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FEATURE

Helio Health Group's Fifth Annual Patient Support Services Compliance Survey

Patient Support Program Compliance Continues Evolving

By Marci Juneau and Ava Mandele[1]

Summary: 2021 caps another active year involving Patient Support and Patient Assistance Programs. This year's Helio Health Groups survey, with its refined questions, continues to provide insights to help compliance professionals balance the legitimate need for these programs with the ongoing legal and compliance risks.

2021 has been a tumultuous year for the life sciences industry and its reputation with the public. Headline-worthy litigation events and a renewed debate over prescription drug prices quickly escalated into a nation-wide television ad campaign reaching living rooms across America have occupied the news cycle.[2]

Patient Support & Patient Assistance Programs

Despite the growing skepticism about drug company motives, the pharmaceutical industry and healthcare providers ("HCPs") use Patient Support Programs ("PSPs") for a variety of reasons to help patients. For example, they are assisting patients in using their medications as appropriately prescribed. Unfortunately, in a world where approximately 50% of chronic illness patients do not take their medications as prescribed, failed medication adherence is associated with increased morbidity and death, costing an estimated $100 billion per year.[3]

Furthermore, Patient Assistance Programs ("PAPs"), a component of most PSPs, help defray the high costs of prescription drugs for patients. Therefore, PAPs continue to be viewed by some as one of the industry's best mechanisms for addressing the health equity issue, which disproportionately impacts uninsured and under-insured patients who are most sensitive to drug costs.[4]

However, as compliance professionals understand well, even the best-intentioned programs can be co-opted for nefarious reasons. Consequently, PSPs and PAPs remain the focus of multi-million-dollar enforcement actions from their alleged misuse and the ensuing reputational damage caused by public distrust.

However, in 2021, 3 out of every 10 Americans reported failing to take medicine as prescribed in the last 12 months because of high drug prices.[5] Therefore, dialing back or disbanding PSPs and PAPs because of continued government scrutiny hardly seems like the right path forward. Instead, we believe the better approach is for drug and device companies to leverage their compliance teams to balance the risks of potential misuse against negatively impacting patients.

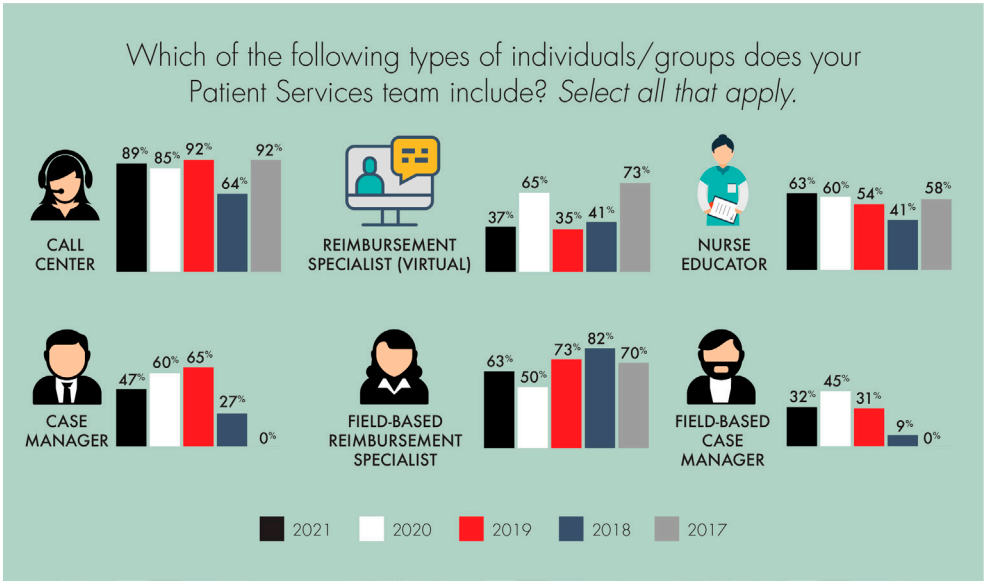
About the Helio Health Survey

Since 2017, Helio Health Group's Annual Patient Support Services Compliance Survey has drawn upon insights from Compliance executives across the industry to track key benchmarks and best practices for addressing the prevailing risks associated with providing any variety of in-house or outsourced PSP services (Figure 1). We refreshed this year's survey in keeping with emerging trends. It also provides a deeper look into some of the operational nuances and internal controls deployed in risk areas, such as patient privacy and funding provided to Independent Charity Patient Assistance Programs ("ICPAPs"), as well as using PAPs to help Medicare Part D beneficiaries.

PSP Enforcement in 2021

Although perhaps more intense, the 2021 regulatory and enforcement landscape remains essentially unchanged from Helio's December 2020 survey. However, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS-OIG") issued two new Advisory Opinions in 2021. In addition, many of the same lawsuits and regulatory probes from last year remain ongoing, but, in some cases, with new players involved.

