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FEATURE

# Helio Patient Services Compliance Survey

## *The Latest Trends and Lessons Learned*

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**Summary:** Patient services programs are continuing to evolve as life sciences companies consider the associated risks, which have been highlighted by government investigations and regulations. This article highlights the major trends and lessons learned in the industry as seen through the third annual patient services compliance survey conducted by Helio Health Group.

In the February issue of the Policy & Medicine Compliance Update, we analyzed the results from the 2017 and 2018 Helio's survey on patient services compliance.[2] Helio's annual patient services compliance survey provides a benchmark as to how the industry is continuing to develop, evolve, and manage their patient services programs, considering the associated risks that are beginning to emerge as these programs become increasingly scrutinized. In this article, we report on 2019 results and analyze the trends and lessons learned over the past three years (2017 to 2019).

## The Overall Patient Services Compliance Landscape

Patient services programs and the ways in which the life sciences industry directly or indirectly interacts with patients is not only an interest for the commercial functions determining how best to reach their target patient populations and use patient data but for Government agencies as well. In 2019, there was an increase in the number of Corporate Integrity Agreements ("CIA") focused on patient services programs and activities between manufacturers and patients. The donations to third-party foundations and charities that provide patient assistance and allegations of violating the False Claims Act ("FCA") and the Anti-Kickback Statute ("AKS") were a particular focus of these CIAs.

In addition to scrutinizing donations to independent charities, the Government also is investigating the use of patient data and how this data is stored by manufacturers. In 2017, one manufacturer entered into a Deferred Prosecution Agreement ("DPA") in the District of Massachusetts to resolve its "criminal liability" involving the Health Insurance Portability and Accountability Act ("HIPAA"), admitting it obtained patients' identifiable health information without patient consent for commercial purposes.[3] Data privacy has been a burning issue in terms of how companies broadly use personal data, even outside of the life sciences industry. HIPAA regulations, the General Data Protection Regulation ("GDPR"), the California Consumer Protection Act ("CCPA"), which is set to be fully implemented in January of 2020, and other state-specific data privacy laws have prompted companies to evaluate their patient data management practices.

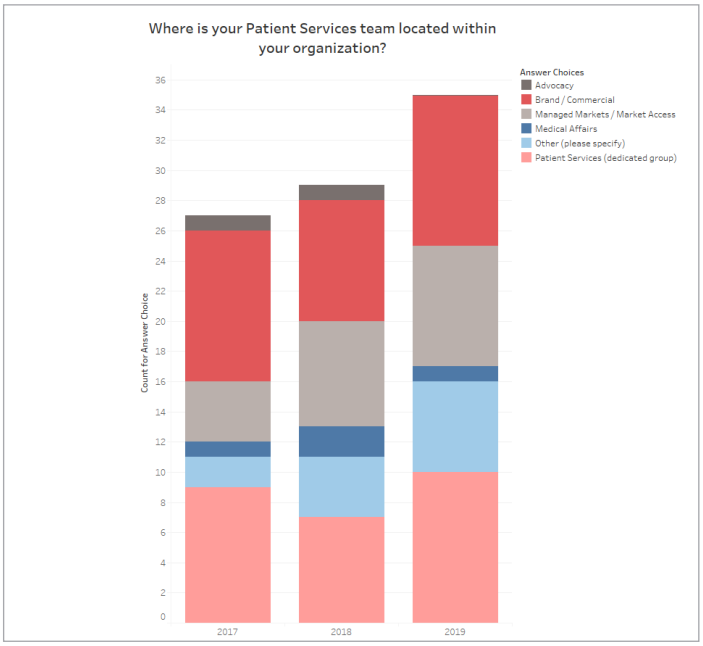
## Year over Year Trends: 2017-2019

The 2017 survey focused on compliance concerns relevant to setting up patient services programs. As the government started pursuing AKS, FCA, and HIPAA violations related to patient services, the 2018 survey included questions regarding monitoring and controls specific to areas where compliance challenges are emerging. In 2019, Helio expanded the survey to include a focus on data privacy and the use of patient data. The surveys included responses from compliance and patient services professionals across small, mid-size (top 21-50) and large (top 20) pharmaceutical and biologic companies.[4] The number of respondents by year is as follows:

