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FEATURE

The Sixth Annual Patient Services Compliance Survey

The Journey Continued in 2022

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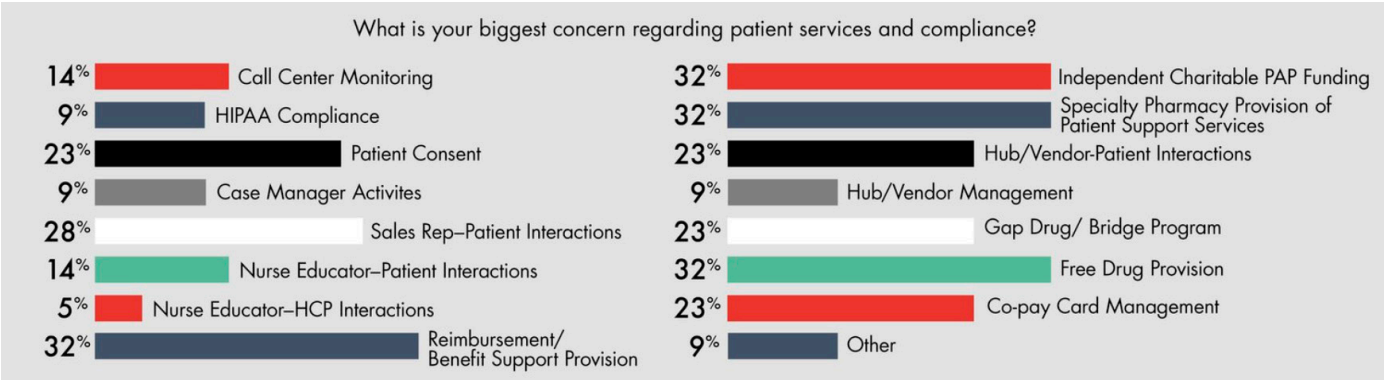
Summary: The landscape of Patient Support Services and Patient Assistance Programs continues to evolve as 2022 marks the 6th year of Helio Health Group's annual Patient Services Compliance survey that captures these changing trends. Results of the survey show that intensified prosecutorial scrutiny in this area has brought improvements to the organization of Patient Support Programs while also increasing the uncertainty and legal risks associated with critical functions.

Comprehensive access to effective medicines is an essential cornerstone of the American healthcare system. However, as pharmaceutical costs continue to rise, a growing number of patients struggle to afford essential medications in the absence of universal health insurance (e.g., Medicare for All). Therefore, Patient Assistance Programs ("PAPs") are recognized as an essential resource for those who may not otherwise be able to afford their prescriptions. Advocates argue that by cutting patients off from this support, many beneficiaries with chronic conditions would be unable to pay for medically necessary prescriptions.[2] Further-more, they contend that limiting these patients' access to their prescriptions can inversely increase the need for hospitalization and other high-cost medical interventions.[3]

PAP critics, including government prosecutors, argue that various programs supported by the pharmaceutical industry, such as copayment cards, result in higher prescription drug prices. Thus, the already heightened focus on Patient Support Services continued to grow throughout 2022. Consequently, to balance the benefits and risks associated with PAPs, many life sciences companies are taking steps to reduce their compliance risks. These steps include separating Patient Services Programs from commercial functions and limiting, or even ending, independent charity contributions altogether.

Helio Health Group's 6th Annual Patient Services Compliance Survey highlights that in the face of the continuing enforcement spotlight on PAPs, the compliance journey continues to address the myriad of compliance issues associated with Patient Support Services. It also emphasizes the critical need for life science companies to stay up to date on continually changing market realities and the enforcement environment.



Enforcement in 2022

New HHS-OIG Advisory Opinions

In 2022, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") issued two new Advisory Opinions covering PAPs. These Advisory Opinions addressed two different scenarios in which companies aimed to subsidize costs for Medicare Part D patients. The opinions also reached differing conclusions, highlighting the complexity of PAP requirements.

In March, the HHS-OIG responded to a requestor inquiring about subsidizing certain Medicare cost-sharing obligations for Medicare patients enrolled in clinical trials.[4] After an extensive review of the facts, the HHS-OIG determined that the arrangement would not trigger sanctions.

