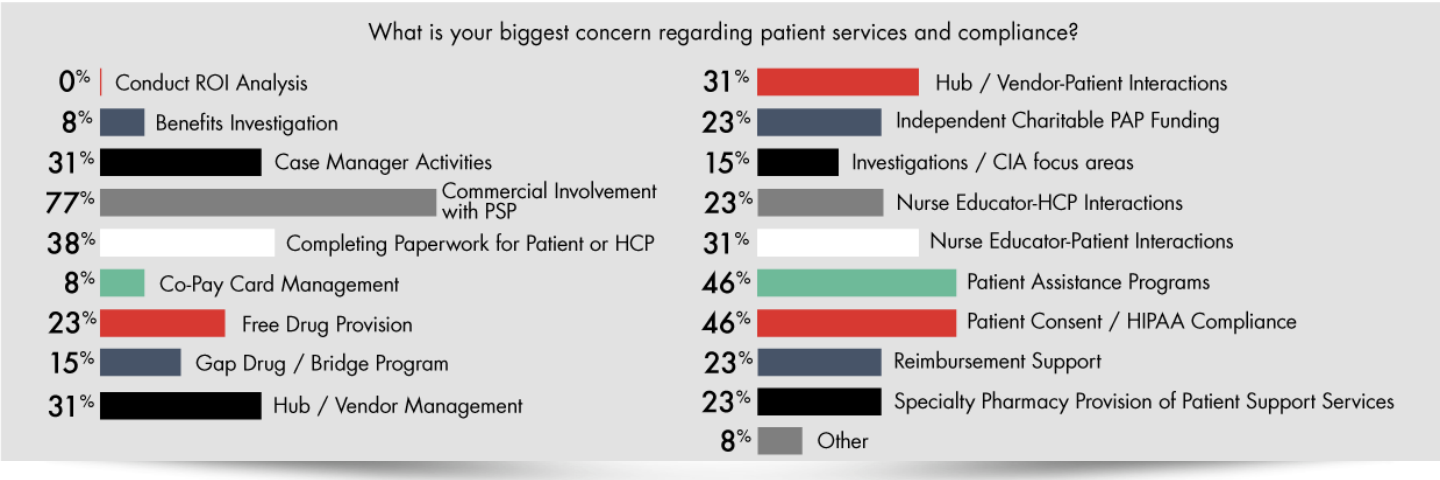
Further highlighting the apparent reversal of commercial influence over PSS, the 2023 survey asked about interactions between field sales organizations and PSS functions. Here, 43% of re-spondents reported that PSS functions can contact sales representatives directly, and of those companies allowing direct interactions, 29% also allow field sales to initiate contact with PSS staff. Nevertheless, 29% of respondents stated that interactions between the two functions were prohibited (Figure 3).

Concerns About Commerical Involvement Remain

Despite the increased commercial involvement with patient support services programs in 2023, significant concerns about that involvement persist. For example, 77% of respondents reported that commercial involvement remains a top compliance concern, demonstrating continuing unease about the potential for commercial interests to unduly influence patient support activities (Figure 4).

Moreover, we have noticed that some companies are taking proactive steps to mitigate the risk in response to

FIGURE 4: *Biggest Concerns Regarding PSS in 2023*



this apprehension. The most common strategies observed include implementing more restrictive policies and procedures regulating interactions between the functions, revamping training programs to ensure appropriate communication between these functions, closely monitoring communications to detect any undue influence, and increasing reliance on third-party vendors to handle patient services functions. Overall, these measures are designed to create a buffer between patient care initiatives and commercial interests, ensuring that the support provided to patients remains unbiased and focused on their needs.

