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FEATURE

Helio's 4th Annual Patient Services Compliance Survey

Patient Services Program Compliance Continues Evolving in 2020

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Summary: Patient Services Programs are likely to be an important cost containment tool in the fight against rising healthcare costs. However, as recent enforcement actions against life science companies demonstrate, these programs are fraught with compliance risks for the unwary. Therefore, companies must rely on their compliance professionals to ensure their organizations are taking appropriate action to plan, assess, and respond to a heightened enforcement focus on PSPs in 2021 and beyond.

Patient Services Programs ("PSPs") are one of the life sciences industry's most valuable contributions to reducing barriers to treatment and improving health outcomes for patients. However, because of the complex relationships between payers, providers, and patients, PSPs are a still-evolving area fraught with potential compliance risks requiring adequate compliance controls to manage those risks.

Since 2017, Helio Health Group has collected insights from life sciences professionals regarding Patient Services Programs ("PSPs").[2] Despite the pandemic and for the fourth consecutive year, Helio's annual Patient Services Compliance Survey provides industry benchmarking for assessing and addressing the risks associated with expanding the PSP model.

Last month, Helio published its 2020 survey in conjunction with the 21st Annual Pharmaceutical and Medical Device Ethics & Compliance Congress ("Compliance Congress") hosted virtually by the Pharmaceutical Compliance Forum ("PCF"). We are presenting that data here as an updated benchmark on current practices, as well as, to highlight the continuing compliance burdens and challenges of monitoring PSPs during the massive shift to digital work environments necessitated by the COVID-19 pandemic.

The State of PSP Enforcement in 2020

When Helio last shared its findings in 2019, the hot button issues included:

1. The provision of co-pay assistance through donations to charitable organizations.
2. Data governance and data privacy issues due to growing regulatory focus on storage and usage of patients' personally identifiable information ("PII"), including HIPAA-regulated private health information ("PHI").[3]

Both issues remain relevant in today's current enforcement environment. However, data privacy has become a subcomponent of a broader examination by regulators of data practices, with a special focus on interactions with patients and providers during the full continuum of treatment delivery.

The Regeneron Case

In June of this year, United States Attorney's Office for the District of Massachusetts filed a lawsuit alleging that Regeneron violated the False Claims Act ("FCA") and Anti-Kickback Statute ("AKS") by paying millions of dollars in indirect kickbacks to induce the prescription of its macular degeneration drug, *Eylea*.[4] The kickbacks consisted of reimbursements to a charitable foundation for the exact dollar amount of any co-pay assistance it furnished to Medicare Part B patients.[5]

Beyond just making the announcement, the Justice Department published 37 unredacted emails belonging to senior executives of Regeneron, which accused the company of repeatedly misleading auditors when inquired about patient data sharing and Regeneron's financial relationship with the foundation and its' patient beneficiaries.[6]

California vs. AbbVie

Less than a month later, the California Department of Insurance announced a $24 million settlement with AbbVie, Inc. to resolve allegations that the company violated California's Insurance Frauds Prevention Act when marketing its lead biologic, *Humira*.[7] The case originated from a whistleblower complaint filed by one of AbbVie's former Nurse Educators (a.k.a. "Ambassadors").[8]

By agreeing to settle with the State of California, AbbVie avoided any admission of wrongdoing and maintained its reimbursement status with state payers. In exchange for this result, AbbVie agreed to implement eleven structural changes to its Patient Assistance Program ("PAP") for Humira (the Humira patient services program, including the Humira Ambassador Program) within 180 days of the agreement (Figure 1).[9]

Continuing Impact of Enforcement

Ever since the Justice Department's landmark settlement with United Therapeutics in 2017, the industry has seen numerous examples of regulatory probes and investigations targeted at companies' internal control failures surrounding their increasing volume of patient interactions.[11] These probes and investigations identified both the importance of the PSP model for healthcare delivery and the potential for misuse. The recent *Regeneron* and *AbbVie* cases continue the trend followed by those earlier probes and investigations and emphasize the critical need for life sciences companies to invest in compliance safeguards for PSPs.