Under the clinical trial protocol, Medicare can cover certain items and services (e.g., the initial appointment, the treatment appointment, six follow-up visits in the following year and a final 2-year follow-up) for Medicare beneficiaries enrolled in the study. However, Medicare only covers a portion of those costs, leaving the beneficiary to cover the remainder. According to the requestor, the uncovered costs could amount to $1,300 per beneficiary, thereby limiting study enrollment by making participation cost prohibitive. The requestor proposed to pay the beneficiary's out-of-pocket costs directly to the institution to offset this burden.

The HHS-OIG noted that the proposed arrangement constitutes potential federal Anti-Kickback Statute ("AKS") and Beneficiary Inducement Civil Monetary Penalties ("CMPs") violations.[5] However, the HHS-OIG believed that the arrangement was low risk because:

1. The clinical trial was designed to be for a single-course therapy and, therefore, was not a violative seeding program; and
2. The institutions conducting the clinical trial would not financially benefit from the covered items and services.

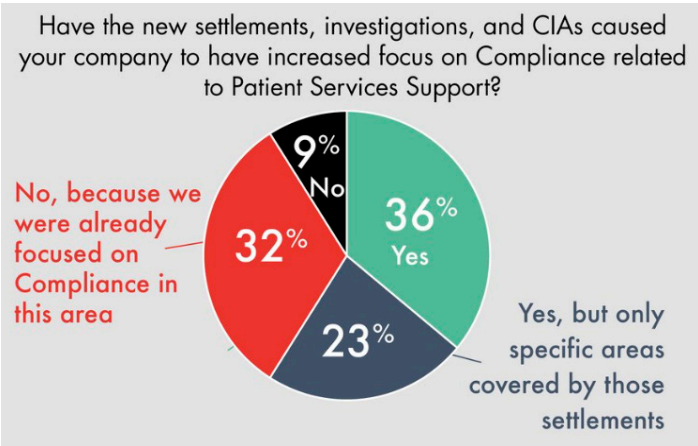
Despite its determination that sanctions were not warranted, the HHS-OIG advised the requestor to implement various guardrails, such as not advertising the availability of the cost-sharing subsidies.

In September, the HHS-OIG issued its second PAP-related advisory opinion.[6] In this situation, the requestor proposed providing cost-sharing subsidies to Medicare beneficiaries for oncology drugs. The requestor also proposed funding certain beneficiaries' health insurance premiums to promote health equity in clinical trials and cover the requestor's operating costs.

According to the requestor, various studies have demonstrated that high out-of-pocket costs for prescription drugs result in patient behaviors that negatively impact health care outcomes. For example, patients delay treatment after diagnosis, delay prescription refills or discontinue using prescribed pharmaceuticals. Thus, the requestor argued that "existing patient assistance models involving cost-sharing subsidies and OIG guidance regarding these models [are] inadequate to facilitate access to prescription drugs."[7]

The HHS-OIG disagreed, noting that the proposed arrangement violated the AKS.[8] Furthermore, unlike the earlier Advisory Opinion, the HHS-OIG concluded that the program was not low risk and, in fact, could increase costs by removing the cost-sharing safeguard that helps control manufacturer pricing. Although the program would lower beneficiary out-of-pocket costs, the government concluded that it could inappropriately steer physician prescribing behavior by incentivizing them to prescribe drugs covered by the program instead of prescribing higher-cost and potentially more effective drugs.[9]

Although these two Advisory Opinions reached opposite conclusions based on differing fact patterns, together, they reflect the complex environment that pharmaceutical and medical device companies must navigate when developing PAPs. Also, they highlight the need for life



sciences companies to have stringent and detailed controls around patient support and patient assistance programs. Finally, while HHS-OIG's opinions are limited to these specific scenarios, they emphasize the "devil is in the details" when setting up guardrails or drawing broad conclusions.