Reading the Tea Leaves

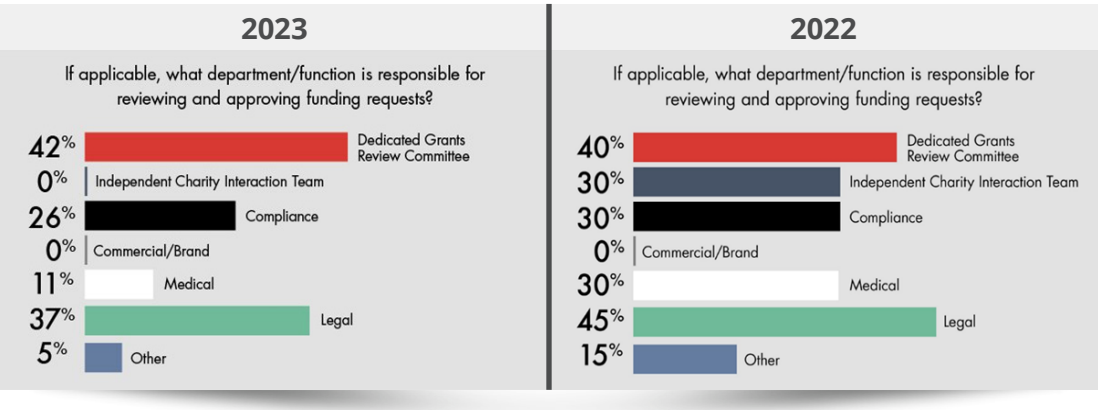
Despite the widespread concern about the impact of commercial involvement with PSS programs, the increase in commercial involvement could be an early indicator of a shift in the industry's approach, including renewed challenges to the previous approach of separating the two functions to maintain the independence of PSS programs. It could also signal that compliance's influence is declining.

Either way, the trend is troubling when juxtaposed with the guidance provided by the Health and Human Services Office of Inspector General ("HHS-OIG"). For example, HHS-OIG in 2003 encouraged the separation of commerical functions from other company activities to ensure independence.[17] Also, while not explicitly stated in terms of PSS programs, the recently released General Compliance Program Guidance highlights concerns about arrangements involving federal healthcare beneficiaries and the need to track and evaluate financial arrangements.[18]

Although it is impossible to pinpoint the reasons for the increased commercial influence, it is likely multifaceted. For example, it could reflect the observed overall slowdown in government enforcement efforts leading to an increased risk tolerance. It also could reflect the increasingly challenging nature of the life sciences business environment. It could also reflect the perception that patient services can indeed safely report to commercial operations within the broader organizational structure. However, as the survey indicates, the interplay between compliance and business operations remains fluid and warrants closer examination and ongoing monitoring to understand the context and the implications on patient care and industry practices.

FIGURE 5: *Percent of Companies Who Support ICAPs (2023)*

FIGURE 6 : *Departments/Functions Responisble for Funding Requests*



Support for Independent Charitable Patient Assistance Programs Decreases

The 2023 survey also revealed a noticeable change in company support for ICPAPs. Overall, there continues to be an overall trend away from supporting ICPAPs. For example, the 2023 data revealed that only 25% of respondents reported supporting ICPAPs, while 65% did not. Moreover, 10% of respondents who previously supported ICPAPs no longer do so (Figure 5).

Paradoxically, despite declining support for ICPAPs, the perception that donating to ICPAPs is too risky because of

government enforcement actions has also appeared to decline. Compared to the 2023 data, 33% of 2022 respondents supported ICPAPs, while 56% did not, and only 7% reported ending their previous ICPAP support. However, in 2023, only 6% of those ending ICPAP support did so because of the risks associated with government investigations and enforcement actions, as opposed to 15% in 2022 (-9%).

Although the reasons behind the reduced support for ICPAPs are unclear, Helio's survey highlights an emerging industry trend: consolidating the review and approval charitable funding requests. We note that funding decisions are increasingly centralized within dedicated grant review committees rather than handled by separate functions (Figure 6).

Using multi-stakeholder committees to review and approve grant proposals for independent educational initiatives (i.e., CME or IME) is familiar and is considered a leading compliance practice. Likewise, many large life science companies have created independent internal foundations to handle their non-commercial charitable funding. However, until recently, charitable activities supported by commercial functions have remained largely outside this framework.

