

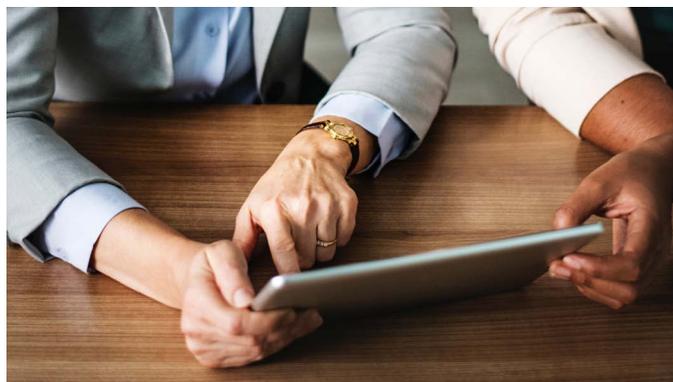
# Pharma Patient Support Programs: What Does the Future Hold?

## Executive Summary

Patient-support services programs have become common in the pharmaceutical industry and are now considered table stakes for certain disease states. Yet recent government scrutiny has left some pharma companies wondering what to do with these programs in the future. This POV reviews the state of the state and lays out recommendations from overall business, compliance, legal, and regulatory viewpoints.

## HISTORY AND CURRENT STATE

In the past decade or so, patient centricity and consumerism grew bigger in the pharmaceutical industry at the same time as the number of specialty drugs being developed and approved increased. As such, a model of patient-support services programs came to be. Pharmaceutical companies piloted services like nursing support, phone support, product-administration training, case management, financial assistance, and disease education. Seeing early successes in the categories of rheumatoid arthritis and multiple sclerosis, the number of brands investing in patient-support services grew slowly but surely over time and expanded across therapeutic areas. From educating patients and caregivers about disease states to helping them access and get started on a prescribed therapy to providing tools and programming to help them stay adherent to their medication, these programs were generally welcomed by patients and healthcare professionals alike.



Today, nearly all large pharmaceutical companies provide some level of patient-support services for medications that treat chronic conditions. Many small and mid-size companies also have invested in these programs. In the rare disease space in particular, these programs are often considered the cost of entry to doing business. Companies are putting marketing dollars behind driving awareness and utilization of these programs. Patients have taken notice.

Andrea, a patient living with rheumatoid arthritis states, “I am a big fan of copay programs. People with a chronic disease are going to have other expenses, so anything like this is helpful. We need every advantage we can [get] to manage our disease and keep the good life we have.”

As the service model has grown in the industry, additional components have been introduced that more directly involve healthcare professionals, particularly in the areas of field nursing (often referred to as nurse educators) and case management. This appears to have attracted the attention of regulators.

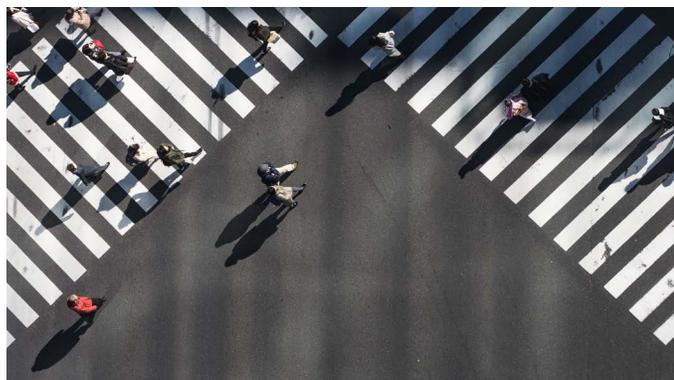
## REGULATOR INVESTIGATIONS AND LAWSUITS

In the pharmaceutical industry, new trends and models generally garner attention and a certain level of scrutiny as they gain traction. The area of patient-support service programs has been no exception, and has come under the microscope in the past two years as the industry as a whole has been gaining more of a black eye. A number of pharmaceutical companies have been or are currently being investigated for alleged violations of the Federal Anti-Kickback Statute and/or the False Claims Act relative to patient-support services they provide. Faced with whistleblower lawsuits in some cases and/or federal prosecutor investigations, at least seven different companies must contend with allegations of script inducement and illegal kickbacks.

The media has been paying close attention, with details of a California case against AbbVie being featured quite unfavorably recently in the [Wall Street Journal](#) and a number of other publications. Several of the accused companies have declared that the allegations are without merit. Others have declined to comment. But nevertheless, this part of the business has become highly scrutinized, with a particular focus on the areas of field nursing and financial assistance programs.

## PLANNING FOR THE FUTURE

Now pharmaceutical companies are finding themselves at a bit of a crossroads. With existing patient-support services programs or new ones planned, the struggle to steer the right path forward is multifaceted. Companies want to maintain and build upon a positive, rich customer experience but know they need to look at current programming through an evolving lens. They are navigating what sometimes seems like constant change in interpretation of requirements and regulations in this part of the business. And, importantly, they must consider innovation, technology, and what is best for patients and their caregivers in the future – while mitigating risk.