Refining the Key Benchmarks

Now that we have established that PSPs continue to be a focus for both State and Federal regulators, the Helio's 2020 Patient Services Survey presents a perspective of compliance strategies and resource deployment in response to regulators' still-ongoing exploration of PSPs. The results provide insight into the actions taken by compliance leaders to preserve integrity and minimize risk while continuing to provide funding to support of patient access, adherence, and maintenance via PSPs.

FIGURE 1: *Summary of Non-Monetary Terms of Agreement Between California & AbbVie*[10]

Functional Area	Changes to be Implemented:
Commercial (Sales)	• A policy that requires at least five (5) RSVPs from Health Care Providers ("HCPs"), outside the speaker's own office, at least 48 hours in advance of any speaker program, or else the speaker program will be cancelled. • A policy prohibiting HUMIRA sales representatives from inviting HUMIRA prescribing HCPs to offsite business meals, except as part of AbbVie-approved speaker programs. • A policy prohibiting the speaker program title from containing the name of the **"Humira Complete" patient assistance program.**
Nurse Representatives (HUMIRA Ambassador Program)	• Guidance and training requiring Ambassadors to **disclose to patients that they are agents of AbbVie** and do not work under the direction of the patient's prescribing HCP. • Guidance and training prohibiting the description of Ambassadors as "**extensions of their (...HCP's) offices**" and the provision of contact information for Ambassadors who interact with Humira patients to HCPs. • Guidance and training that Ambassadors **may not have patient-specific discussions with HUMIRA-prescribing HCPs.** • Guidance and training instructing **Ambassadors not to actively participate in conversations between patients and insurance companies.** • Guidance and training that Ambassadors may **not be evaluated or compensated based on patient adherence** to Humira. • Specific language in Humira Complete **enrollment forms** disclosing that Ambassadors are agents of AbbVie.

Building upon the snapshot of patient data privacy standards featured in Helio's 2019 survey, the 2020 survey includes questions that probed compliance leaders' perceptions of their companies' own level of preparedness to address patient services compliance challenges in the context of 2020's forced spike in telehealth visits and virtual sales interactions.

The Survey Says

Transitioning PSPs out of Commercial

The 2020 survey results show that companies involved with PSPS continue to make progress on transitioning PSPS away from their commercial functions. Thus, they are continuing to establish the necessary boundaries to ensure independence between medical and commercial activities as first outlined in 2003 by the OIG's *Compliance Program Guidance for Pharmaceutical Manufacturers*.[12]

In 2020, 87% of our respondents reported their companies were operating PSPs. However, just 12.5% of those respondents indicated their program was managed under the brand or commercial component of their organization. This response represented a 56.2% **decrease** year-on-year ("YoY") and 66.2% **decrease** overall since 2017 (Figure 2).

The proportion of companies reporting a dedicated, internal Patient Services group remained steady (2.1% increase YoY), but the 2020 results showed that companies, which were transitioning their PSPs out of commercial, tended to relocate them either to the Managed Markets or Market Access groups (45.5% increase YoY, 125% overall increase since 2017) or Medical Affairs (191.3% increase YoY, 125% overall increase since 2017).

During the recent Compliance Congress, the panelists discussing PSPs underscored the importance of housing the programs under the appropriate functional group to manage external perceptions about the company's patient-oriented services. Stefanie Doebler, Partner & Co-Chair of the Life Sciences Practice at Covington & Burlington, LLP, offered the following advice to Congress attendees:

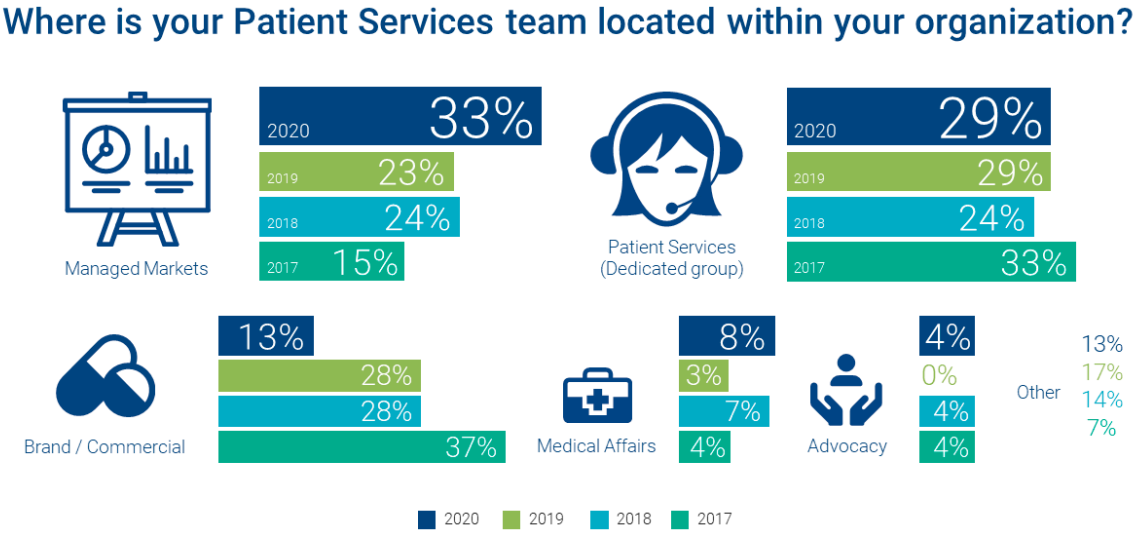
> When you have [patient services] programs that are this ubiquitous, I think that translates into government interest, and we've seen that already with contributions to charitable foundations as well as the provision of co-pay assistance cards. So, if they haven't already, I really think every company should be thinking about how the government might perceive the programs they're offering or planning to offer to their patients in the future.[13]

The Changing Composition of PSP Teams & Services

Looking at the types of professionals that make up PSP teams, the spike in digital business interactions in 2020 appears to have accelerated the already-existing trend of replacing centralized Call Center employees and Case Managers with field-based personnel trained to alleviate specific issues along the course of treatment, such as payer coverage and medication adherence (Figure 3).

Respondents reported YoY **decreases** of 7.9% and 31.6% in utilization of Call Centers and Case Managers, respectively, as part of their Patient Services teams. There also were notable increases in respondents that reported using Field-Based Case Managers (43.3%

FIGURE 2: *Organizational Structure of Patient Services Programs, 2017-2020*



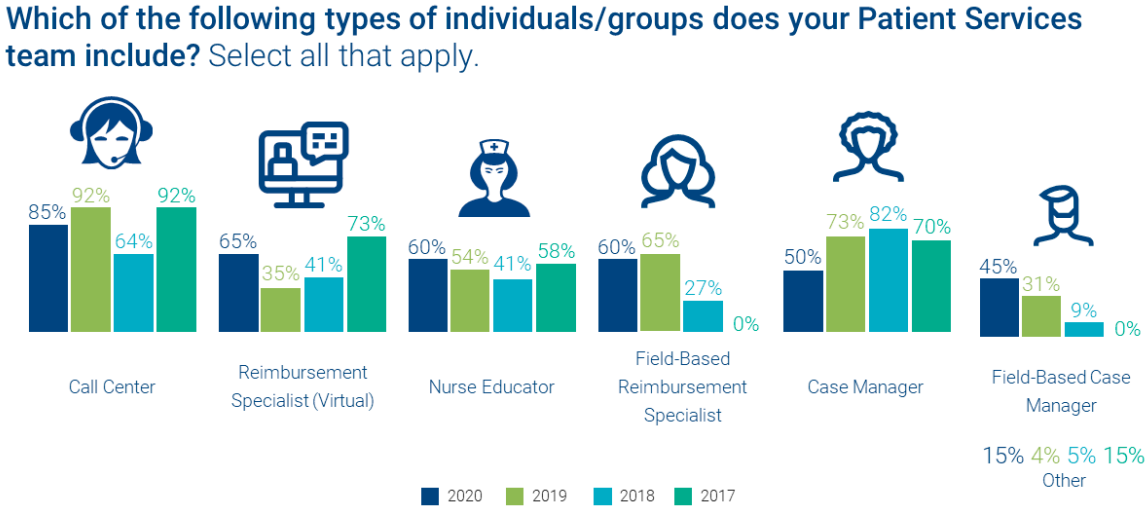


FIGURE 3: *Composition of Patient Services Teams, 2017-2020*

increase YoY), Nurse Educators (11.4% increase YoY), and virtual Reimbursement Specialists (87.8% increase YoY).