Now, companies are expanding the traditional remit of these educational grant review committees to include charitable giving to ICPAPs. There are several possible reasons for this shift. For example, centralizing the review and approval under a single grant review committee can increase efficiency by avoiding duplication and improving consistency. In addition, centralization could reflect a broader strategic business decision to consolidate budgets for independent educational initiatives and charitable giving. Finally, in light of government concerns and enforcement actions involving ICPAPs, centralization could be an attempt to improve compliance oversight and reduce the risks associated with these donations.

It is too soon to conclude how the changes highlighted by the survey will impact support for ICPAPs or the broader landscape of patient services and life science commercial operations. Nevertheless, the evolving landscape of charitable contributions and patient services indicates that the industry is adapting to changing headwinds.

Monitoring and Auditing Efforts Lose Momentum

Monitoring and auditing are well-established compliance tools. Monitoring is a continuous, real, or near-real-time activity using established criteria to demonstrate adherence to specific legal and compliance standards.

Unlike monitoring, which is a real or near real-time activity, audits are retrospective, "snapshots in time" to ensure that employees adhere to the required processes.[19] Properly structured audits also provide a method for assessing whether established monitoring efforts are achieving their intended effect.

In addition to being core elements of an effective compliance program,[20] the DOJ views robust monitoring and auditing activities of high-risk areas as a critical component of whether a company's compliance program is "well-designed" and "works in practice."[21] Given the established risks associated with patient support services, it is imperative that PSS compliance monitor and audit these programs and therefore, why Helio's survey examines the techniques and trends in this area.

Call Recording

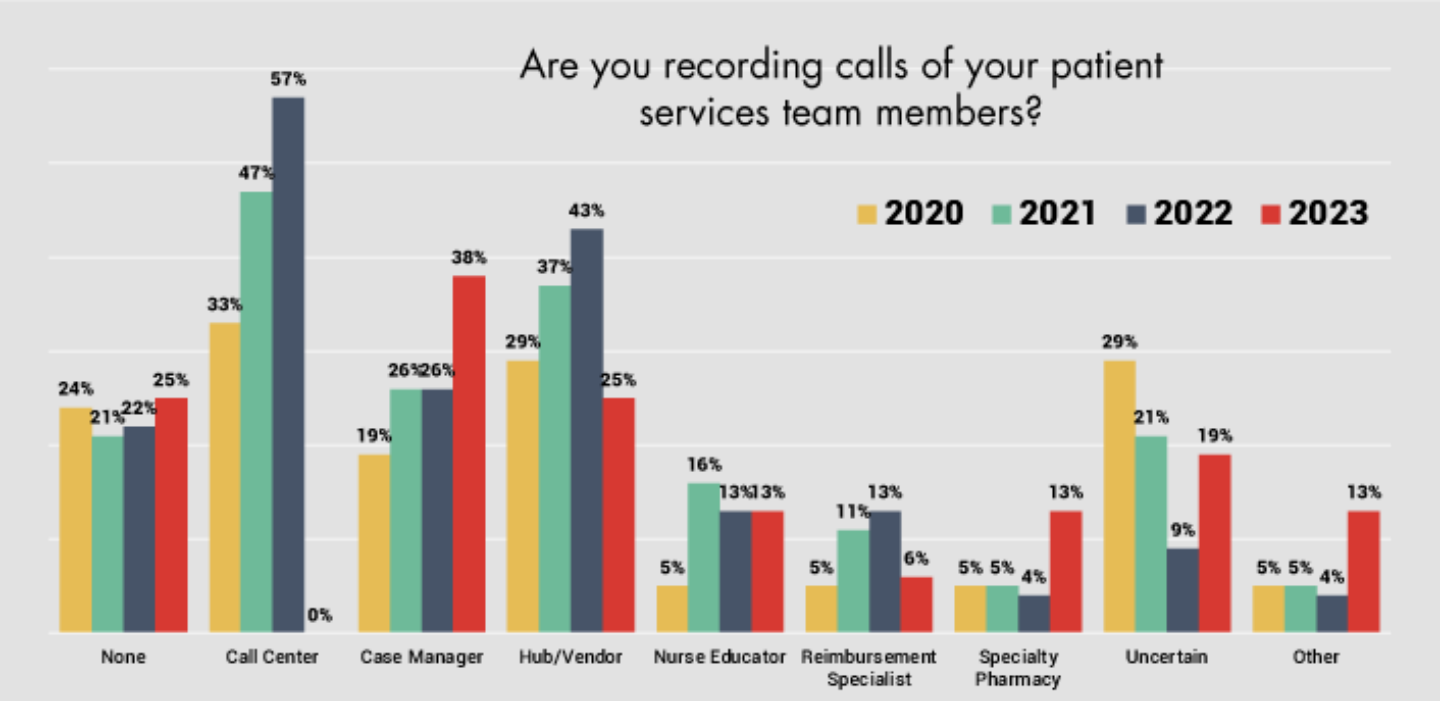
In the face of compliance concerns with PSS programs, recording and evaluating patient services team calls has emerged as a useful monitoring technique. However, there has been a notable shift in call recording practices over the years.

