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FEATURE

Operating in the Gray Zone

Patient Support Programs and the Guardrails to Mitigate Risk

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Summary: As the number and types of patient support programs continues to grow, drug and device manufacturers continue to struggle with significant regulatory uncertainty resulting in uncharted risks. Therefore, life science compliance professionals must prepare their organizations to defend the integrity and the utility of their patient support programs from every angle.

Even though patient support programs have become a staple of the health care delivery system, the guardrails for executing them compliantly remain largely uncharted. As the industry continues to create more specialized therapies and expand their support offerings, which include everything from co-payment assistance to at-home injection training, the key guardrails for a compliant program remain dependent upon the broad strokes of the False Claims Act ("FCA") and Anti-Kickback Statute ("AKS"). Unlike other life science operational areas where companies are provided with a large amount of guidance (e.g., speaker programs or clinical research payments) companies and their compliance professionals are left with few resources and less clarity on safely executing their patient support programs and controlling the new high-risk interactions involving patients and caregivers. As a result, drug and device manufacturers continue to operate their programs in a "gray zone" of regulatory uncertainty.

Uncharted Waters

Although sometimes supported by the government enforcers and patient advocacy groups, this lack of clarity frustrates drug and device manufacturers.[2] The manufacturers view themselves as working harder than ever to deliver on their patient-centric missions by providing support in ways that reduce barriers to treatment and improve patient care outcomes.

A landmark global patient-centricity survey conducted by the Aurora Project found that over half of pharma company leaders surveyed ranked the *importance* of achieving patient-centricity a 10 out of 10, but only 5% gave the same rating for their *confidence* in their organization's ability to execute on it.[3] Even though this survey occurred five years ago, most industry leaders facing the same conundrum. The rapidly evolving area of patient support has generated a higher degree of scrutiny from government regulators. However, companies and compliance professionals continue to struggle with limited visibility into the government's stance on such services.

Unlike other compliance areas, the traditional channels through which insight is often gleaned – such as OIG fraud alerts, enforcement settlements, and Corporate Integrity Agreements ("CIAs") – do not provide a readily available roadmap.[4]

Consequently, as life science companies continue developing more nuanced patient support strategies, it becomes ever more difficult to anticipate the parameters for executing these strategies without exposure to significant future enforcement risks. Thus, many companies are left with no choice but to navigate "uncharted waters" as they execute their patient-focused missions.

Charting the Known - Existing OIG Guidance

Compliance leaders are left to work with imperfect and inaccurate charts in the absence of an established industry playbook and a substantial enforcement history to guide patient support program development and execution. Thus, the specifics surrounding the guardrails for compliant programs are not easy to determine.

One of the few public statements espousing the government's view of patient support programs, came at the end of a motion by the U.S. Department of Justice ("DOJ") to dismiss multiple *qui tam* complaints in 2018. In the widely publicized dismissal, the DOJ appeared to recognize the inherent value of patient support programs noting:

> [G]iven the vast sums the government spends on the medications at issue, federal healthcare programs have a strong interest in ensuring that, after a physician has appropriately prescribed a medication, patients have access to basic product support relating to their medication, such as access to a toll-free patient-assistance line or instructions on how to properly inject or store their medication.[5]

Therefore, the Justice Department concluded in this instance:

> These relators should not be permitted to indiscriminately advance claims on behalf of the government against an entire industry that would undermine common industry practices the federal government has determined are … appropriate and beneficial to federal healthcare programs and their beneficiaries.[6]

Beyond the *Health Choice* case, the government has provided a few snapshots further illuminating its stance on individual companies' specific patient services programs. These snapshots take the form of Advisory Opinions issued by the Department of Health and Human Services, Office of Inspector General ("OIG").[7] Together with recent settlements these Advisory Opinions form most of the guidance that is available on patient support programs.[8]

While these Advisory Opinions provide a critical look into the OIG's thinking, they are neither as specific as the U.S. Federal Sentencing Guidelines for Organizations, nor as prolific as guidance memos issued by the Centers for Medicare & Medicaid Services ("CMS"). Their utility also is more limited because each Advisory Opinion applies to a unique set of facts and lack broad applicability. Therefore, companies are left to sift through the details to figure out which considerations are applicable to their company's business model and product portfolios.

Uncharted Shoals – Continuing Areas of Uncertainty

The limitations of the existing guidance and enforcement history leaves shoals that companies must avoid running aground on. Thus, significant areas remain that generate divergent opinions leading to potential enforcement risks.