The increased variety of professionals serving on Patient Services teams was also accompanied by an upswing in the quantity of internally managed services that companies were able to provide to patient groups (Figure 4).

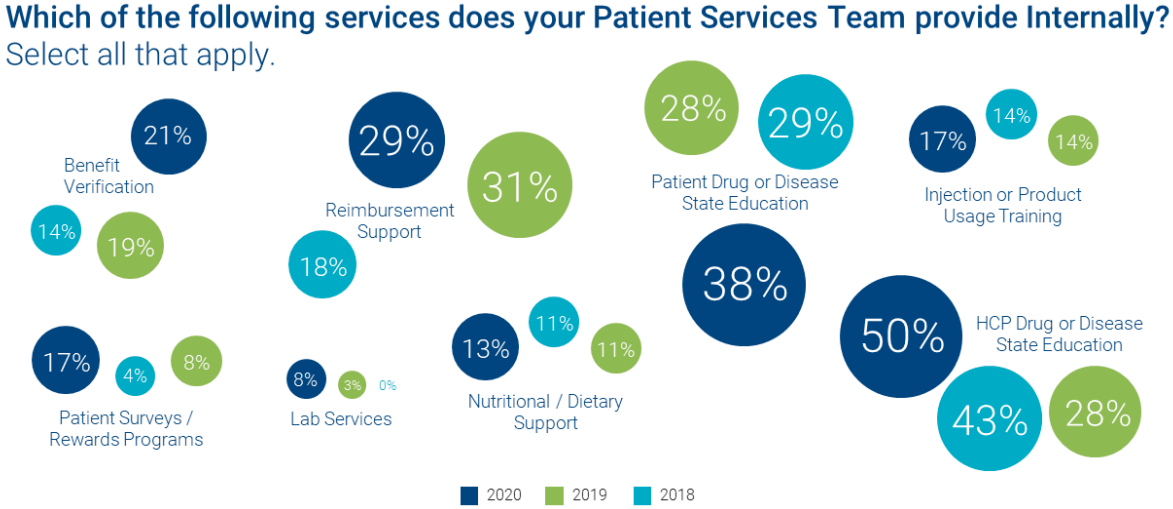
The 2020 survey recorded four-year highs with respect to four broad categories of patient support services managed internally, most notably:

- HCP Drug or Disease State Education (50% total, 80% increase YoY),
- Patient Drug or Disease State Education (37.5% total, 35% increase YoY),
- Patient Surveys / Rewards Programs (16.7% total, 100% increase YoY), and
- Injection or Product Usage Training (16.7% total, 20% increase YoY).

Commenting on these trends from the 2020 data, Stefanie Doebler expanded her cautionary advice to attendees emphasizing the need to be sensitive to the quantity, as well as the types, of individuals involved throughout a patient's experience with PSPs:

> A lot of compliance problems arise when people are trying to be helpful, and when you've got this many people trying to be helpful towards one particular patient, I think it courts trouble. So while there's nothing that says [your PSP team] cannot have all these different roles, it's really important to have clearly delineated responsibilities, to know what each team member is doing, and to be monitoring their activity.[14]