While the recording of calls involving case managers saw an uptick in 2023, there was a corresponding downward trend in the recording of calls with hubs/vendors and reimbursement specialists. The data suggest the emergence of a targeted approach towards monitoring and quality control, driven by a need to ensure compliance and improve patient service management (Figure 7).

Examining the specific responses to the survey provides additional insightful context. Below is a summary of that data:

- **None:** 25% of 2023 respondents reported not recording any calls. While this is consistent with prior surveys, it represents a potential data capture and oversight gap.

FIGURE 7: *Call Recording Trends (2020-2023)*



- **Case Manager:** 38% of respondents reported recording case manager calls in 2023. This is a marked increase from the 26% reported in both 2021 and 2022 and could reflect an increased focus on ensuring that interactions with patients adhere to compliance standards.
- **Hub/Vendor:** In 2023, only 25% of respondents reported recording hub/vendor calls, representing a significant decrease from 2022 levels (-18%). The increased reliance on outsourcing and reliance on vendors' internal compliance mechanisms could account for the decrease.
- **Nurse Educator/Trainer:** The level of call recording involving nurse educators and trainers remained unchanged in 2023. However, at 13%, this level represents another potential data capture and oversight gap.
- **Reimbursement Specialist:** The number of respondents reporting that they record reimbursement specialists decreased by 7% between 2022 and 2023 (13% versus 6%, respectively). Although providing reimbursement advice has been a problematic area in the past, the low level of monitoring suggests that this is a neglected area.
- **Specialty Pharmacy:** In 2023, 13% of respondents reported recording specialty pharmacy calls. The data represent a significant increase over 2022 activities (+9%) and may indicate the increasing importance of specialty pharmacy activities to industry commercial operations.