| Year | # of Respondents |
|---|---|
| 2017 | 27 |
| 2018 | 28 |
| 2019 | 36 |

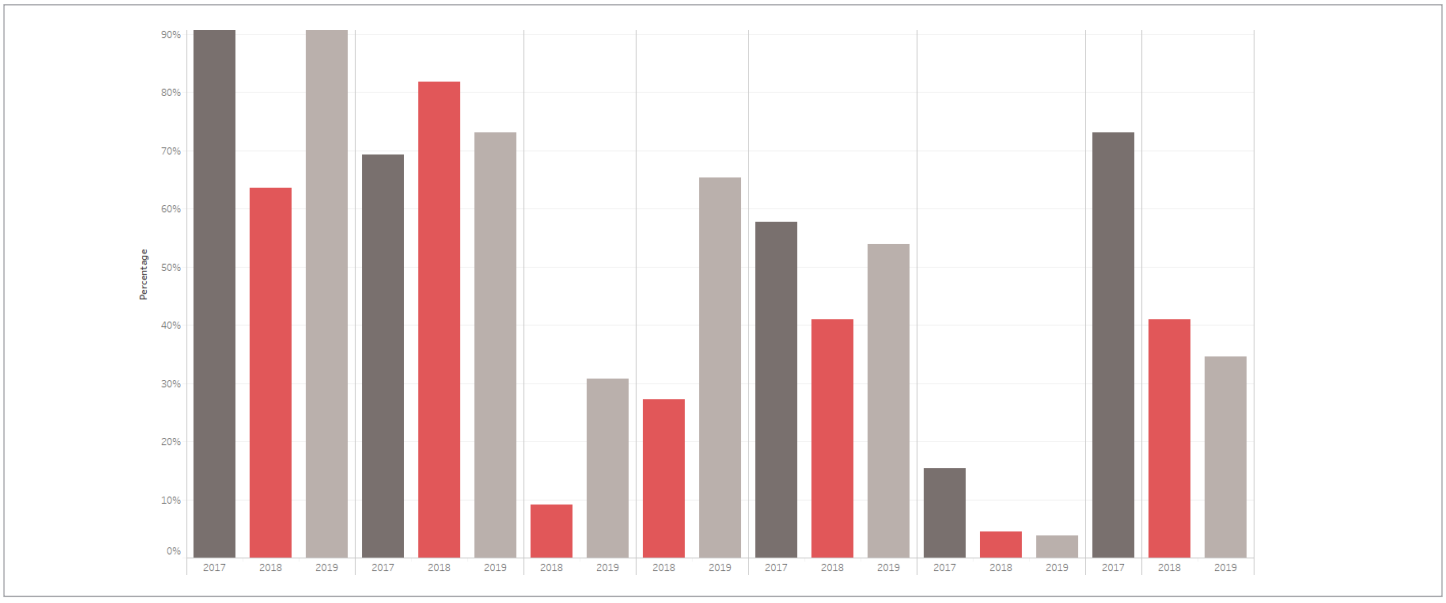
## Organizational Reporting Structure

Between 2017 and 2018, companies shifted their patient services team out from under Brand/Commercial operations into its own group or other functional areas. In 2019, companies continued to follow this trend in addition to "Other" categories where patient services reports to both Brand/Commercial and Managed Markets or have dotted lines between Brand/Commercial and Patient Services.




## The Makeup of the Patient Services Team

Over the last three years, companies have increased their field-based patient support teams, particularly with reimbursement specialists. Note that in 2017, the



survey did not differentiate between field-based and virtual reimbursement specialists. However, the sum of field-based and virtual specialists in 2018 and 2019 was greater than that of 2017.