FIGURE 4: *Scope Patient Services Being Managed Internally, 2018-2020*



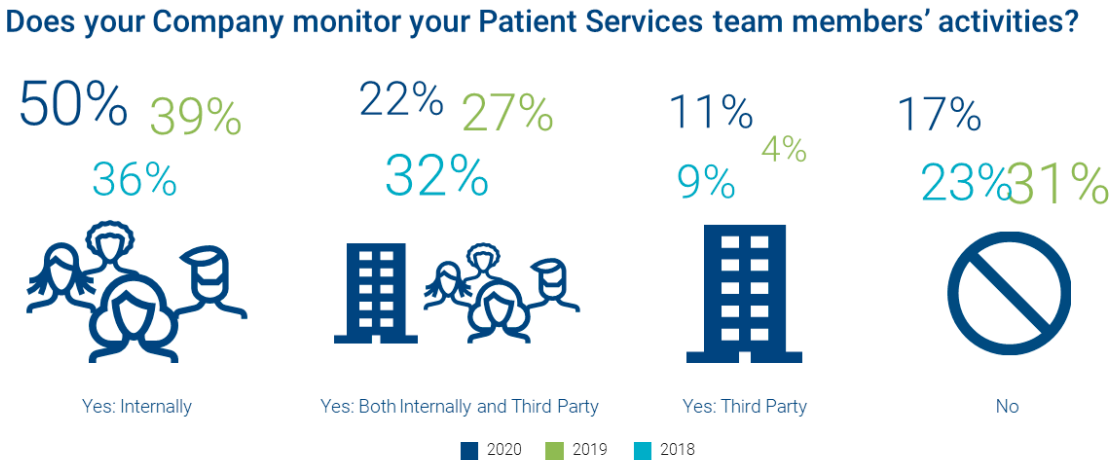


FIGURE 5: *Scope Patient Services Being Managed Internally, 2018-2020*

The Increased Monitoring Burden of Virtual PSP Interactions

The increase in personnel, services, and utilization of virtual business platforms to address PSP activities, unsurprisingly, resulted in greater monitoring of high-risk interactions. For 2020, the percentage of respondents who did not monitor their PSP activities dropped to a three-year low of just 16.7% (Figure 5).

With new digital meeting platforms such as VeevaEngage, Zoom, and Microsoft Teams being used to interact with both HCPs and patients, the proportion of respondents conducting in-house monitoring of their PSP team activities jumped to a three-year high of 50%, (an **increase** of approximately 30% YoY). The increased monitoring burden of PSPs brought on by the forced adoption of fully digital patient engagement has created a new challenge for compliance teams.

Compliance teams are already stretched thin to adapt to all the other high-risk business activities that have gone digital. Speaker programs, advisory board meetings, sample drug requests, and even HCP office visits have all been transitioned to digital platforms just as rapidly as patient support programs, generating terabytes of new data which often falls to Compliance to monitor.[15]

As Compliance leaders map out their monitoring program plans for the coming year, it is essential that they understand the volume of new data generated, which systems are generating it, and what resources will be required to adequately monitor and mitigate risks.

Focus Areas & Recommended Best Practices

The Compliance Congress also included a lengthy and detailed discussion by a panel of industry experts on the most pressing compliance concerns involving PSPs in 2020. These experts highlighted three areas to focus on including:

1. Mitigating organizational risks associated with data privacy & data integrity.
2. The increasing role of the Nurse Educator on PSP teams.
3. The relationships with Patient Services HUB vendors.

Data Privacy and Date Governance as Differentiators

For the current edition of our survey, we included more comprehensive questions to better understand the various industry approaches to address the still-evolving risk areas of data privacy, data integrity, and patient consent related to PSPs. Despite the growing volume of patient data being collected, stored, and utilized cross-functionally to support the execution of Patient Services Programs, roughly one in three companies surveyed indicated that they do not routinely monitor the company's use of patient data usage to ensure compliance with data privacy regulations and patient consent (Figure 6).

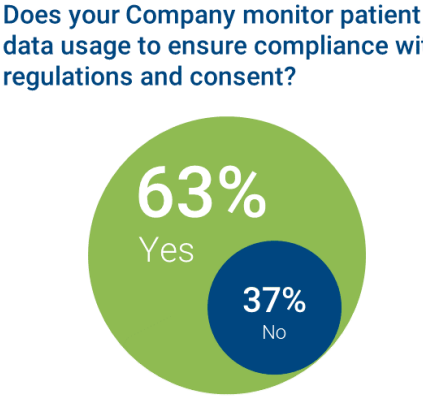


FIGURE 6: *Patient Data Privacy & Consent Monitoring, 2020*

Though we found this fact interesting, we also found it alarming. As the volume of patient data exchanges between functional areas and third-party vendors increases, companies must be diligent with their data governance practices for safeguarding data integrity and patient privacy (Figure 7).