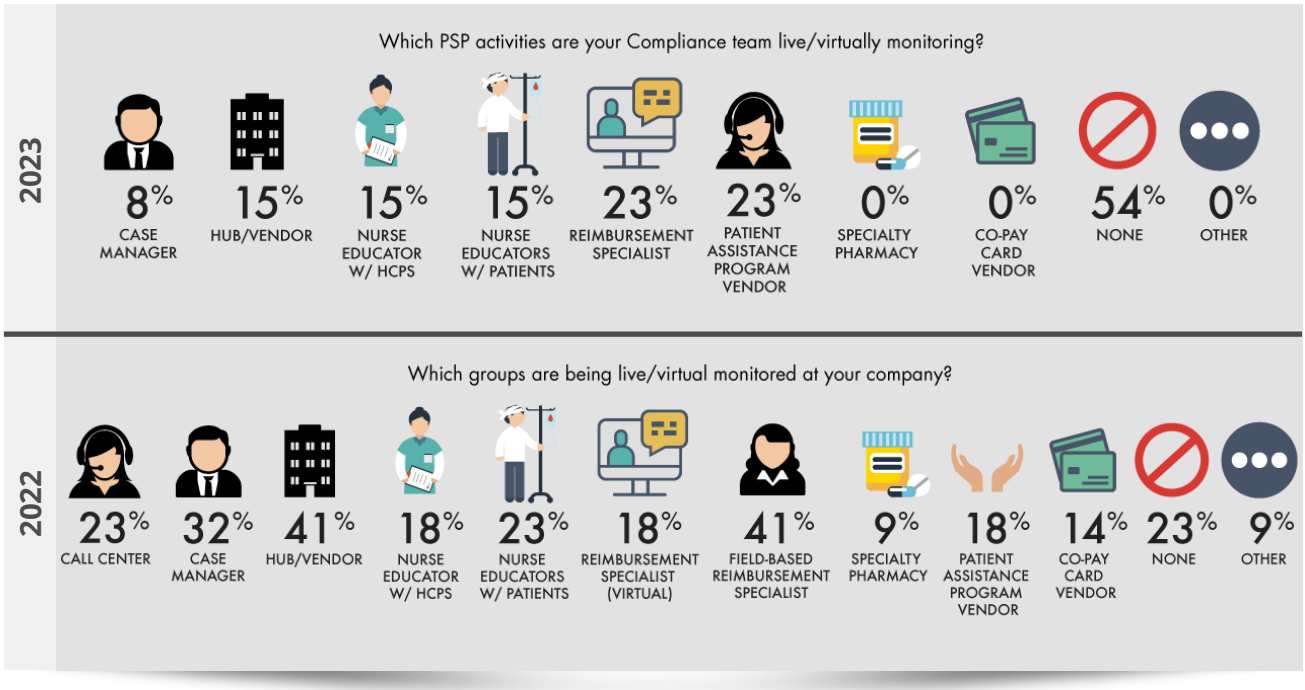
Viewed holistically, the 2023 survey responses highlight an overall decline in call recording efforts as a monitoring technique. When viewed with the specific areas where call recording occurs, the figures could indicate an increased belief in the effectiveness of established processes or using a risk-adjusted basis, allowing more efficient allocation of limited resources to address higher-risk activities. Conversely, the increase in other areas, particularly case management, highlights the heightened focus on roles with significant influence over patient care and service delivery.

Virtual and Live Monitoring

The 2023 survey data related to live and virtual monitoring highlights a striking shift in monitoring practices for various PSS program components compared to 2022.

For example, the number of respondents engaging in live or virtual monitoring dropped precipitously from 2022

FIGURE 8: *Virtual and Live Monitoring Practices*



to 2023 (23% versus 54% respectively). This 31-point drop year-on-year suggests a fundamental strategy shift, possibly due to a reassessment of the value or efficacy of such monitoring. While the cause is unknown, we believe a further detailed examination is warranted to understand the nature of the change.

Moreover, except for reimbursement specialists,[22] all other live or virtual monitoring activities show a precipitous decline year on year. For example, case manager monitoring dropped by 24 points, while monitoring of hubs and nurse educators involved with patients dropped by 26 points and 8 points, respectively. Finally, in the cases of co-pay cards and specialty pharmacies, live or virtual monitoring was eliminated entirely.

The reasons for such abrupt changes are unknown, but possibilities include a shift to relying on other less costly and potentially more effective controls or a belief in the adequacy of established compliance practices. Nevertheless, given the government's belief in the importance of monitoring, coupled with their continuing concerns about PSS programs, we believe it is prudent for compliance officers to engage in further proactive research to understand and explain the observed shifts before the government inquires or assumes, in the absence of evidence to the contrary, that the compliance programs are ineffective (Figure 8).