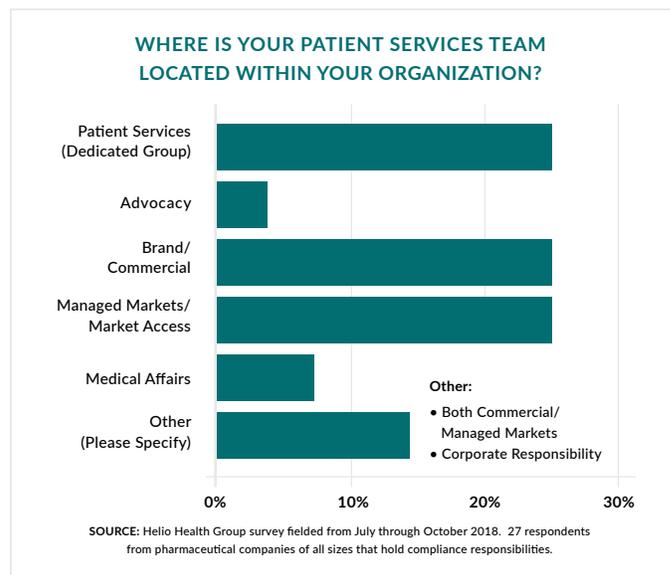


## Important Considerations: Legal, Compliance, and Regulatory Perspective

### OVERALL STRUCTURE – WHERE SHOULD THE PROGRAM ELEMENTS SIT WITHIN THE ORGANIZATION?

There really isn't a "right or wrong" answer to this one. Pharmaceutical companies are structuring their patient-support services programs in a variety of ways. This continues to evolve over time as more companies enter the patient-support services space, customer needs change, and regulators continue to look closely at operations and intent. A survey recently conducted by Helio Health Group, a management consulting firm focused heavily on compliance and patient services, showed a proportionate split

in structure location for 75% of companies today, between three business areas: dedicated group, brand/commercial, and managed markets/market access.



This breakdown looks different from even just a year ago, when the same survey showed over 40% of companies structuring patient-support services programs within the brand/commercial area.

Of note, whether your patient-support services program is outsourced or managed internally, the risks and liability are the same. Many companies do outsource their programs or specific program elements for reasons such as cost, efficiency, and expertise; this does not, however, minimize or shift risk, as any outside vendors are still acting on behalf of the pharmaceutical company.

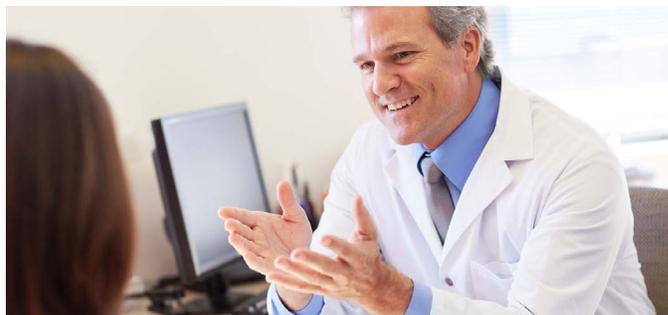
There is need for proper diligence with respect to where the patient-support services program resides and structuring services and controls accordingly:

- Set up proper firewalls where necessary.
- If using outsourced vendors, make sure that they have controls in place and that you are auditing them regularly.
- Watch the scope of roles within patient-support services.

Manny Tzavlikis, managing partner at Helio Health Group, states that, most importantly, “ensure that wherever ‘patient services’ sits within an organization that the right people are paying attention to it, take responsibility for it, and monitor on an ongoing basis.”

## ATTENTION TO SPECIFIC AREAS

Specific components within patient-support services programs require individual consideration and evaluation. Generally, companies should ensure that the scope of the roles is consistent with where they sit within the organization, consider how these roles are being positioned, train accordingly, and ensure strong monitoring and controls are in place. Additional recommended diligence within specific program components is outlined below.



## Program Component Considerations

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### FIELD NURSING

- Avoid activities that could be construed as “white coat marketing,” and ensure processes and training are mapped in a way that enables a clear defensive stance.
- Remember the importance of staying on label! (unless structured within medical affairs).
- Know that driving adherence can be a gray area, so look for defensible ground that demonstrates that what you are doing in this area is for the good of the patients (versus just driving revenue).
- Ensure that nurses are acting as representatives of a company rather than as medical professionals.

### ROLE OF DATA

- Consider doing a diagnostic on all patient data sets in order to put new compliance controls into place.
- Always keep HIPAA front and center, and consider using de-identified data whenever possible.
- Pay close attention to how data is being obtained and secured.
- Be mindful of new and emerging regulation and how they apply to your programs, such as the EU’s [General Data Protection Regulation](#) (GDPR) and the [California Consumer Privacy Act \(CCPA\)](#).

### CALL CENTER

- Create scripting and train accordingly.
- Perform continuous audits.
- Prevent off-label discussion.
- Ensure HIPAA compliance.
- Consider leveraging automated technology to record and transcribe calls for review.