FIGURE 1: *Summary of Patient Support Services Team Structure, 2017-2021*



New HHS-OIG Advisory Opinions

These new Advisory Opinions addressed providing benefits, including travel, lodging, meals, and free drug product to patients needing specialized therapies.[6] They also updated the HHS-OIG's interpretation of specific PSP elements in the context of the Anti-Kickback Statute ("AKS") and the "seeding issue."[7] The HHS-OIG defines "seeding" as providing inducements for future referrals of a drug when it would be payable by a federal health care program.[8] Typically, the potential seeding issue stems from free or discounted drug programs.[9]

However, the HHS-OIG concluded that because the programs involved specialized, one-time treatments "seeding" was not a concern. Therefore, based on the narrow scope of the programs involved, these Advisory Opinions provide little guidance for programs involving commonly prescribed therapies, thereby leaving most industry PSPs in the gray zone.[10]

Enforcement

New Payers Emerge in Regeneron's Civil Litigation

In June 2020, the U.S. Department of Justice ("DOJ") filed suit against Regeneron Pharmaceuticals, Inc. for "funnel[ing] tens of millions of dollars in kickbacks through a third-party foundation," the Chronic Disease Fund d/b/a Good Days ("CDF"), but only after confirming that the funds would be used for Regeneron's product and not competitive products.[11]

In July 2021, Humana, one of the largest U.S. health insurers, filed a separate civil suit against Regeneron that parallels the government's accusations.[12] Humana seeks to recover damages it allegedly incurred for paying Eylea's inflated price. Humana alleges the kickbacks "eliminated any sensitivity by patients or their physicians to the true price of Eylea, and at the same time, allowed Regeneron to price Eylea well-above what the market would otherwise support."[13]

With private health insurers responsible for roughly one-third of the $3.8 trillion spent on U.S. healthcare, other insurers are likely watching this case closely.[14] As a result, life science legal and compliance professionals also need to monitor the suit lest they need to defend against government enforcement actions and private civil actions.

Incyte's Run-In with the Eastern District of Pennsylvania

In May 2021, the DOJ announced a settlement for $12.6 million with Incyte to resolve federal False Claims Act ("FCA") allegations.[15] The Justice Department alleged that from November 2011 to December 2014, Incyte used a charitable foundation as a conduit to pay the copays of federal healthcare beneficiaries.[16]

The case was initially filed by Justin Dillon, the U.S. Region Compliance and Ethics Officer for Incyte, from January 2015 to October 2018.[17] Before joining Incyte, Dillion served in several compliance roles with Merck, GlaxoSmithKline, and Ipsen Biopharmaceuticals.[18]

According to the complaint, Incyte allegedly used a patient-assistance charity, CDF, to make the copay payments.[19] Established in November 2011, the fund was intended to assist myelofibrosis ("MF") patients. However, Incyte was the sole donor to the fund, and the company's support was earmarked only for MF patients taking Jakafi.[20]

While the issues surrounding the pharmaceutical's use of independent copay foundations are not new, the Incyte case suggests a broadening of the scope and collaborations by government enforcers. First, this Eastern District of Pennsylvania case is the first, to our knowledge, occurring outside the District of Massachusetts. Second, the settlement involved a collaborative effort between "the [DOJ's] Civil Division's Commercial Litigation Branch, Fraud Section, and the U.S. Attorney's Office for the Eastern District of Pennsylvania, with assistance from the U.S. Department of Health and Human Services Office of Inspector General, the Department of Defense Office of Inspector General, and the Office of Personnel Management Office of the Inspector General."[21] Thus, according to the Justice Department, the "investigation and resolution of this matter illustrates the government's emphasis on combating health care fraud."[22]

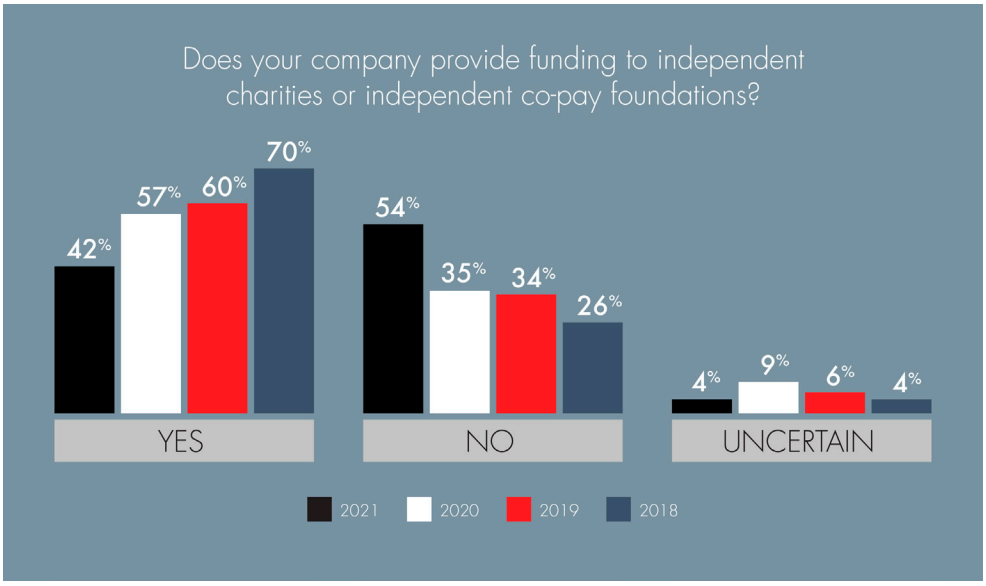
Pfizer's Copay Assistance Program Struggles Continue