The Seeding Issue

A central issue for companies looking to provide patient support programs is the issue of *seeding*. The OIG defines seeding as providing inducements for future referrals of a drug when it would be payable by a federal health care program.[9] Typically, the potential seeding issue stem from free or discounted drug programs and this type of seeding has been routinely evaluated part of the OIG's decisions to support the program or warn the requester that its proposed actions could lead to AKS enforcement.[10]

Although, the OIG's definition of a seeding program is relatively straight-forward, application of the definition involves evaluating numerous considerations including:

- Program type (e.g., free trials vs. ongoing co-pay assistance),
- Type of eligible patients (e.g., standard Part D plan beneficiaries vs. commercially insured patients), and
- Product attributes (e.g., the ease with which a patient can switch to or from alternative products).

Furthermore, based upon the OIG's seeding position, it seems plausible that a company with only an investigational product could run afoul of this issue by providing support and assistance to future prescribers before approval and a reimbursement decision.

Given the lack of applicable guidance, some of the program elements must be considered "in-play," meaning that they are potential avenues for prosecutors or *qui tam* relators to assert that a company's program, however well intentioned, violates the AKS and FCA. Examples include the total annual value of the offered products or services, the duration of the benefits provided, and renewal restrictions. The net result is that even the most altruistic and well-designed patient assistance program, especially one serving a patient population with many federal healthcare participants, runs the risk of being misconstrued as a seeding program if sufficient guardrails and data stewardship practices are not in place.

Increased Patient Contact Through More Patient-Centric Strategies

The regulatory foundation and guidance surrounding patient assistance programs has remained relatively stagnant in the face of an explosion of innovative ways to bring patients closer to out of reach therapies. Life sciences companies' shift towards more patient-centric strategies has fostered the creation and standardization of field-based roles targeted at improving patient outcomes. Two prime examples are the use of Clinical Nurse Educators and new Hub-based or Hub-adjacent services, including in-home injection training provided by Clinical Nurse Trainers.

As manufacturers continue to increase the volume of touchpoints along the patient journey from prescription through administration and adherence, their activities involve a new set of risks that warrant focused compliance attention (Figure 1).

For example, the increased use of personnel with clinical care backgrounds requires heightened safeguards – such as call scripts and call monitoring – for a company to demonstrate that its patient interactions do not encroach upon patient privacy, provide any improper medical advice, or engage in improper direct-to-patient product promotion. In the absence of clear guidance from regulators, the crucial question is not *if* the company should monitor these new types of interactions, but *how* they should do so.