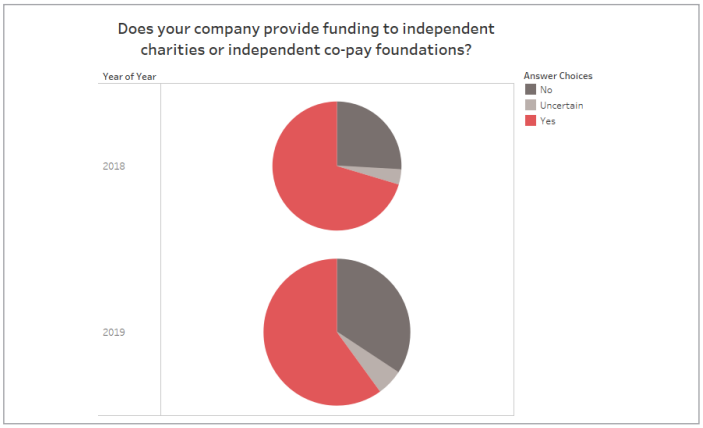
## Management of Services Provided by the Patient Services Team:

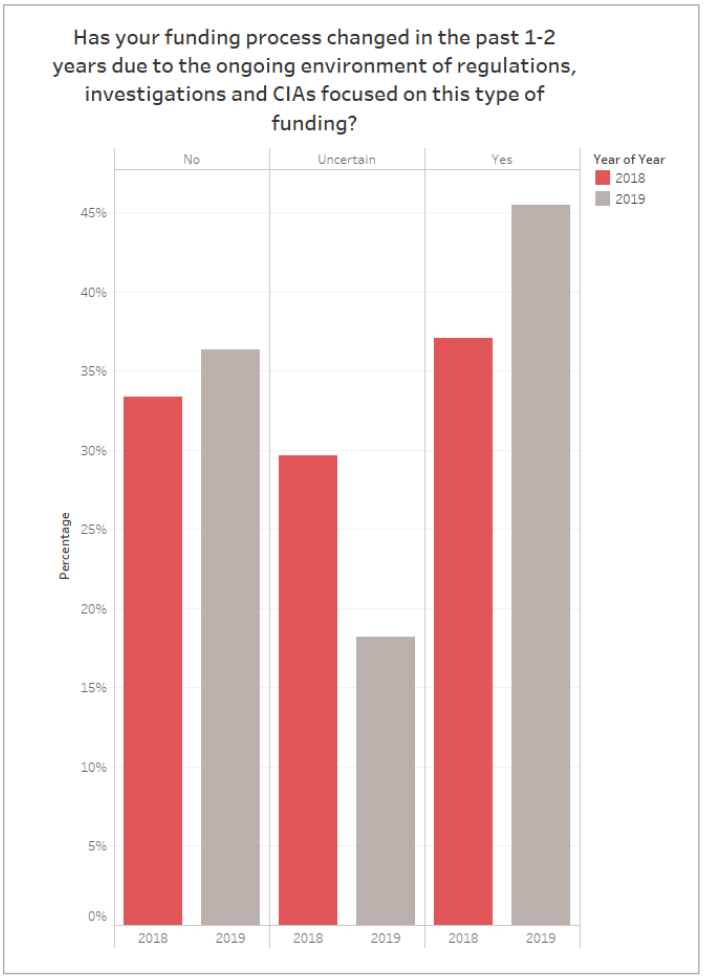
Between 2018 and 2019, there has been an increase in the outsourcing of financially related patient services (Benefit Verification, Co-Pay Assistance, Reimbursement Support, and Prior Authorization Support) to Hubs and Specialty Pharmacies. Also, there has been a slight decrease overall in HCP and Patient Disease and Product education services.