Recently, Pfizer suffered a setback in its efforts to provide copay assistance programs to Medicare Part D patients prescribed one or both of its new heart failure medications, Vyndaqel and Vyndamax.[23] The U.S. District Court for the Southern District of New York dismissed Pfizer's 2020 lawsuit against HHS seeking a declaratory judgment "setting aside OIG's determination that the Proposed Copay Assistance Programs implicate the AKS or BIS [Beneficiary Inducement Statute]."[24]

In June 2019, despite being under a five-year Corporate Integrity Agreement ("CIA") from 2018 for improperly making donations to an independent charity to cover the copay cost of Medicare beneficiaries, Pfizer requested a favorable advisory opinion from the HHS-OIG on its "Direct Copay Assistance" and "Indirect Charity" programs.[25]

However, the HHS-OIG rejected the request, in part, "because the same or substantially the same course of action is under investigation or has been the subject of an enforcement proceeding involving HHS or another governmental agency," thus setting the stage for Pfizer's suit.[26] The Pfizer programs also conflicted with the HHS-OIG's Special Advisory Bulletins issued in 2005 and 2014.[27]

FIGURE 2: *Prevalence of ICPAP Funding, 2018-2021*



At the end of September, Judge Mary Kay Vyskocil dismissed Pfizer's challenge despite the company's extensive efforts to demonstrate that the programs did not violate the AKS nor carry any intent to defraud government healthcare programs.[28] Instead, focusing on the plain meaning of the AKS, the Court ruled that the AKS prohibits "knowingly and willfully" offering remuneration to induce a government purchase.[29] Thus, the statute "simply does not refer to a 'corrupt' mental state as an element of the offense," and

therefore, "the text of the AKS [is] unambiguous."[30] Consequently, Judge Vyskocil focused her decision on the assertation that Pfizer intended these programs to increase sales to Medicare beneficiaries.[31]

Furthermore, in applying the Administrative Procedure Act ("APA"), the Court recognized that it owed no deference to the HHS-OIG's Special Advisory Bulletins, its Advisory Opinion, or other informal guidance provided to Pfizer relative to copay assistance programs.[32] However, the Court also concluded the regulatory guidance provided about the Direct Copay Assistance Program was not contrary to law, indicating that the government got it right.[33]

Survey Results from Refined Key Benchmarks

Turning to the 2021 Survey results, we detected a shift in how companies are approaching PSPs and PAPs. We attribute this shift to the government's continuing scrutiny and enforcement in this space and our refining key benchmarks as previously discussed.

Heightened Scrutiny Leads to Reduced ICPAP Funding & Increased Controls

Despite the known compliance risks associated with providing funding to independent charities and copay foundations, a majority of compliance executives surveyed from 2017 through 2020 have consistently responded that their companies continued to provide funds to these organizations. However, that is changing.

Funding Reductions

In 2021, just 41.7% of respondents reported that they provided funds to these types of organizations, representing a year-over-year ("YoY") decrease of 26.3%. It also marks the first time in the survey's history that less than half of the companies surveyed reported contributing to independent charities or copay foundations (Figure 2).

The heightened scrutiny of ICPAP activities seen in this year's litigation and enforcement activity may be the reason for the decline and indicate that some companies are reconsidering whether the benefits of providing funds to independent copay assistance foundations outweigh the legal and compliance risks.

Although these decisions are both understandable and rational, it is unfortunate that those likely to be most impacted by these decisions are patients, especially those who cannot afford to lose their aid from the potential cutbacks.