More Commercial Insurance Companies File Suit Against Regeneron

In June 2020, Regeneron Pharmaceuticals, Inc. joined the long list of other pharmaceutical manufacturers whose PAPs came under fire from government prosecutors. According to the U.S. Department of Justice ("DOJ"), Regeneron allegedly "funneled tens of millions of dollars in kickbacks through a third-party foundation" that would only be used for Regeneron products.[10] In July 2021, Humana filed a separate but parallel case against Regeneron. Humana claimed that the kickbacks caused patients and their providers to be desensitized to the true price of Eylea, thus allowing Regeneron to increase the price of Eylea to unjustifiable levels.[11] Later in December 2021, two Massachusetts Blue Cross and Blue Shield entities also sued Regeneron, claiming that the company used an illegal kickback scheme to boost the sales of Eylea.[12]

In 2022, two more commercial insurance companies, Horizon Healthcare Services and Medical Mutual of Ohio filed nearly identical actions against Regeneron.[13]

These four actions highlight that commercial insurers are paying close attention to government enforcement efforts and will not hesitate to file suits to recover the costs of inappropriate price increases. Thus, commercial insurer cases represent an additional risk for companies engaging in patient support services.

Pfizer Heads to the Supreme Court

Although Pfizer previously settled allegations that its use of an independent copay foundation violated the Anti-Kickback Statute ("AKS") and the Beneficiary Inducement Statute ("BIS") in 2018, the company has continued challenging the HHS-OIG's assertations that copay support for federal beneficiaries is illegal.[14] At issue in the case is Pfizer's attempts to provide copay assistance to Medicare Part D patients for its new high-cost heart failure drugs, Vyndaqel and Vyndamax.[15] Since the HHS initially rejected Pfizer's proposal in 2019,[16] Pfizer has suffered two court losses in its attempt to challenge HHS-OIG's opinion that its program violated the AKS and BIS.[17]

In October, Pfizer, despite being rebuffed by the lower courts, petitioned the U.S. Supreme Court to hear the case.[18] According to Pfizer, "[t]his case is about how respondents' overbroad interpretation of a criminal statute outlaws a wide swath of routine, beneficial conduct in connection with federally funded healthcare."[19] On appeal, Pfizer is supported by several industry groups, including the Pharmaceutical Research and Manufacturers of America ("PhRMA").[20] PhRMA filed an *amicus* brief contending that the Second Circuit's decision "encourages arbitrary enforcement and raises series due process concerns."[21] Thus, PhRMA supports Pfizer's position that the case constitutes an "overcriminalization" of the AKS.

While it is uncertain how the Supreme Court will react to Pfizer's arguments that HHS is attempting to over-criminalize "routine commercial interactions," HHS issued a statement in December urging the Supreme Court to reject Pfizer's petition. This case is crucial for companies providing patient support services as the breadth of the AKS remains a significant hurdle for pharmaceutical companies to overcome when implementing PAPs.

Survey Highlights Key Patient Services Trends

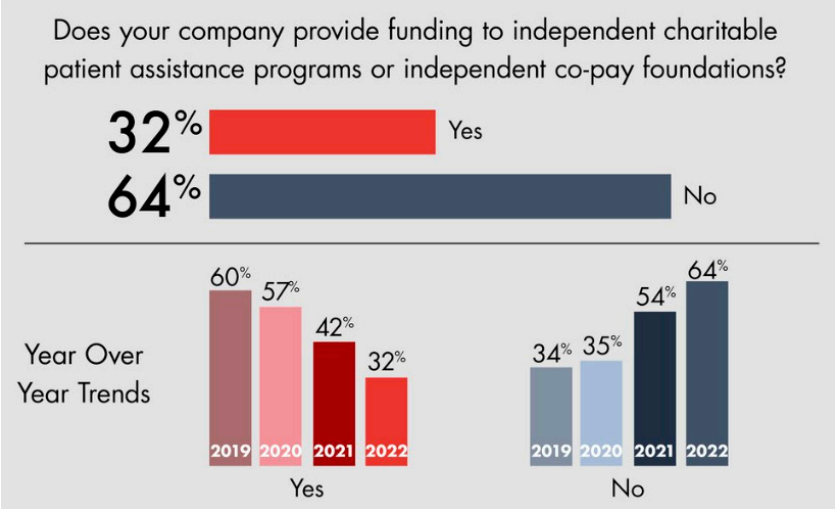
Beyond the government enforcement efforts in 2022, the current Helio Patient Services survey continues to illuminate critical issues for life sciences companies considering or delivering patient support services ("PSS"). While some of the issues are not new, others reflect the continuing governmental scrutiny of these activities.