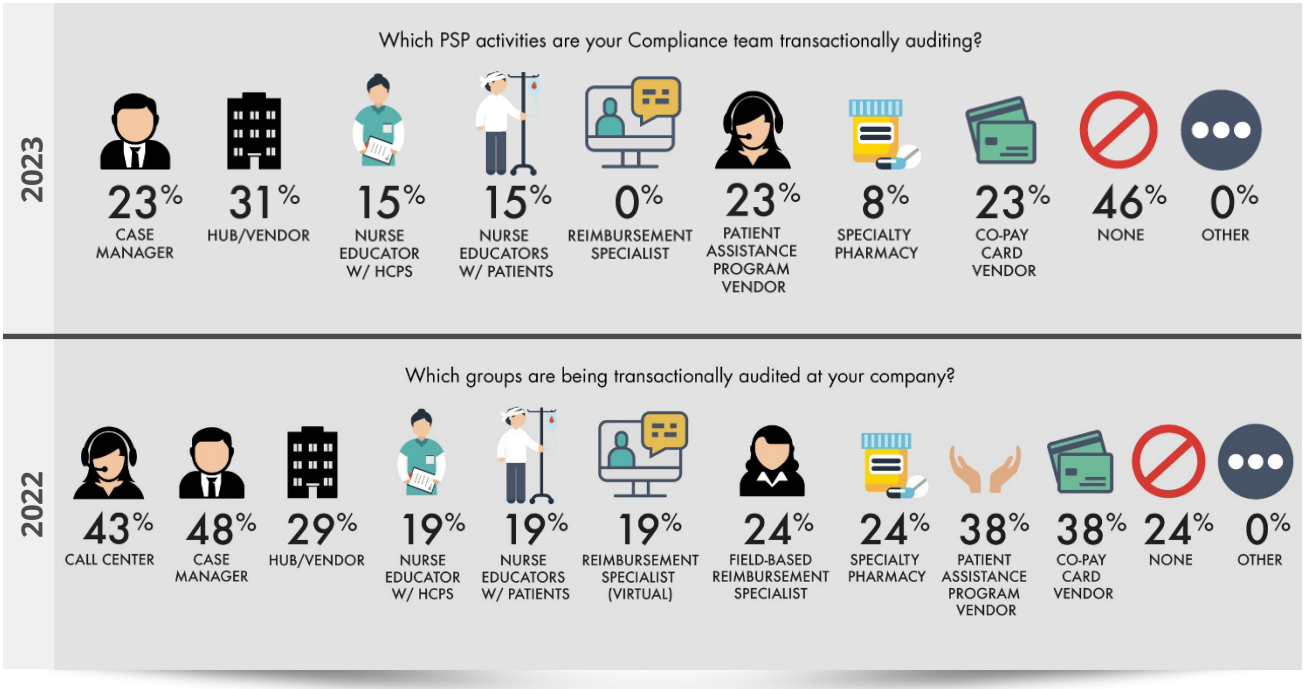
Transactional Auditing

We also explored the extent to which compliance teams conduct transactional audits of PSS activities. Like all facets of monitoring, we observed similar and disturbing trends with audits. For example, the number of organizations not undertaking transactional PSS auditing increased 22 points from the previous 2022 survey (46% in 2023 versus 24% in 2022). This significant upward trend suggests a broad move away from transactional auditing. While the reasons are unknown, it may indicate a shift towards more strategic, risk-based, or outcome-focused compliance approaches.

Moreover, except for hub audits, which showed a modest increase,[23] transactional audits declined across all survey categories. The most precipitous declines involved transactional auditing of case managers (-25 points), co-pay cards (-15 points), reimbursement specialists (-19 points), and specialty pharmacies (-16 points). More modest declines involved nurse educators with healthcare providers ("HCPs") (-4 points).

Like the monitoring declines, the reasons for the shift are unclear, but here again, we urge compliance officers to undertake further proactive research to understand the context. Failure to understand and be able to explain the shifts creates a significant risk that the government

FIGURE 9: *Transactional Auditing*



will view PSS compliance efforts lacking transactional auditing as ineffective (Figure 9).

Government Enforcement

In parallel with the industry's PPS compliance efforts, government enforcement activity involving PAPs in 2023 declined from the levels seen in 2017-2020. However, two settlements in the last quarter of 2023 suggest that the government's concern and interest in PAPs have not abated.

In October 2023, the DOJ announced a settlement with BioTek reMEDys Inc., a specialty pharmacy in Delaware.[24] The whistleblower case involved BioTek's routine waiver of Medicare patient co-pays. According to the government, BioTek waived the patients' obligations for many medications with high co-pays without reviewing or determining their financial status. As a result, the government asserted that the waivers were illegal inducements (i.e., kickbacks) that resulted in unnecessary or increased costs to Medicare (i.e., false claims). According to U.S. Attorney Jacqueline Romero:

> BioTek's alleged scheme…to routinely waive these copays – without regard for whether the patients were experiencing financial hardship – ensured a steady revenue stream for BioTek and undermined patient care to citizens of this District.[25]

BioTek settled the matter for $20 million.