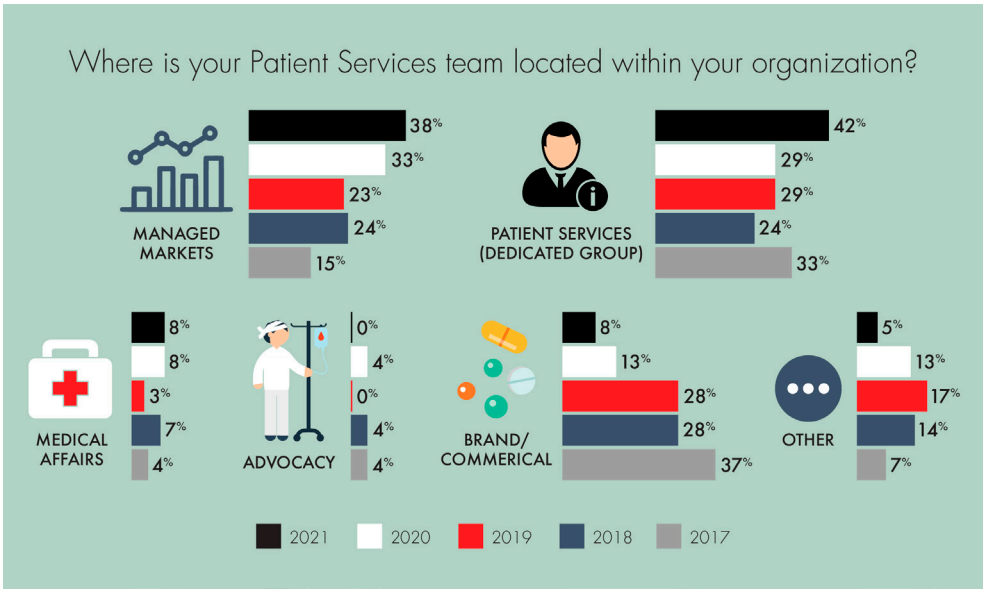
Increased Controls

For companies continuing to maintain their relationships with independent charities and copay foundations, just over two-thirds of the respondents (68.8%) indicated they use a dedicated Grants Review Committee for the final review and approval of company contributions to ICPAPs. This year's response is a 21.6% increase YoY.

This uptick in additional governance also corresponded to an increase in oversight, with respondents reporting that either the legal (56.3%) or compliance (43.8%) department served as final gatekeepers in their ICPAP contributions process. These governance and oversight changes may signal that companies are implementing HHS-OIG requirements outlined in recent ICPAP funding settlements and CIAs.

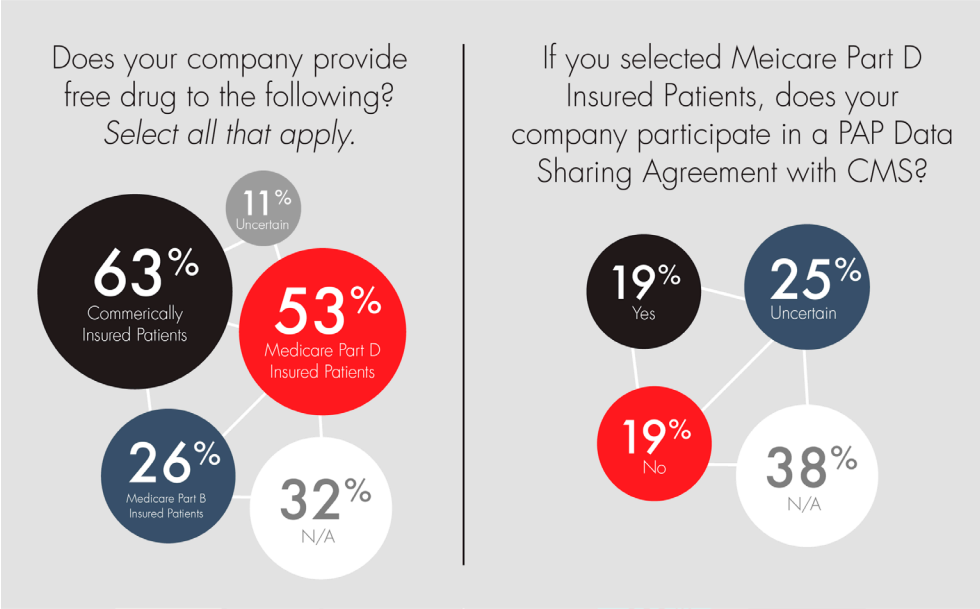
In addition to these governance and oversight enhancements, a shrinking minority of respondents reported

FIGURE 3: *Summary of Patient Support Services Organization & Oversight, 2017-2021*



that their organizations still had a brand or commercial representative involved with the ICPAP funding approval process. The decrease indicates that life science companies continue to separate Patient Support Services and ICPAP funding requests from commercial interference or influence. Further supporting the trend is that 41.7% of 2021 respondents stated that their organizations had a dedicated Patient Support Services function, up from 29.1% just a year ago. It also was the highest percentage in the survey's five-year history (Figure 3).