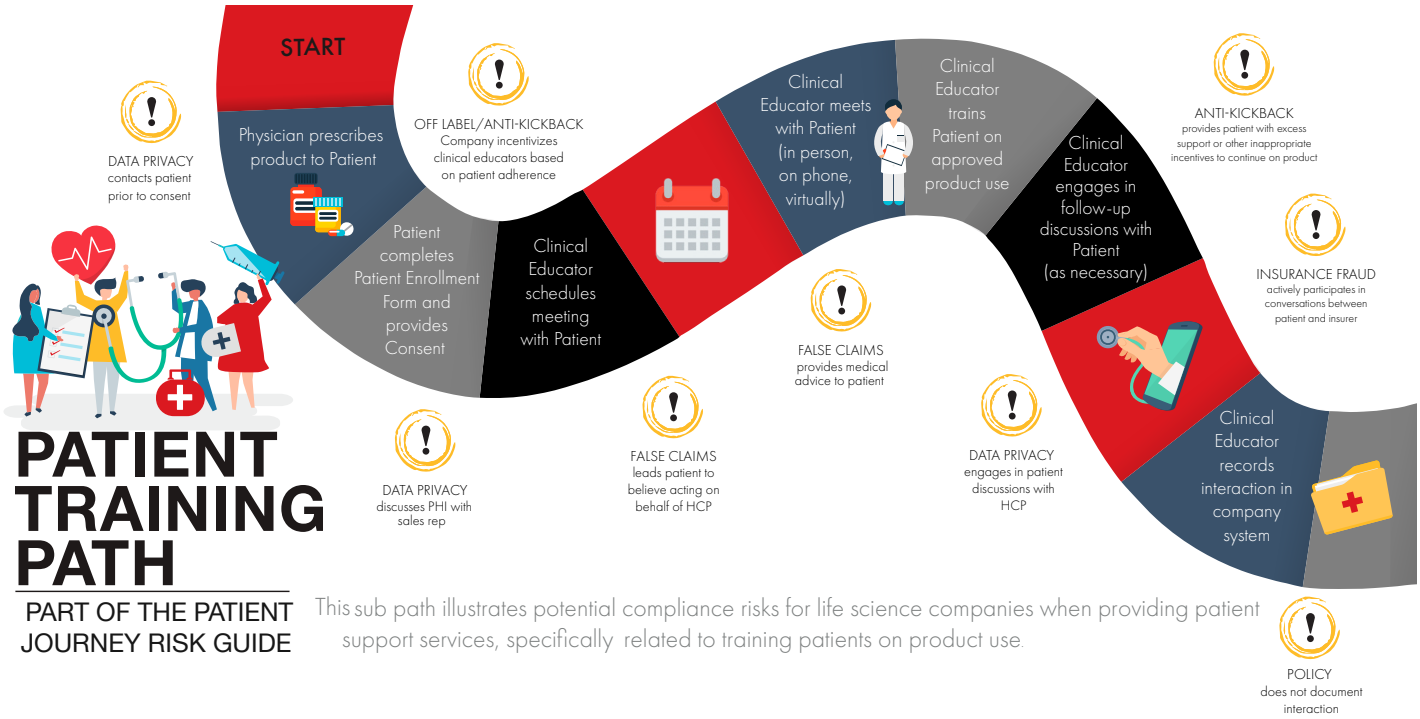
State Regulators Fill the Void

While the federal regulators have yet to target most of the newest forms of patient-facing support activities, the state regulators have been much more aggressive. For example, in August 2020, the California Department of Insurance settled with AbbVie Inc. for $24 million for its use of Clinical Nurse Educators and their interactions with patients and health plans.[12]

The settlement drew unprecedented attention to what was once an underexamined area.[13] It also prompted additional state and federal probes.[14]

Now it appears that other states have taken notice and to date in 2021 more than 100 new state bills have been introduced across more than 40 states concerning activities related to transparency, patient coupons, and cost-sharing.[15] All this attention suggests that prudent compliance professionals should take a fresh look at their organizations' safeguards surrounding patient interactions.

FIGURE 1: *Key Risk Areas Along the Patient Training Journey*[11]



Safe Navigation - Best Practices and Guardrails

While there are a few specific areas that are clearly "off-limits" in patient support programs (e.g., prohibitions on completion of prior authorization for healthcare professionals ("HCPs")), it may not always be clear how generous companies can be when facilitating patients' access to their treatments. Notwithstanding the current ambiguities, it is critical that companies utilizing patient support programs take preemptive and decisive compliance action in anticipation of the heightened attention from state and federal regulators.

Do Not Be Myopic When It Comes to Adequate Oversight of Controls

Although many companies today offer a wide variety of patient support programs, including reimbursement support, co-pay assistance, and free trial drug, these programs only represent one area of high-risk activities that a compliance team is charged with overseeing and monitoring.

For many organizations, the pandemic has stressed the already thin monitoring and auditing resources of compliance teams to the breaking point. However, with the continuing spotlight on patient support programs, it is essential that these programs are included in the universe of live monitoring plans and periodic audits.

Therefore, it is not reasonable or sustainable for companies to increase spending on their patient support programs without a corresponding investment to enhance the compliance team's capabilities to adequately monitor and oversee these activities. Robust documentation demonstrating proactive compliance efforts to ensure the necessary guardrails are in place is perhaps the best way to reduce the risk that inappropriate activities are rationalized as a benefit to patients.