Decommercialization

Since the first survey conducted in 2017, Helio has focused on determining the role PSS plays with life sciences companies, including its position within the organization and how it relates to other company functions. In that first survey, a plurality of respondents reported that PSS was located within the Commercial group.[22] However, in subsequent years, fewer and fewer

participants reported placing PSS within the Commercial function, and this year's survey marks the first time that no respondent (n=29) reported locating its PSS function within the commercial function.

The separation of the PSS and Commercial functions could reflect the increasing compliance risks of commercial influence over services and financial assistance dedicated to patient support. However, it does reflect ongoing efforts to separate commercial operations from other company functions (e.g., R&D) that date to 2003.[23]



Among this year's respondents, 41% reported placing the PSS function within Managed Markets, while 45% reported creating PSS as a separate dedicated function. These latest results align with the trends from previous surveys; from 2018, the placement of the PSS team within Managed Markets has increased by 70%, and the creation of a dedicated PSS group increased by 88%.

For the 2022 survey, Helio expanded the question of PSS placement. Respondents reporting that they had a dedicated PSS group were asked if the group has any reporting relationship to the Commercial function. Of those respondents with dedicated PSS groups, only 31% indicated that their PSS dedicated group is entirely outside of Commercial. This result is not surprising, given the wide variety of patient support services provided by each company. Therefore, expecting an industry-wide consensus appears unrealistic with the complexity and cross-functional nature of many PSS activities.

Regardless of placement, perhaps the most impactful change involves the oversight of PSS activities. For example, all respondents reported that their PSS received dedicated support from either the legal or compliance functions, but 64%, a clear majority, indicated they provided dedicated support from both functions. The dedication of both legal and compliance support is a 39% increase over the 2021 results.

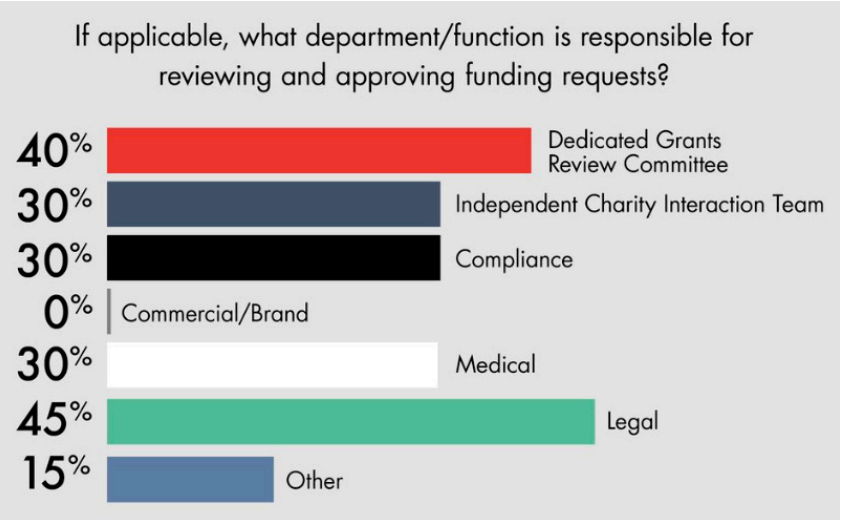
Funding Declines for Independent Charity Assistance Programs

Another key trend is the reduction of donations and funding provided by manufacturers to Independent Charity Patient Assistance Programs ("ICPAPs"). Helio identified this trend in last year's survey and continued to observe the consequences of heightened government scrutiny in this area.[24]

The 2021 results followed the three years (2017-2020) when more than ten pharmaceutical companies settled with the DOJ to resolve alleged AKS and False Claims Act ("FCA") violations related to the funding of different ICPAPs.[25] The DOJ continues to assert that ICPAP donations often are attempts by manufacturers to mask subsidized copays for only their own drugs. Doing so turns those donations into indirect kickbacks, thus violating the AKS. Moreover, the HHS-OIG continues to put strong limitations in place for the ways in which pharmaceutical companies can support ICPAPs through its interpretation of the AKS and FCA, as previously discussed.