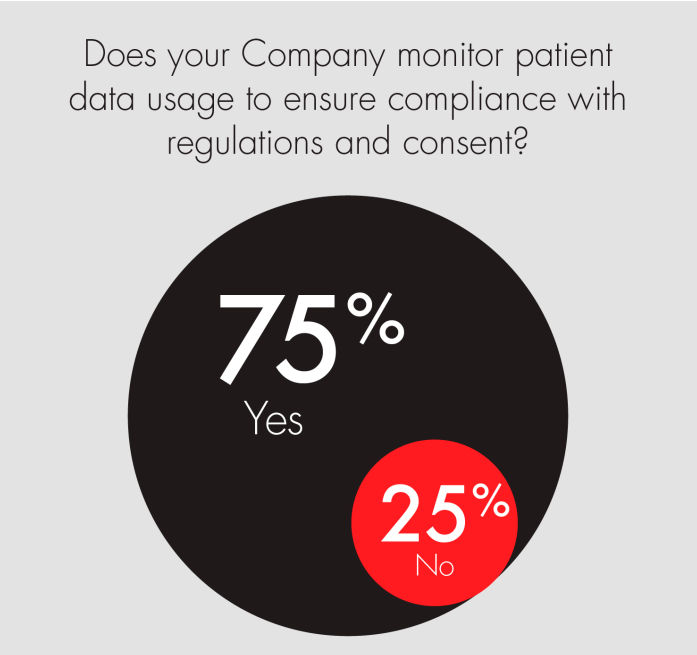
FIGURE 4: *Provision of PAP Benefit Programs to Medicare Part D Patients, 2021*



Risk Tolerance for Including Medicare Part D Beneficiaries in PAPs is Increasing

Somewhat paradoxically, this year's survey results highlighted a significant increase in respondents reporting that they provide free drug programs to Medicare Part D patients. More than half of the respondents (52.6%) reported that their companies supported enrollment of Part D beneficiaries, representing a 92.9% YoY increase (Figure 4). However, manufacturers in this group must take special precautions to avoid triggering the AKS or BIS. Thus, if any discounted or free drugs are provided to Part D beneficiaries, the mechanism must not impact the patient's true out-of-pocket ("TrOOP") costs for purposes of health plan coverage determinations.[34]

FIGURE 5: *Monitoring Patient Data Usage, 2021*



Since the survey first started, we have noticed a steady increase in companies using PAPs to support Part D beneficiaries. Therefore, this year, we inquired whether those companies do so under an established Patient Assistance Program Data Sharing Agreement ("PAP DSA") with the Centers for Medicare and Medicaid Services ("CMS"). In 2006, CMS advised that upfront data sharing exchanges, specifically PAP DSAs, are the "most effective – and ultimately, for the beneficiary, the safest – way for PAPs to operate outside the Part D benefit."[35]

However, despite CMS's guidance, just 19% (or one-third of those not indicating N/A) of respondents with PAPs serving Part D beneficiaries reported having a PAP DSA in place with CMS. Thus, it appears that most respondents in this area are missing an essential governance mechanism that could be considered a "low-hanging fruit" when the government evaluates a company's continuous program improvement efforts.[36]

Shifting to More Advanced Monitoring Technologies

In this year's survey, we also observed an increase in PSP patient data monitoring, with three-quarters of survey respondents revealing that they monitor patient data usage to ensure compliance with regulations. Thus, the percentage of companies that reported no defined patient data monitoring program decreased from 50.0% in 2020 to 22.2% in 2021. With these changes, 27.8% of respondents in 2021 responded that their company had implemented a defined process with system automation for patient data monitoring using more advanced monitoring tools.

The increase in PSP patient data compliance monitoring is not surprising given the DOJ's increasing expectations for in-house compliance functions. For example, in June 2020, during the COVID-19 pandemic, the Justice Department updated its 2019 guidelines for government prosecutors to use when evaluating the effectiveness of corporate compliance programs.[37] The updated guidance stressed the expectation that compliance functions, in their role as organizational data stewards, must have "sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions."[38]

In the 18 months since the update, it appears that many compliance functions have made improving the ability to utilize the ever-growing pool of available data into an effective monitoring approach a strategic imperative.

Additional Focus Areas Highlighted by the Survey

Beyond the shifts in company approaches to PSPs and PAPs, the 2021 survey also illuminated several essential areas for additional compliance focus.

Methods for Determining Patient Financial Eligibility

Consistent with the Justice Department's renewed emphasis on proper data use by compliance, a vital area for compliance functions to address is how the company determines a patient's program eligibility. Therefore, this year's survey included a new question probing companies' different methods to standardize and document these crucial benefit determinations.

The survey results demonstrated that PAPs indeed employ a diverse set of income and benefit verification methods. These methods range from using third-party credit verification services to simply obtaining the patient or caregiver's attestation to their financial status (Figure 6). From a compliance perspective, the decisions over which income or benefit verification methods determine patient eligibility have the most impact in the resulting audit trails created.