Chapman Richardson, Global Head of Data Consumerization at Sanofi, urged virtual congress attendees to ensure that their organizations are equipped to handle the inevitable upswing in enforcement of data privacy laws such as GDPR,[16] CCPA,[17] and other regulations at the state and local level. However, he noted that this requires a careful assessment of the value and the effort necessary to protect the integrity of data on hand:

> When we ask ourselves questions like "Do we need all of this information?" and "What are we going to do with it?" and our answer is "Not much," then there's probably not a lot of reward there for us to take on the risk of actually capturing this information. I think the challenge with that, though, is that by not doing so we're missing out on some big opportunities. By not taking on this data, we may potentially not be providing the best possible services to our patients, and we may also not be taking advantage of what could be a very valuable data asset – not only for improving how we engage with our patients, but also for secondary usage elsewhere, such as in understanding how therapies are being administrated by providers or leveraging other data captured on the Commercial side to help identify comorbidities to explore on the Research side.[18]

In addition to minimizing the risk of regulatory penalties, taking the extra steps to monitor and manage compliance in key data privacy areas such as HIPAA and patient consent may ultimately reap benefits in the form of maintaining the trust of patients.

Monitoring and Controlling Nurse Educator Interactions

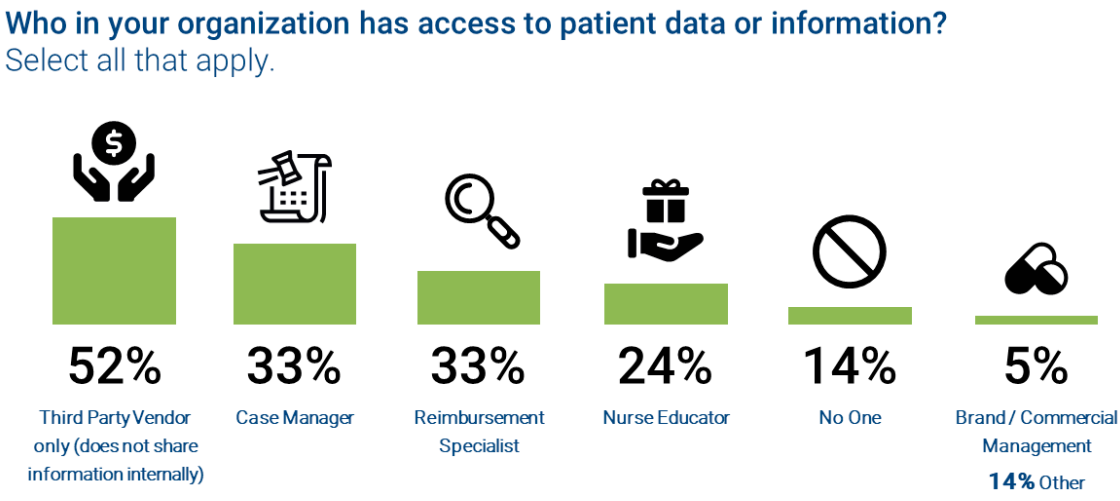
The issues surrounding the use of nurse educators or so-called "white coat marketing" are not new.[19] However, in light of new state-level enforcement targeted at the Nurse Ambassador role, we also focused on nurse educators. This year's survey also provided a snapshot of the types of nurse educator interactions and the types of resources they are provided to facilitate compliance in those interactions.

According to our results, one out of three companies surveyed in 2020 reported their nurse educators were in contact with both patients and their HCPs. However, less than half of those surveyed reported that they provided resources such as interaction guides, call scripts, or pre-approved FAQ responses to address improper commercial or off-label discussions (Figure 8).