In December 2023, the DOJ announced a settlement with Ultragenyx Pharmaceutical Inc. to settle kickback and false claims allegations involving its rare disease drug, Crysvita.[26] Crysvita is a drug used to treat X-linked hypophosphatemia ("XLH"), a rare inherited blood disorder. Before approving coverage for Crysvita, many insurance companies required patients to undergo genetic testing to confirm their diagnosis.

As a result, Ultragenyx began offering free genetic tests to patients. Beyond paying for free genetic testing, Ultragenyx also paid the laboratory a fee to send test outcomes directly to the company, together with the ordering HCP's identity, an anonymized patient identifier, the date of the test order, and the test results. The company provided the data to its field sales representatives, allowing them to target ordering HCPs with patients who had received positive test results.

Because one purpose of the scheme was to increase Crysvita prescriptions, it violated the AKS one-purpose rule, which holds that:

> If one purpose of a marketing scheme is to induce the provision of a prescription item reimbursable by Medicaid [Medicare], then the criminal anti-kickback statute is implicated. There is no statutory exception or "safe harbor" to protect such activities.[27]

> Therefore, the free genetic tests constituted an illegal inducement, making any prescriptions generated from the kickbacks false claims if submitted to the government for payment. Ultragenyx settled the case for $6 million.[28]

Both cases serve as a stark reminder that regardless of the number of annual settlements, the DOJ, HHS-OIG, and others remain vigilant to the inappropriate use of PAPs to increase prescriptions. Therefore, we urge companies that scale back compliance efforts because of a perceived lack of government focus to proceed with extreme caution.

Conclusion

Since its inception, our annual survey has tracked compliance trends and highlighted the evolving nature of PSS programs. Without wholesale revisions to the existing healthcare system, the importance of these programs will continue and likely grow. Moreover, while compliance controls can and should evolve to meet changing needs, now is not the time to reduce compliance efforts, especially if the industry's primary goal is supporting patients. Regulatory compliance and avoiding unnecessary distractions from needless litigation is the floor, not the ceiling. Therefore, we can and must do better, which means continuing to support practical, pragmatic compliance measures.

References

1 Ms. Bak is a Director and Ms. Wright is a Manager and In House Counsel with Helio Health Group. Helio is a life sciences consulting firm comprised of career compliance professionals providing traditional consulting services and a growing suite of technology-based compliance solutions to provide strategic and operational compliance assistance to pharmaceutical and medical device companies.

2 *See* Issac Strauss, *Corrupt or Charitable? Patient Assistance Programs and the Case for Narrowing the Breadth of the Federal Anti-Kickback Statute*, 44(2) Cardozo L. Rev., 669-670 (2022), https://cardozolawreview.com/corrupt-or-charitable-patient-assistance-programs-and-the-case-for-narrowing-the-breadth-of-the-federal-anti-kickback-statute/.

3 *Id.* at 669.

4 *See* PAN FOUND., ABOUT US (last accessed Jan. 31, 2024), https://www.panfoundation.org/about-us/.

5 *See* PAN FOUND., THE IMPACT OF PATIENT ASSISTANCE ON ACCESS, MEDICATION ADHERENCE AND QUALITY OF LIFE (Mar. 1, 2019), https://www.panfoundation.org/the-impact-of-patient-assistance-on-access-medication-adherence-and-quality-of-life/.

6 *Id.*

7 *Id.*

8 *See* Strauss, *supra* n. 2.

9 *See* Jacob T. Elberg, *et al.*, *Patient-assistance programs, kickbacks, and the courts*. 388(26)The New Eng. J. of Med., 2407–2409, 2409 (2023).

10 *See* Strauss, *supra* n. 2 at 670.