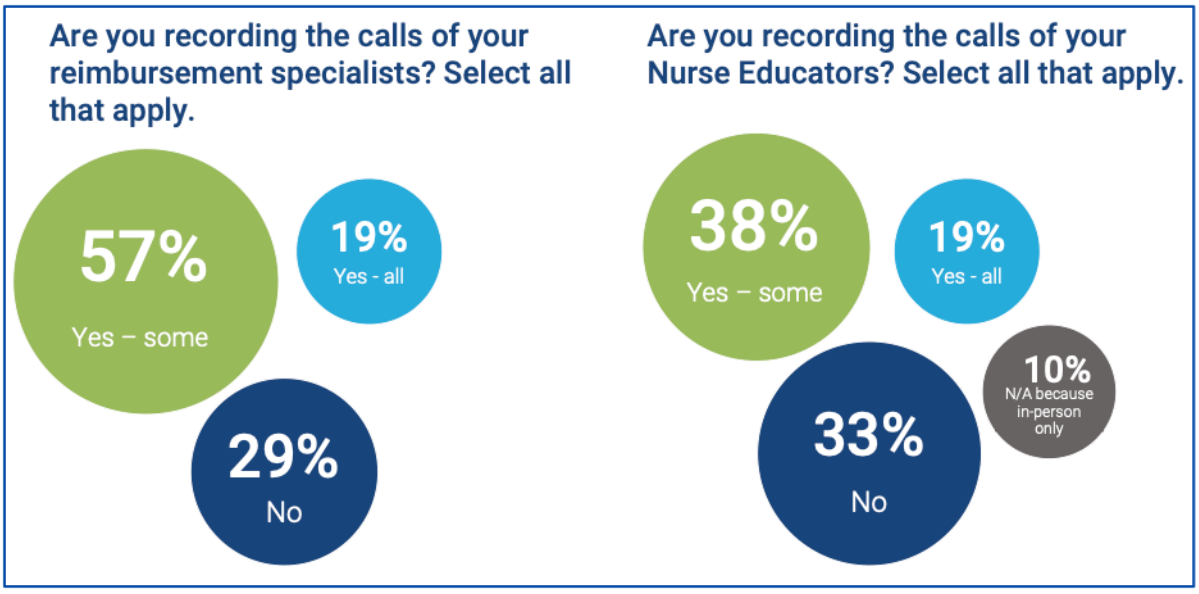
Remember Compliance is a Team Sport

While many Chief Compliance Officers ("CCOs") already have begun making the necessary changes to their organizational structure, program design, and external communications strategies to address the overarching, *programmatic* risks generated by high-patient contact activities, they are not enough.

Addressing implementation risks is not something that can be achieved by the CCO or even the compliance team alone. Ensuring that employees, contractors, and vendors understand and can adhere to the essential guardrails established in program policies requires cooperation and buy-in from leadership across the business in the form of education, training, coaching, and oversight of high-risk field interactions.

Therefore, revisions to training or field manuals is essential to ensure personnel being onboarded as Field

FIGURE 2: *Selected PCC Audience Poll Survey Questions & Results*[17]



Reimbursement Managers or Clinical Nurse Educators understand the operation of the program's processes and the key enforcement rubrics governing their activities. Furthermore, as state regulators become more focused on patient support services offered to their specific Medicaid populations, additional focused sessions with regional leaders may be necessary to ensure key personnel understand the state-level restrictions on the interactions or services they may offer patients and providers.

Establish Clear Data Stewardship Protocols and Responsibilities for Patient Support Program Data

In addition to the AKS, FCA, and the Beneficiary Inducements Civil Monetary Penalties ("CMPs"), the new types of value-added services being offered to patients and caregivers also carry adjacent but equally significant risks associated with data privacy, data integrity, and data stewardship. As advancements in Customer Relationship Management ("CRM") technology have enabled companies to capture call recordings and numerous key performance indicators ("KPIs") related to patient and HCP interactions, companies must pay special attention to the data practices associated with these activities. Thus, the pressure to utilize advanced data analytics technologies to improve monitoring and oversight of company-generated data is increasing.[16]

When Helio published its last annual Patient Services Compliance Survey in 2020, the proportion of respondents indicating they were auditing their Nurse Educators and their Reimbursement Specialists activities were just 36% and 29%, respectively.[18] An audience poll taken during a recent Pharmaceutical Compliance Congress ("PCC") meeting in April 2021, however, revealed a potential divide between the increasing volume of data being generated and the resources available for compliance teams to adequately oversee and monitor that data.

Notably, more than three-quarters of the audience members indicated their companies are recording at least some of their reimbursement specialists' calls, and more over half do the same for their Nurse Educator calls (Figure 2). As companies continue to increase the amount of data they capture and store as part of their patient services programs, they must also ensure they are prepared with a plan, a team, and the necessary systems to effectively monitor it.

Conclusion

With more than 9 out of 10 life science executives in agreement that a patient-focused strategy improves business outcomes, it is no surprise that companies are developing new and innovative ways of providing patients and caregivers with specialized programs to reduce barriers to access, improve the care experience, and positively impact health outcomes.[19] However, becoming a more patient-centric organization without a clearly defined industry standards or guidance from regulators comes with significant risks.