As a result of the Justice Department's and HHS-OIG's activities, respondents have shifted their approach and reduced the support provided to these organizations. For example, only 32% of respondents confirmed that they provide funding to ICPAPs. This decline represents a 24% decrease from 2021 and more than a 47% decrease since the question was first posed in 2019. Digging further, 29% of companies that discontinued ICPAP funding did so because they determined it was too risky, while 14% cited a lack of funds as the reason.

When it comes to reviewing and approving ICPAP funding requests, none of the survey respondents indicated that the responsibility was delegated to the Commercial function. Instead, respondents identified other approval mechanisms, including a dedicated Grants Review Committee (40%) and the Legal function (45%) to review and approve ICPAP donations. The lack of commercial involvement is consistent with



respondents (32%) highlighting ICPAP donations as one of the most significant areas of concern because of prosecutorial scrutiny and industry changes generating substantial compliance uncertainty for manufacturers.

Increasing Monitoring Efforts

For companies continuing to provide patient assistance programs, these manufacturers have increased the intensity of compliance activities related to internal PAPs. For example, 59% of respondents indicated that recent settlements, investigations, and Corporate Integrity Agreements ("CIAs") had increased the focus on PSS compliance, while 32% pointed out that they already focused on compliance in this area.

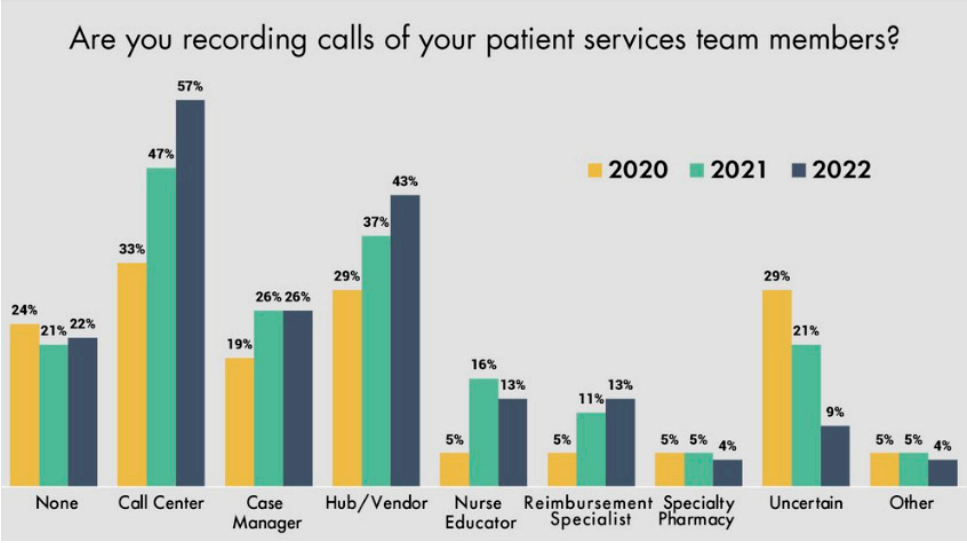
Helio's survey shows that the most significant change involves recording calls across PSS teams. Specifically, the call recordings (i.e., live monitoring) target call centers, hubs/vendors, and reimbursement managers. Moreover, companies also conduct transactional monitoring of PAP and copay card vendors using the available data captured when financial assistance is provided.