11 *See, e.g.,* PAN Found., The Impact of Patient Assistance, *supra* n. 5.

12 *See, e.g.,* Strauss, *supra* n. 2.

13 *See, e.g.,* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005); *see also* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).

14 *See* Marci Juneau, *et al.*, *Helio Health Group's Fifth Annual Patient Support Services Compliance Survey*, 7.12 POLICY & MED. COMPLIANCE UPDATE 1 (2021).

15 *See* Minna Bak, *et al.*, *The Sixth Annual Patient Services Compliance Survey*, 9.1 POLICY & MED. COMPLIANCE UPDATE 17 (2023).

16 *See* John C. Hood, *Are Good Deeds Being Punished?: Independent Charity Patient Assistance Programs and the Anti-Kickback Statute*, 72 FLA. L. REV. 639 (2021); Press Release U.S. Attorney's Off., D. Mass., *Actelion Pharms. Agrees to Pay $360 Million to Resolve Allegations that It Paid Kickbacks Through a Co-Pay Assistance Foundation* (Dec. 6, 2018), https://www.justice.gov/usao-ma/pr/actelion-pharmaceuticals-agrees-pay-360-million-resolve-allegations-it-paid-kickbacks; Press Release, U.S. Dep't of Justice, *Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More than $35 Million to Resolve Criminal Charges & Civil False Claims Allegations* (Sept. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and; Press Release U.S. Attorney's Off., D. Mass., *Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks* (May 24, 2018), https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay; Press Release, U.S. Dep't of Justice, U.S. Attorney's Off., D. Mass., *United States Files Suit Against Drug Manufacturer Regeneron for Paying Kickbacks Through Copay Foundation* (Jun. 24, 2020), https://www.justice.gov/usao-ma/pr/unitedstates-files-suit-against-drug-manufacturer-regeneron-paying-kickbacksthrough-co; Press Release, U.S. Dep't of Justice, *Three Pharm. Cos. Agree to Pay a Total of Over $122 Million to Resolve Allegations that They Paid Kickbacks Through Co-Pay Assistance Foundations* (Apr. 4, 2019), https://www.justice.gov/usao-ma/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they; Press Release, U.S. Attorney's Off., D. Mass., *Sanofi Agrees to Pay $11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation* (Feb. 28, 2020), https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

17 *See, e.g.,* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

18 *See* U.S. Dep't of Health & Human Servs., Off. of Inspector Gen'l, *General Compliance Program Guidance* (Nov. 6, 2023), https://oig.hhs.gov/compliance/general-compliance-program-guidance/.

19 *See, e.g.,* 68 Fed. Reg. at 23741.

20 *See* U.S. Sentencing Guidelines Manual, § 8B.2.1 (U.S. Sentencing Comm'n 2021).

21 *See* U.S. Dep't of Justice, Crim. Div., *Evaluation of Corporate Compliance Programs* (updated Mar. 2023).

22 Live or virtual monitoring of reimbursement specialists increased by 5% from 2022 levels.

23 Hub transactional auditing increased by 2% from 2022 levels.

24 *See* Press Release, U.S. Dep't of Justice, *United States Settles Kickback Allegations with BioTek reMEDys Inc., Chaitanya Gadde and Dr. David Tabby* (Oct. 2, 2023) https://www.justice.gov/opa/pr/united-states-settles-kickback-allegations-biotek-remedys-inc-chaitanya-gadde-and-dr-david; *see also United States ex rel. Wyatt, et al. v. BioTek reMEDys, Inc.*, No. 19-6069 (ED. Pa. 2023).

25 *Id.*

26 *See* Press Release, U.S. Dep't of Justice, *Pharmaceutical Company Ultragenyx Agrees to Pay $6 Million for Allegedly Paying Kickbacks to Induce Claims for Its Drug Crysvita* (December 21, 2023), https://www.justice.gov/opa/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce; *see also United States ex rel. Ruggiero v. Ultragenyx Pharmaceutical, Inc.* No. 1:21-cv-11176-ADB (D. Mass. 2023).

27 *See U.S. v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

28 *Id*.

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