Andrea L. Kocharyan, VP & Head of Legal & Compliance at Zealand Pharma US, emphasized to PCF 2020 attendees to be cognizant of the ease with which risks can emerge in Nurse Educator interactions:

> [Nurse Educators] go into this field because they are concerned about patient care and they want to assist these individuals. I think it's very easy to go off-script and be "helpful" in that view. The tension between being compliant and being perceived as helpful is a real one. So, I think resources like FAQs are great tools for helping Nurse Educators deliver the key messages without getting too far away from compliant language.[20]

FIGURE 7: *Patient Data Privacy Practices, 2020*



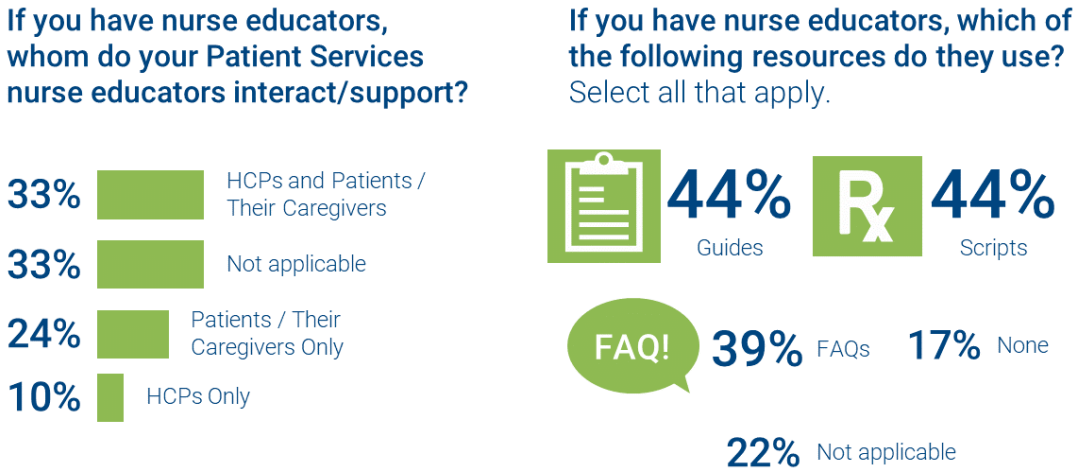


FIGURE 8: *Spotlight on Compliance Practices Related to the Nurse Educator Role, 2020*

The resulting discussion highlighted the emerging need to implement robust monitoring control procedures, the most controversial of which were the recording of Nurse Ambassadors' calls. While all panelists agreed they would like to record and review their PSP team members calls, they highlighted areas of uncertainty, such as employee privacy, future litigation discovery, and patient consent, as reasons for caution. We think that these concerns may contribute to why less than 5% of companies surveyed in 2020 responded that they currently record nurse educator communications.

To address data privacy concerns with respect to call recording, Chapman Richardson laid out a strategy framework that enables companies to minimize the risks with collecting this type of data and in turn avoid the risk that a decision to not monitor call recordings be perceived as a "head in the sand" strategy:

> To engage in this safely, companies need to clearly define what they want to use the call recordings for, and how long they will store them. Whether [call recordings] are being collected for improving the quality of the services, for monitoring compliance with company SOPs, or whatever other business purpose – companies should be deliberate in defining what that purpose is, communicating that purpose while obtaining consent, and then sticking to it throughout the storage and use of the recordings. If executed with a clear and transparent plan, there should be no real major risk to the company in collecting this data.[21]

The "HUB as An Extension of You" Doctrine in PSP Compliance

Our 2020 survey found that the percentage of respondents, which partnered with a HUB vendor for at least one part of their PSP, remained unchanged from 2019 at 75% (Figure 9). While this trend was consistent across the most popular HUB-outsourced services such as prior authorization support and benefit education, we observed a significant increase for other patient-facing services such as patient surveys and rewards programs (88% increase YoY), as well as patient drug or disease state education (29% increase YoY).

Once more, Stefanie Doebler was quick to remind Congress attendees that selecting a HUB partner and outsourcing the delivery of patient services is far from the end of the journey for Compliance leaders. Thus, she underscored the importance of monitoring the HUB's activities because they are acting on the company's behalf.