### PRODUCT ACCESS AND FINANCIAL ASSISTANCE

- Ensure that controls in place demonstrate that services are not being performed to induce prescriptions, but rather for the good of the patients.
  - » Be comfortable letting patients go if the product is not the best fit.
  - » Be ready to defend your motive, and have supportive processes in place.
- Demonstrate that the company is not taking on a role that a healthcare professional should be doing instead.
- With copay card:
  - » Ensure there is a trail of information.
  - » Construct program parameters so that the copay card is helping patients where they need assistance.
  - » Consider the role and opportunity for digital.
- With Medicare donations (i.e., charitable donations), ensure that the company is not doing anything to affect/direct where the product goes, as that can be considered influencing product choice.
- With prior authorizations and medical appeals assistance:
  - » Consider how the processes are set up and how far they go.
  - » Avoid activities that could be construed as influencing the script or taking on responsibilities that a healthcare provider should be doing themselves.

## Conclusion

### **PATIENT SUPPORT SERVICES ARE HERE TO STAY, BUT CHANGE IS INEVITABLE**

As more and more companies have begun to provide or expand patient-support services programs over the past five to ten years, it is not a realistic possibility for these programs to just cease to exist. They are too important to patients and caregivers, and frankly, are table stakes to operate and compete in certain disease-state categories. Consumers and healthcare professionals alike have grown to expect and appreciate that these programs will be there to support patients, as consumerism and patient centricity now fundamentally underpin a holistic patient experience.

Further, two significant dynamics in U.S. healthcare actually increase the opportunity and need for these types of patient-support services programs:

- Heavy focus and pipeline in specialty drug development
- Attention and changing requirements with regard to evidence-based medicine (proving outcomes)

This said, while it does not make sense for pharmaceutical companies to “throw in the towel,” patient-support services programs will need to become more controlled over time.



### **CONTINUED SCRUTINY**

The various investigations and lawsuits will progress, others will emerge, and more negative media attention will be garnered. The focus that the government is placing on patient-support services programs will likely continue for some time, particularly amidst the broader government focus on pharma. Regulators and pharmaceutical companies will have to find a reformed path forward.

It is likely that the same types of controls in place for interactions between healthcare professionals and pharmaceutical sales reps will be created for interactions between patients and pharmaceutical patient-services reps, inclusive of the healthcare professional interactions in between. Pharmaceutical companies will need to prepare for this, stay current along the way, and create or modify programs, processes, and systems accordingly to mitigate risk.

Guidelines are likely to change moving forward. Legal and Regulatory expert Darshan Kulkarni, vice president at Synchrogenix and owner of Kulkarni Law Firm, states, “I think it’s important that companies stay abreast of the latest OIG and CMS guidelines as they are changing, and that they interpret these programs in the larger context of what is going on. Being conservative in some areas at this point probably makes sense. The administration wants to incentivize people to come forward with allegations.” Field nursing could become the area most highly scrutinized in the future, as the interactions between sales reps and healthcare professionals are now so controlled. Requirements for financial assistance programs will surely change as well, so this is another arena to keep high on the radar.

### **NAVIGATING A PATH FORWARD**

Tighter controls and active monitoring are the keys in moving ahead. It is important to regularly leverage legal, compliance, and regulatory experts in this area. Pharmaceutical companies may want to consider hiring roles within these functions specifically dedicated to patient-support services programs, if these roles are not already in place. Consultants and outside counsel can also help serve as primary or incremental resources. Paying attention to what other companies are doing, and identifying best practices, will help as well.

### **THE ROLE OF DIGITAL**

Digital, as in other areas of healthcare, will be integral to the future of patient-support services programs. As companies continue to focus on modernizing the customer experience, patient-support services programs should evolve to integrate artificial intelligence, multiple data sets and sophistication, and “real-time” digital experiences. The channels used within patient-support services programs, and the methods of interaction within those channels, should become instrumental in the overall customer experience ecosystem.

With digital, there is opportunity to help with risk mitigation. Technology can enable automation, control, and broader, more efficient auditing. Digital data can enable new methods for tighter control, perhaps with something like enhancing

or validating qualifying criteria for financial assistance programs. But as increased digital programming and integration come into play in this space, security protocols and active monitoring will be critical. These will need to be in place at the beginning of program and system launches and modified over time appropriately as changes occur.

## CLOSING THOUGHT

At the end of the day, when it can often feel like engaging in this area of the business is analogous to sailing through “choppy waters,” remember why you’re doing what you’re doing. At the heart of all of this is the patient, and these programs matter to patients.

“Every day, there are people diagnosed with chronic conditions and that moment changes their life. They need support and education to have some control of how much the disease affects their life.”

— Andrea, rheumatoid arthritis patient

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## Interviews

Darshan Kulkarni, Vice President at Synchrogenix and owner of Kulkarni Law Firm  
Manny Tzavlakis, Managing Partner at Helio Health Group

## Other

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- <http://pharmaceuticalcommerce.com/brand-marketing-communications/patient-centricity-and-the-growing-role-of-hub-services/>



Want to learn more about patient support services?

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