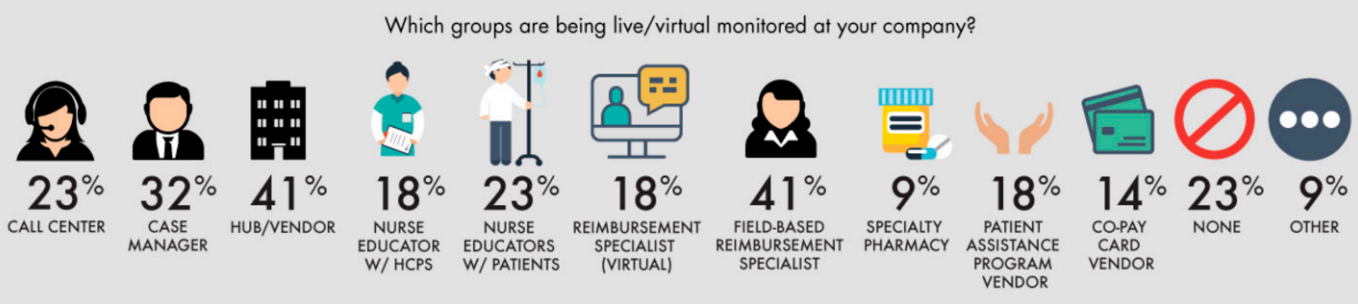
Although the survey reveals a heightened compliance focus on PSS activities, the overall number of respondents performing transactional and live monitoring remains quite low. For example, the survey asked manufacturers if they were monitoring and auditing case managers, nurse educators, and reimbursement specialists, as well as external hub vendors, PAP and copay card vendors, and specialty pharmacies. However, fewer than 50% of respondents were monitoring and auditing any given class of patient services members or external partners.

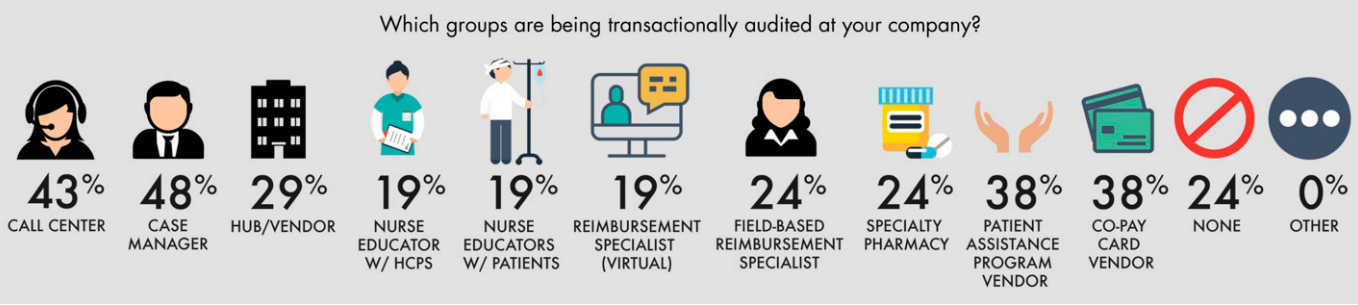
This lack of adequate monitoring practices is troubling and suggests that many companies still lack the necessary control to mitigate potential risks. For example, such low levels of monitoring in the face of the plethora of available data run counter to government expectations. They suggest that a company's compliance program is ineffective in detecting and preventing potential violations.[26]

At the recent Informa Compliance Congress for Specialty Products in September, Jolie Apicella, former Chief of the Civil Health Care Fraud Unit for the United States Attorney's Office in the Eastern District of New York, succinctly described the problem and the risks:

> Companies are not using their own technology, their own data, to even initially find the problem that seems so glaringly evident from the government's perspective. Once we have the hindsight, we can go back and think: Well, why didn't you see that your numbers jumped so high for those five months?[27]