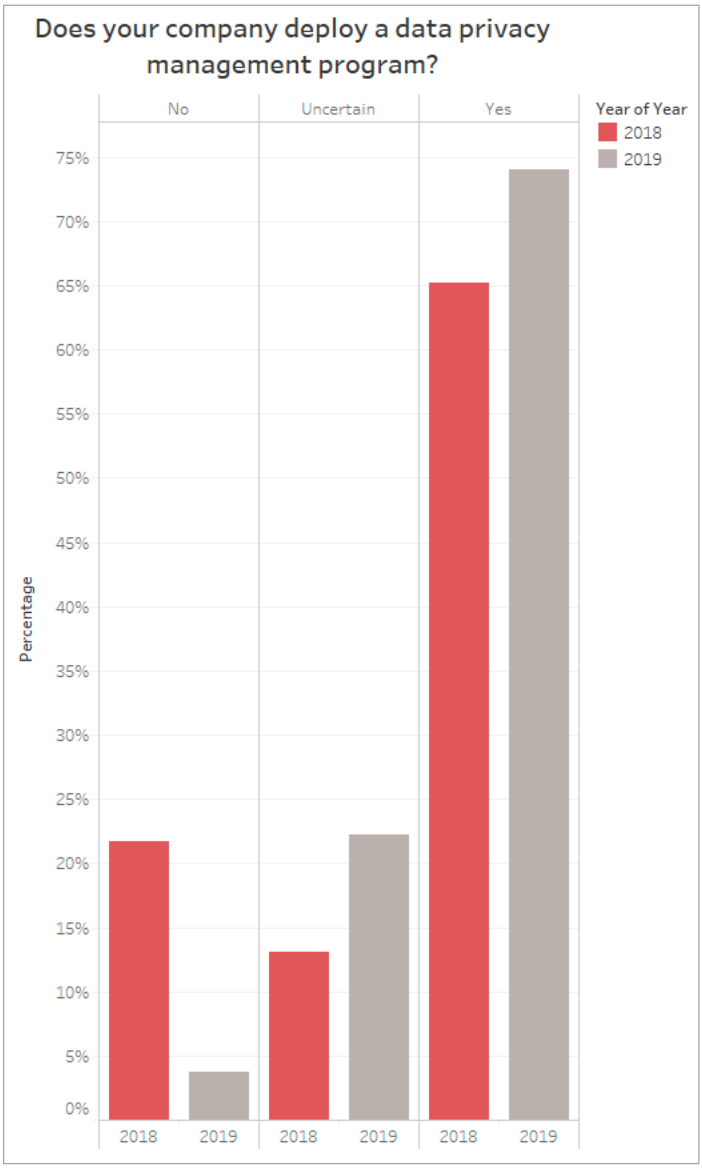

## Independent Charities and Co-pay Assistance Foundations

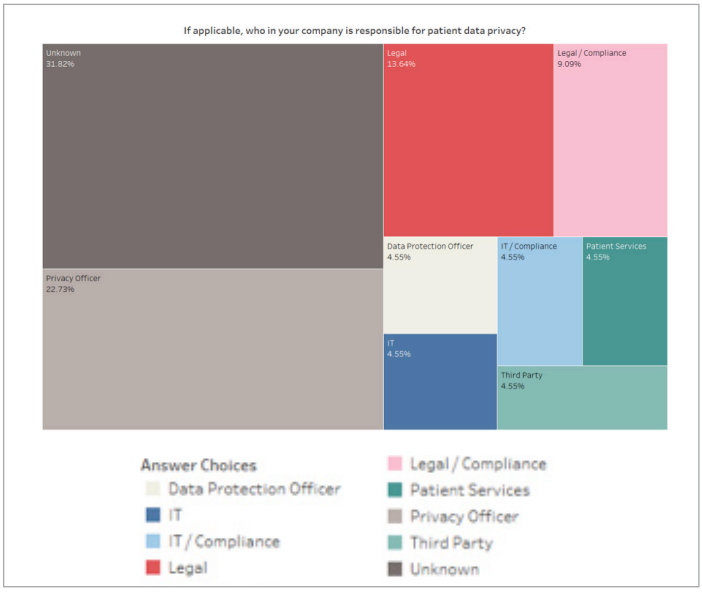
Over the last several years, the Government has launched various investigations into pharmaceutical manufacturers' donations to independent charities. In April of 2019, six pharmaceutical manufacturers settled with the Department of Justice ("DOJ") to resolve allegations of violating the FCA for paying through third-party foundations the copays for patients insured by federal healthcare programs to induce patients to purchase the manufacturers' drugs.[5] According to the Justice Department, "[u]nder the Anti-Kickback Statute, a pharmaceutical company is prohibited from offering, directly or indirectly, any remuneration — which includes paying patients' copay obligations — to induce Medicare patients to purchase the company's drugs." Each of these companies also entered into five-year CIAs with the Department of Health and Human Services, Office of the Inspector General ("OIG"), which included specific provisions to ensure that their interactions with and donations to independent patient assistance programs comply with federal requirements.