As outlined by the OIG, each company's unique program characteristics, product attributes, and patient population ultimately will impact the way these provided benefits are evaluated against federal anti-fraud laws. Until more universal guidance or industry standards becomes available, life science compliance professionals must prepare their organizations to defend the integrity and the utility of their patient support programs from every angle.

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 United States' Motion to Dismiss Relator's Second Amended Complaint, U.S., et. al. ex rel. Health Choice Group, LLC, V. Bayer Corporation, et al., No. 5:17-CV-126-RWS-CMC (E.D. Tex. Dec. 17, 2018); see also T. Sullivan, "DOJ Defends Motion to Dismiss Eleven Qui Tam Suits," Policy & Medicine (Mar. 5, 2019) available at https://www.policymed.com/2019/03/doj-defends-motion-to-dismiss-eleven-qui-tam-suits.html.*

3 *See The Aurora Project, "The Top Five Insights from Pharma's Global Patient-Centric Survey," (Mar. 2016), available at https://synapse.pfmd.org/resources/second-annual-patient-centric-benchmark-survey-the-aurora-project/download.*

4 *"Optimizing Compliant Patient Interactions" remarks of D. Selvig, A. Kocharyan, M. Datta, K. Durousseau at the Pharmaceutical Compliance Congress Virtual Spring Kick-Off Event, (Apr. 27, 2021).*

5 *See United States' Motion to Dismiss, supra n. 2 at 16.*

6 *Id.*

7 *See e.g., U.S. Dep't Health & Human Services, Office of Inspector Gen'l, "OIG Advisory Opinion No. 06-16" (Oct. 3, 2006); "OIG Advisory Opinion 15-11" (Aug. 5, 2015); "OIG Advisory Opinion 20-02" (Jan. 15, 2020), "OIG Advisory Opinion 20-05" (Sept. 18, 2020); "OIG Advisory Opinion 20-09" (Dec. 28, 2020). All available at https://www.oig.hhs.gov/compliance/advisory-opinions/index.asp.*

8 *See K. Norris and Dr. S. Whitelaw, Top Ten Compliance Issues of 2020 (Part 2), 7.3 Policy & Medicine Compliance Update 1, 4-6 (2021).*

9 *See OIG Advisory Opinion 15-11, supra n. 7.*

10 See OIG Advisory Opinion 15-11, supra n. 7 at 9; OIG Advisory Opinion 20-02, supra n. 7 at 7; OIG Advisory Opinion 20-05 at 7; OIG Advisory Opinion 20-09, supra n. 7 at 7; see also U.S. Dep't Health & Human Services, Office of Inspector Gen'l, "OIG Advisory Opinion 08-04 (Feb. 2, 2008).

11 Patient Training Path: Part of the Patient Journey Risk Guide, Helio Health Group (2021), available at http://www.heliohealthgroup.com/s/Helio_Patient-Journey-Risk-Guide_Patient-Training-Path.pdf. This roadmap highlights examples of Potential risk areas in the provision of patient training and is not a comprehensive list of all related patient training activities offered by life science companies or all their associated risks.

12 See M. Tzavlakis and B. Schein, "Helio's 4th Annual Patient Services Compliance Survey," 6.12 Policy & Medicine Compliance Update 1, 3 (2020).

13 See, e.g., N. Fiorentino, "'White Coat' Marketing Gone Awry," 3.6 Life Science Compliance Update 1 (2017).

14 See G. Ball and S. Whitelaw, "Sending a Message to Drug Makers – Congress Subpoenas AbbVie for Drug Pricing Documents," 6.10 Policy & Medicine Compliance Update 6 (2020); see also U.S. H. Rep., Committee on Oversight and Reform, Press Release, "Chairwoman Maloney Announces Oversight Committee Hearing with AbbVie CEO," (Apr. 29, 2021), available at https://oversight.house.gov/news/press-releases/chairwoman-maloney-announces-oversight-committee-hearing-with-abbvie-ceo.

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16 See A. Pawloski, G. Sutherland, and B. Schein, "Your Data & You: Who Works for Whom? The Burning Platform for Compliance Data Analytics," 7.5 Policy & Medicine Compliance Update 1 (May 2021).

17 "Optimizing Compliant Patient Interactions," audience poll at the Pharmaceutical Compliance Congress Virtual Spring Kick-Off Event, (Apr. 27, 2021).

18 See See M. Tzavlakis and B. Schein, supra n. 12.

19 See Aurora Project, supra n. 3.

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