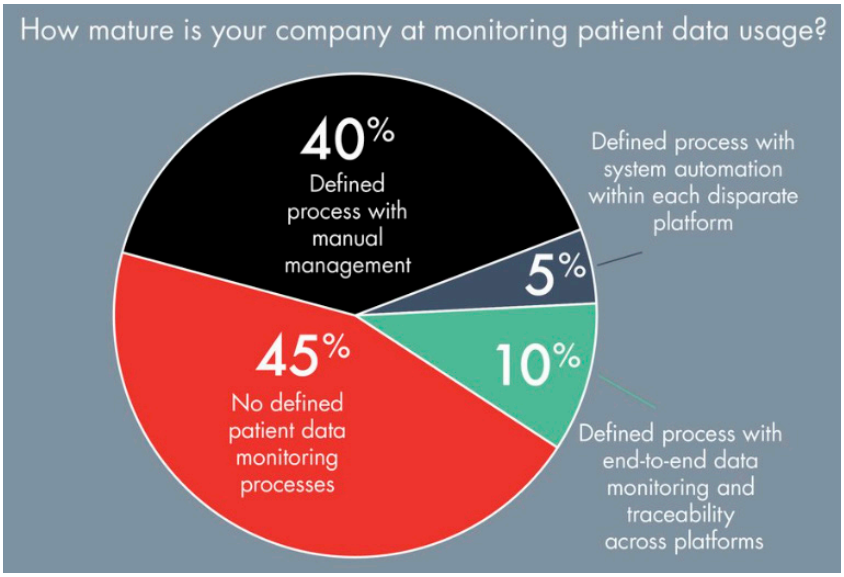


Patient Data Privacy

Concerns about patient health data are not new and can be traced back to the passage of the Health Insurance Portability and Accountability Act ("HIPAA") in 1996.[28] Since HIPAA's passage, those concerns have increased, resulting in additional international and state requirements.[29]

Unsurprisingly, the 2022 survey revealed that patient data privacy remains an area of focus for many companies. According to the survey, there was a 7% increase in the number of companies deploying data privacy programs. At the same time, the use of only de-identified patient information has risen from 69% in 2021 to 81% in 2022, and 14% of those surveyed reported that patient information is not shared between functional areas of PSS Teams.

However, in another troubling development, the percentage of respondents using HIPAA-compliant PSS platforms declined 7% since 2021 (71% in 2021 versus 64% in 2022). Moreover, although 55% of respondents indicated that they implemented a patient data usage monitoring process, nearly three-quarters (40% out of the 55%) of those processes are manually managed.



Off-Label Uses & Patient Assistance

Like patient data privacy, the risks associated with providing information about off-label product use are not new. While generally associated with product promotion, providing off-label information also can be associated with providing patient support services. However, the provision of off-label services to patients in assistance programs remains relatively low, with 64% of respondents reporting that they do not provide any services to patients using their product for an unapproved indication.

Nevertheless, 14% of the respondents indicated they provided copay assistance, and 10% provided benefits verification to off-label

patients. Furthermore, 5% of respondents acknowledged providing product training or education to healthcare professionals and patients about off-label usage.

These data highlight that off-label issues surrounding product promotion versus legitimate scientific exchange persist. Given the government's continued negativity about off-label information, even truthful and non-misleading information, the survey indicates that most companies are not willing to engage in the debate. As Gustav Eyler, former Director of the U.S. Department of Justice's Consumer Protection Branch, said regarding assistance related to the provision of copay cards and prescriptions:

> One thing that we have seen as a development is that through the provision of prescription saving cards or other benefits being provided directly to patients, it is changing some of the focus of our investigations...now we're also looking at how is the company incentivizing not just the issuance but the filling of prescriptions and does it have reason to know that those prescriptions are invalid.[30]

Conclusion

Compliance is a journey, not a destination.

Assisting patients with obtaining necessary medicines remains a critical national healthcare priority. Given the inherent conflict that often arises between assisting patients and being profitable, the continuing challenge is how life science companies should participate in aiding patients.

Despite the increasing risks and complexities associated with PSS programs, Helio's 2022 survey demonstrates that many life science companies will continue providing these programs. However, as the HHS-OIG Advisory Opinions indicate, the form of such programs and the corresponding controls needed to show legitimate intent will continue to change.

Therefore, as the annual surveys highlight, companies must continue investing in the compliance journey. Although uncertain, one can argue that increasing PSS compliance efforts, including seeking government guidance, is having an impact by reducing the number of enforcement actions in this area.

Likewise, the surveys reveal that compliance efforts continue to evolve and improve. Companies are employing new monitoring methods, including call and transactional monitoring and automated compliance monitoring systems, to bolster their efforts to provide compliant patient support and services. These efforts ultimately benefit all healthcare stakeholders, but especially the patients.

References

1 Ms. Bak is a Director, Ms. McKinley is an Associate, and Mr. Mijakowski 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.

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