FIGURE 6: *Determining Patient Eligibility for PAP Assistance, 2021*

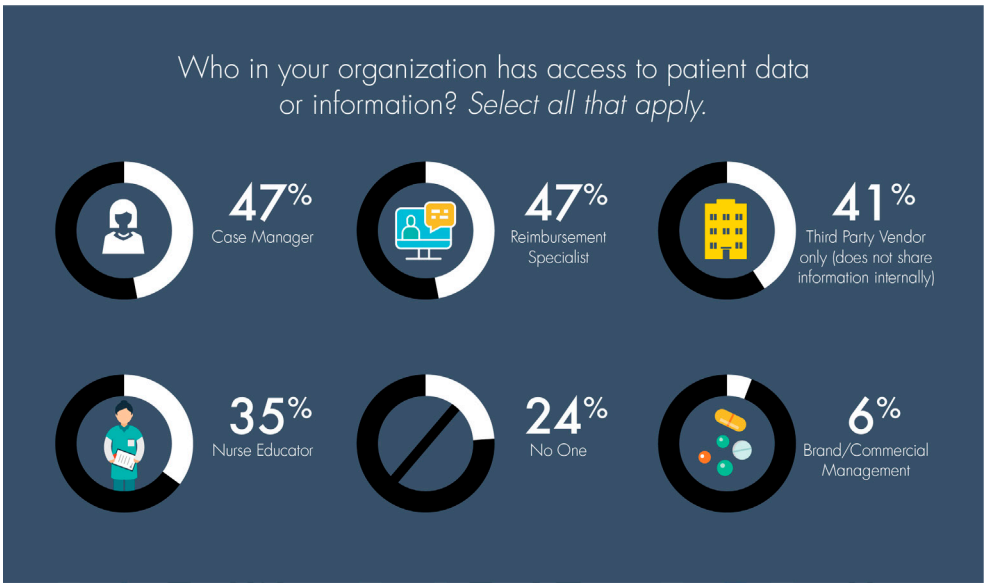
Therefore, when imputing on PSP operational considerations, such as program structure and enrollment, compliance functions must look to the future to carefully avoid overlooking considerations that could materially impact the company's ability to monitor or audit PSP Hub records for policy compliance effectively. Furthermore, considering the potential high-dollar impact extending across the program's universe of patients, payers, and providers involved in the PSP, maintaining a robust and consistent audit trail, including verification of patient financial status, is paramount.

Patient Data Governance & Stewardship

The protection of patient data and privacy remains a primary concern in industry compliance discussions. However, somewhat surprisingly, our 2021 survey noted almost an 18-point decrease in respondents reporting that their companies employed a data privacy management program (68.4% versus 85.7% in 2020).

At the same time, we noted an increase in the respondents (from 9.5% in 2020 to 10.5% in 2021), noting that they were "uncertain" whether their organization had a privacy program in place. This increase highlights the increasing difficulty of staying current with emerging global data privacy regulations. At the same time, we observed an upswing in respondents reporting expanded access to patient data amongst internal team members in different functional areas (Figure 7).

FIGURE 7: *Data Governance and Stewardship for of Patient Data, 2021*



Respondents also noted that the top three types of sensitive case-level information shared internally included:

- De-identified patient information (68.8%),
- Drug shipment information (37.5%), and
- Insurance information (37.5%).

We also saw a notable decrease (from 52.4% in 2020 to just 41.2% in 2021) in companies controlling access to sensitive patient data by delegating the data stewardship responsibility to their third-party vendors (i.e., PSP Hubs).

Nurse Educators

Since 2018, our survey has seen increasing concerns over the use of nurse educators and their interactions with healthcare professionals ("HCPs").[39] In 2021, the use of nurse educators secured the top spot of compliance concerns.

41.2% of 2021 respondents ranked this area as the top concern with PSP compliance. This increased concern mirrors the growing prevalence of nurse educator roles on PSP teams, which rose to 63.2% in 2021.

Respondents reported that the most common internal controls employed to reduce the compliance risks in this area were:

- Nurse educator interaction guides (57.9%),
- Call scripts (36.8%), and
- Frequently Asked Questions ("FAQs") documents (36.8%) (Figure 8).

Perhaps most notable was the fact that we observed a more than a three-fold increase (from 4.7% in 2020 to 15.8% this year) in companies reporting that they record nurse educator calls.