Interestingly, according to the survey, between 2018 and 2019, there was an 8% increase in manufacturers that stated that they did not provide funding to independent charities or co-pay foundations, which correlated to an 8% increase of manufacturers that claimed that their funding process has changed in the past 1-2 years due to the ongoing environment of regulations, investigations, and CIAs focused on this type of funding. Thus, clearly the Justice Department's activities in this area are having a deterrent effect.





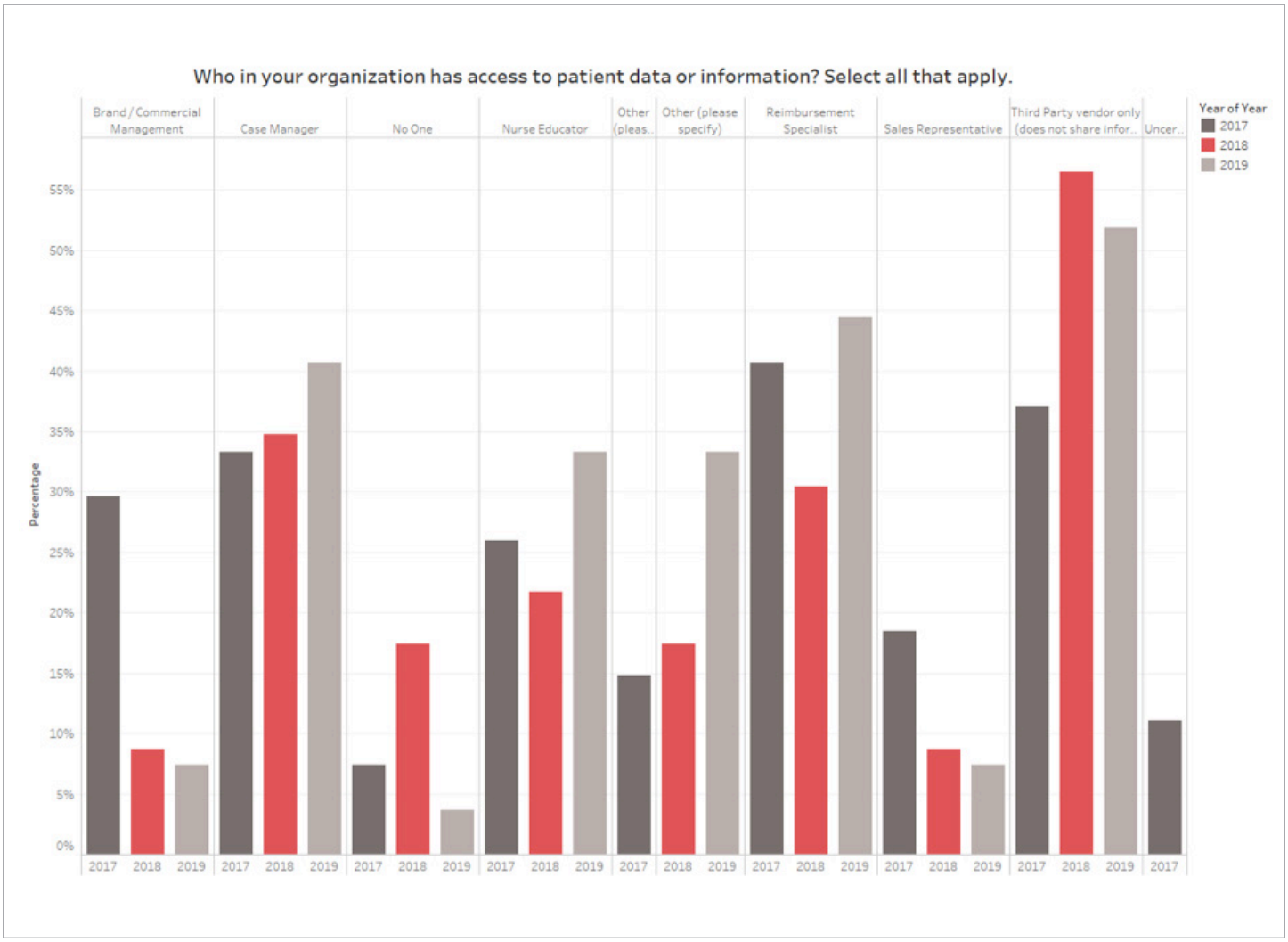




As companies determine which charities and how to set up the donations to these organizations, specific and defined criteria are critical to ensure that these donations are not being used to incentivize the organizations to provide assistance to certain patients and to ensure that patients are not directed to specific organizations. However, challenges may arise in rare disease areas where there are limited foundations supporting these disease states, and thus underscores the importance that contracts have robust guidelines and that policies are clearly written regarding communication and any data received from the organizations.

## Patient Data and Data Privacy

Various government investigations and regulations have caused companies to examine aspects of their