> The HUB stands in your company's shoes, and many HUB vendors even introduce themselves on the phone as representatives of your company. It's important to be reviewing their business rules for these types of programs, to audit and monitor their activities, and if they are making calls to patients, to be listening to those calls.[22]

Conclusion

Despite the increased state and federal government scrutiny of PSPs that is expected to increase in months ahead, our survey indicates that PSPs blending both field-based and digitally based services will not be disappearing any time soon. With legislators and the public paying more attention to the rising costs of health care and prescription drugs and devices, PSPs are likely to be an important cost containment tool. However, as demonstrated by the industry's settlement agreements this year, they will remain a key area of scrutiny. As PSPs are still a comparatively new and evolving space,

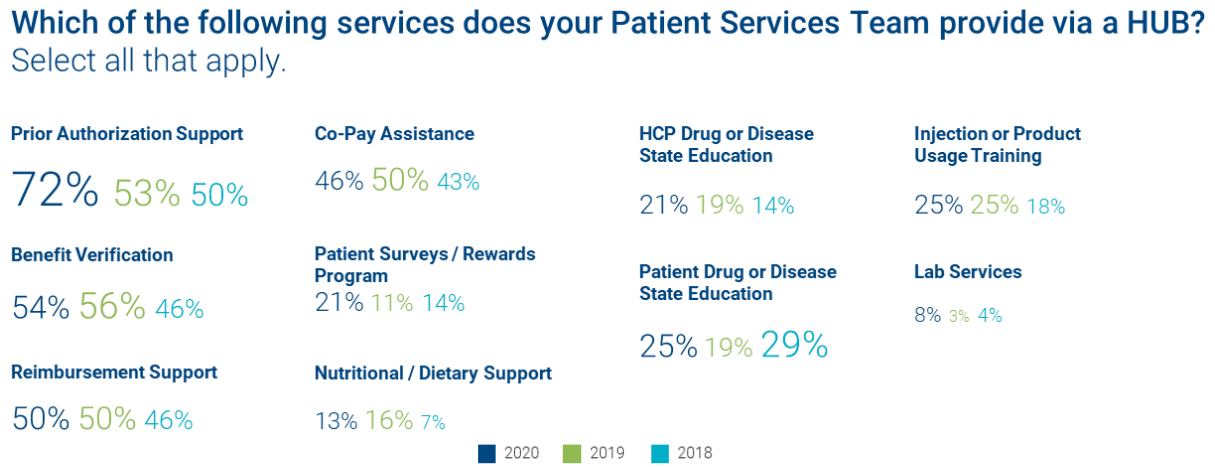


FIGURE 9: *Spotlight on Patient Assistance Services Provided via HUB Vendors, 2018-2020*

companies must rely on their compliance professionals to ensure their organizations are taking appropriate action to plan, assess, and respond to a heightened enforcement focus on PSPs in 2021 and beyond.

References

1 *Helio Health Group is a management consulting and small data engineering-centric firm that utilizes its broad portfolio of industry experience and its automated Compliance monitoring solution HelioPDR to provide strategic and operational compliance insights to stakeholders across the Commercial, Medical, and Patient Services areas of Life Sciences organizations.*

2 *See M. Bak and J. Poulin, Helio Patient Services Compliance Survey, 5.11 Policy & Medicine Compliance Update 1 (2019); M. Bak, et al., Patient Services Compliance Survey, 5.2. Policy & Medicine Compliance Update 1 (2019).*

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8 *Id.*

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13 *Remarks of Stefanie Doebler at the Pharmaceutical Compliance Forum, Virtual 21st Annual Pharmaceutical and Medical Device Ethics & Compliance Congress. Mini Summit XX: Patient Services Compliance Survey (Year 4) Update, (Nov. 5, 2020).*

14 *Id.*

15 *See M. Tzavlakis, Monitoring the New Normal: Top 5 Compliance Challenges to Consider in the Changing Digital Workspace, 6.7 Policy & Medicine Compliance Update 15 (2020).*

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