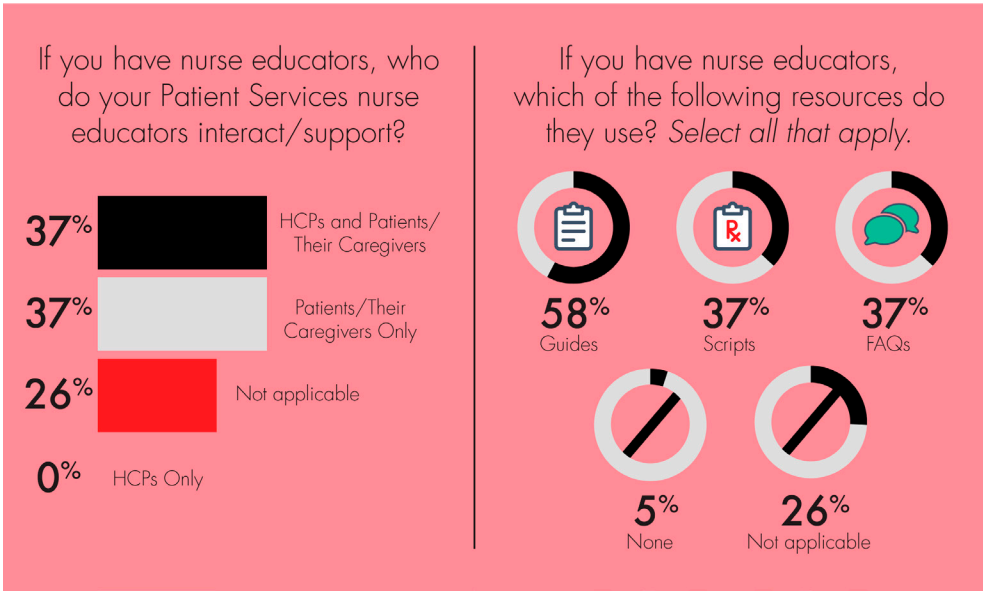
Conclusion

Based on the survey data collected, it is apparent that the life sciences industry continues to develop innovative therapies and ways of reaching underserved patient populations. However, just like compliance programs, it is unlikely that companies or regulators can ever establish a "one-size-fits-all" solution or even a set of explicit and uniform standards apply given the diverse variables and stakeholders involved in PSP and PAP programs.

Nevertheless, our current survey demonstrates that compliance professionals are aware of the risks posed by these programs. They are also developing flexible approaches to balance the need to break down barriers

to access for patients while mitigating the risks of misuse and abuse to the greatest extent possible. Finally, compliance professionals play a crucial role in maintaining the appropriate balance with the continuing government scrutiny.

FIGURE 8: *Summary of Nurse Educator Activities & Guardrails, 2021*



References

1 *Ms. Juneau is a Partner and Ms. Mandele is an Analyst with Helio Health Group LLC. Helio Health Group is a management consulting firm that utilizes its broad portfolio of industry experience and its automated Compliance monitoring solution HelioPDR to provide strategic and operational compliance services to Life Sciences organizations.*

2 *See Peter Sullivan, "PhRMA Launches 7-figure Ad Campaign Against Democrats' Drug Pricing Measures," The Hill (Sept. 15, 2021), available at: https://thehill.com/policy/healthcare/572397-phrma-launches-7-figure-ad-campaign-against-democrats-drug-pricing-measures; see also Gwendolyn Ball, "Prevarication Versus Action – Efforts to Control Prescription Drug Prices Shift to the States," 7.9 Policy & Medicine Compliance Update 12 (2021); Gwendolyn Ball, "Turning Up the Heat on Prescription Drug Prices – Part 1: AbbVie Goes to Congress," 7.7 Policy & Medicine Compliance Update 1 (2021).*

3 *See Marie Brown and Jennifer Bussell, "Medication Adherence: WHO Cares?," 86(4) Mayo Clin .Proc., 304-314 (2011), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/.*

4 *See, e.g., Hauser Transplant Health Benefits, "Do Patient Assistance Programs Work?," https://hauserthb.com/employers/do-patient-assistance-programs-work/ (last accessed Nov. 29, 2021).*

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7 *See M. Juneau and B. Schein, "Operating in the Gray Zone: Patient Support Programs and the Guardrails to Mitigate Risk," 7.6 Policy and Medicine Compliance Update 1, 2-3 (2021).*

8 *See U.S. Dep't of Health and Human Serv., Off. of Inspector Gen, "OIG Advisory Opinion 15-11," (Aug. 5, 2015), available at: https://www.oig.hhs.gov/compliance/advisory-opinions/index.asp.*

9 *See M. Juneau, supra n. 7 at 2.*

10 *Id. at 3.*

11 *See U.S. Attorney's Off., D. Mass., Press Release, "United States Files Suit Against Drug Manufacturer Regeneron for Paying Kickbacks Through Copay Foundation" (Jun. 24, 2020), https://www.justice.gov/usao-ma/pr/united-states-files-suit-against-drug-manufacturer-regeneron-paying-kickbacks-through-co; Complaint, U.S. v. Regeneron Pharmaceuticals, Inc., Civ. No. 20-11217 (D. Mass. Jun. 24, 2020); see also Craig Bleifer, "Helping Patients or The Bottom Line? – The Regeneron Copay Foundation Case," 6.9 Policy & Medicine Compliance Update, 5 (2020).*