data service programs for compliance and risk mitigation. These investigations are a result of data breaches and the discovery of previously unknown use of personal data. Some of the largest data breaches in the past year include MyHeritage – 92 million people,[6] Facebook – 50 million users,[7] and Salesforce – an outage that led to data access irrespective of permissions.[8]

Data breaches also plagued the healthcare industry, as well. In June 2019, Quest Diagnostics, one of the nation's largest providers of clinical laboratory testing services, left the personal records of 12 million customers exposed to an unknown party, when the American Medical Collection Agency ("AMCA") of New York, a billing collections vendor, was hacked.[9] The hackers gained illicit access to personally identifiable information ("PII") such as social security numbers and protected health information ("PHI"). In August 2019, another data breach at Massachusetts General Hospital in the neurology department exposed PHI of nearly 10,000 people via computer programs used by researchers.[10]

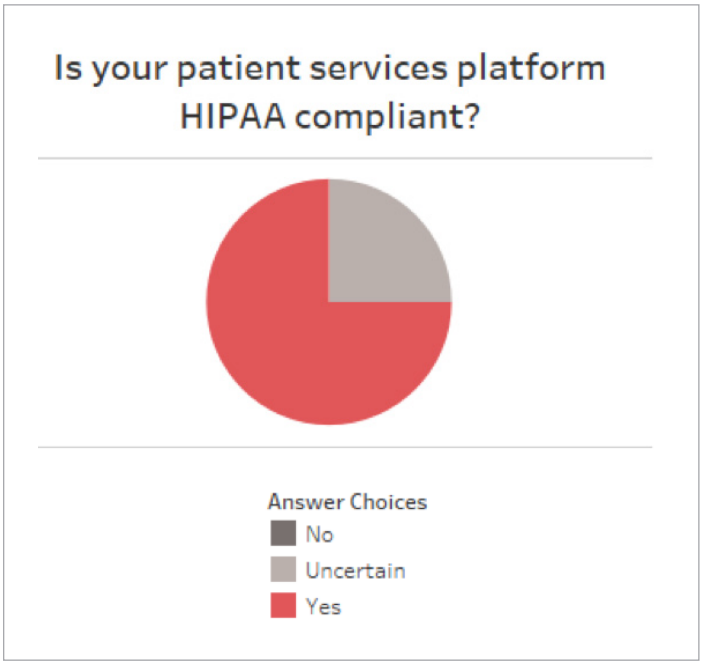
In 2019, there was a 9% increase in respondents that stated that their company deployed a data privacy management program.

When looking at the responsibility of patient data privacy, 23% of respondents stated that they had a

dedicated Privacy Officer, while 14% stated that Legal was responsible. The rest was a mix of IT, Compliance, Patient Services, and Data Protection team.

From 2017 to 2019, there was a significant decline (-20%) in the usage of data by Brand / Commercial Management and Sales Representatives (-11%), but an increase in sharing data with third-party vendors.

Although manufacturers are not directly regulated by HIPAA as they are not considered a covered entity ("CE") or a business associate ("BA"), manufacturers often must structure their data to meet HIPAA standards to ensure that their partnerships with CEs and BAs meet their data regulation. When building patient services programs and platforms, 75% of respondents noted that their platforms were HIPAA compliant.




Manufacturers have been known to repurpose existing CRM Platforms as patient service platforms in order to reduce implementation costs and simplify their IT Infrastructure. This does, however, introduce other complexities beyond poor optics, such as managing access roles to these systems and fire-walling the brand and commercial teams from the patient data. Many CRM systems are designed for massive-scale and not necessarily data privacy. For example, as mentioned earlier, the Salesforce CRM Cloud Platform had a recent high-profile failure where a broad amount of data was being shared between customers accidentally regardless of login or access controls.

## Conclusion

Prosecutorial action and regulations continue to shape how Patient Services Programs and patient data are managed by manufacturers. While donations to independent charities continue to be scrutinized heavily, there also are a large number of inquiries focused on the management of patient data and data privacy. As companies continue to create and modify their patient services programs, they must ensure that effective controls and protections are in place to ensure that these programs purely benefit the patient and provide appropriate access to treatments they otherwise would be unable to obtain, while simultaneously protecting the sensitive asset they have in managing patient data.

### References

1 *Helio Health Group is a management consulting and small data engineering-centric firm that specializes in providing consulting services across compliance and patient services areas of life sciences organizations.*

2 *See M. Bak, et al., Patient Services Compliance Survey – Trends and Insights into this Highly Scrutinized Area, 5.2 POLICY & MEDICINE COMPLIANCE UPDATE 1 (2019).*

3 *See U.S. Dept. of Justice Press Release, Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations, (Sep. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and.*

4 *See Pharm Exec's Top 50 Companies 2019, PHARMACEUTICAL EXECUTIVE (Jul. 12, 2019), http://www.pharmexec.com/pharm-execs-top-50-companies-2019.*

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6 *See Kanishka Singh, Security breach at MyHeritage website leaks details of over 92 million users, REUTERS (Jun. 5, 2018), https://www.reuters.*

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8 See Savia Lobo, Salesforce suffers major outage providing data access irrespective of the permission settings, PACT PUBLISHING (May 20, 2019, 8:12 a.m.), https://hub.packtpub.com/salesforce-suffers-major-outage-providing-data-access-irrespective-of-the-permission-settings/.

9 See Jeremy Hill, Debt Collector Goes Bankrupt After Health Care Data Hack, BLOOMBERG (Updated Jun. 17, 2019, 6:35 p.m. EDT), https://www.bloomberg.com/news/articles/2019-06-17/american-medical-collection-agency-parent-files-for-bankruptcy.

10 See THE BOSTON GLOBE, MGH reports data breach that exposed information of nearly 10,000 people, (Aug. 22, 2019), https://www.boston.com/news/local-news/2019/08/22/mgh-reports-data-breach-that-exposed-information-of-nearly-10000-people.


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