12 *See Paige Minemyer, "Humana Sues Regeneron, claiming drugmaker overpriced its popular drug Eylea," Fierce Healthcare (Jul. 28, 2021), available at: https://www.fiercehealthcare.com/payer/humana-files-suit-against-regeneron-claiming-drugmaker-overpriced-its-popular-drug-eylea.*

13 *See id.*

14 *See Centers for Medicare and Medicaid Services, National Health Expenditure Data: Historical (Dec. 16, 2020), available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.*

15 *See U.S. Dep't of Justice, Press Release, " Incyte Corporation to Pay $12.6 Million to Resolve False Claims Act Allegations for Paying Kickbacks," (May 4, 2021) (hereafter "DOJ Press Release"), available at: https://www.justice.gov/opa/pr/incyte-corporation-pay-126-million-resolve-false-claims-act-allegations-paying-kickbacks; see also Robert Wilkey, "Incyte into a Qui Tam Case – Another Compliance Officer Blows the Whistle," 7.6 Policy & Medicine Compliance Update 22 (2021).*

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17 *See Justin Dillion, https://www.linkedin.com/in/justindillon/ (last accessed May 29, 2021).*

18 *See id.*

19 *See Nate Raymond, "Incyte to pay $12.6 million to resolve drug charity kickback claims," Reuters, (May 4, 2021), available at: https://www.reuters.com/business/legal/incyte-pay-126-million-resolve-drug-charity-kickback-claims-2021-05-04/.*

20 *See U.S. ex rel. Dillon v. Incyte Corp., No. 2:18 -cv-2642 (E.D. Pa. 2021), https://www.courtlistener.com/docket/13464786/united-states-of-america-v-incyte-corporation/; see also Mario Cattabiani, "Ross Feller Casey Whistleblower Case Leads To $12.6 Million Settlement with Pharmaceutical Company," (May 5, 2021), available at: https://www.rossfellercasey.com/news/ross-feller-casey-whistleblower-case-leads-to-12.6-million-settlement-with-pharmaceutical-company/.*

21 *See DOJ Press Release, supra n. 15.*

22 *Id.*

23 *See Stuart Silverman, "District Court Denies Declaratory Judgement and Other Relief In Suit Challenging the Application of the Anti-Kickback Statute and the Beneficiary Inducement Statute," XI Nat'l L. Rev., No. 278 (Oct. 5, 2021), available at: https://www.natlawreview.com/article/district-court-denies-declaratory-judgment-and-other-relief-suit-challenging; Opinion and Order Granting Defendant's Motion to Dismiss and for Summary Judgment and Denying Plaintiff's Motion for Summary Judgement, Pfizer Inc. v. U.S. Dept' of Health and Human Serv., et. al., 1:20-cv-4920 (MKV) (S.D. N.Y. Sept. 30, 2021).*

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25 *See Complaint, supra n. 24 at 33-34, ¶¶ 103-105.*

26 *See id.*

27 *See U.S. Dep't of Health and Human Serv., Off. of Inspector Gen, "OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees," 70 Fed. Reg. 70,623-70,628 (Nov. 22, 2005), available at: https://www.federalregister.gov/documents/2005/11/22/05-23038/publication-of-oig-special-advisory-bulletin-on-patient-assistance-programs-for-medicare-part-d; "OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120-31,124 (May 30,2014), available at: https://www.federalregister.gov/documents/2014/05/30/2014-11769/supplemental-special-advisory-bulletin-independent-charity-patient-assistance-programs.*

28 *See S. Silverman, supra n. 23.*

29 *Id.*

30 *Id.*

31 *See id.*

32 *See id.*

33 *See Opinion and Order, supra n. 23 at 30.*

34 *See OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, supra n. 27.*

35 *See Memorandum from Cynthia Tudor, Director, Medicare Drug Benefit Group, Centers for Medicare and Medicaid Services, Center for Beneficiary Choices to All Part D Sponsors, "HPMS Q&A – Patient Assistance Programs," 3 (Oct. 4, 2006), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/MemoPAPsOutsidePartDBenefit_100406.pdf.*

36 *Id. at 7.*

37 *See U.S. Dep't of Justice, Criminal Division, Evaluation of Corporate Compliance Programs (updated June 2020), available at: https://www.justice.gov/criminal-fraud/page/file/937501/download; see also Kirt Kraeuter, "Proving Effectiveness Remains the Compliance 'Holy Grail' – The DOJ Revises Its Evaluation Guidance Again," 6.7 Policy & Medicine Compliance Update 15 (2020).*

38 *See DOJ Evaluation of Corporate Compliance Programs, supra n. 41 at 12.*

39 *See M. Tzavlakis, "Helio's 4th Annual Patient Services Compliance Survey Patient Services Program Compliance Continues Evolving in 2020," 6.12 Policy & Medicine Compliance Update 1, 1 (2020); see also Nicodemo Fiorentino, "'White Coat' Marketing Gone Awry," 3.6 Life Science Compliance Update 1 (2017).*

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