

## Introduction

The U.S. specialty pharmaceutical market is expected to reach \$280 billion by 2021, nearly tripling in size over a single decade. The most significant contributor to this growth is an uptick in patient utilization of specialty drugs, largely due to the regulatory approval of new drugs, as well as broadened indications for existing drugs. As it stands today, 60% of the 508 new drugs awaiting approval from the U.S. Food and Drug Administration (FDA) between now and 2021 are specialty pharmaceuticals.<sup>2</sup>

In seeking to improve medication adherence, care coordination, and clinical outcomes for their patients while also capitalizing on this projected growth in the market, health systems continue to drive patients to in-house specialty pharmacies. The population of patients utilizing health systems' specialty pharmacy services has therefore been on the rise. To meet patient demand and compete with large Pharmacy Benefit Managers (PBMs), health systems must continue to expand the number and types of specialty drugs that they offer. Over the last few years, health systems have reported increased success at securing access to Limited Distribution Drugs (LDDs). However, this remains a considerable challenge as new therapies are developed and access to these drugs remains restricted. Moreover, health systems must contract with diverse payer networks to ensure that they are in-network with their patients' health plans, a challenge that continues to grow year after year.

The Health Management Academy (The Academy), in collaboration with CSI Specialty Group, set out to discern the changing landscape of health systems' specialty pharmacy programs over the last three years and better understand the strategies by which health systems, independent specialty pharmacies, and drug manufacturers will address challenges on the horizon.

<sup>&</sup>lt;sup>1</sup> Barclays US Health Care Distribution and Technology Specialty Market Model 2017 Update: A Focus on Biosimilar Opportunities. Jan 30, 2017.

<sup>&</sup>lt;sup>2</sup> CVS Health. Today's Specialty Landscape. May 2, 2019. https://payorsolutions.cvshealth.com/insights/todays-specialty-landscape

### **Key Findings**

#### The Specialty Pharmacy Patient Census Grows by 27% Each Year

Health systems have increased the utilization of in-house specialty pharmacies, with 40% of executives indicating high success at driving utilization of these programs.

### Access to Limited Distribution Drugs (LDDs) is Increasing, with 69% of Health Systems Having Access to at Least One LDD by 2019

Whereas oncology/hematology drugs have consistently been the top driver of growth in specialty pharmacies for the past three years, health systems have also expanded access to a wider variety of disease states.

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### Payer Contracting Continues to be an Obstacle for Operating Specialty Pharmacies, with 56% of Executives Indicating Access to Payer Contracts as the Top Challenge

Accreditation and the use of a robust data infrastructure and software programming are key criteria payers use in evaluating the strength of specialty pharmacy programs. Health systems strive to meet these criteria in order secure payer contracts.

# I. Specialty Pharmacy Growth

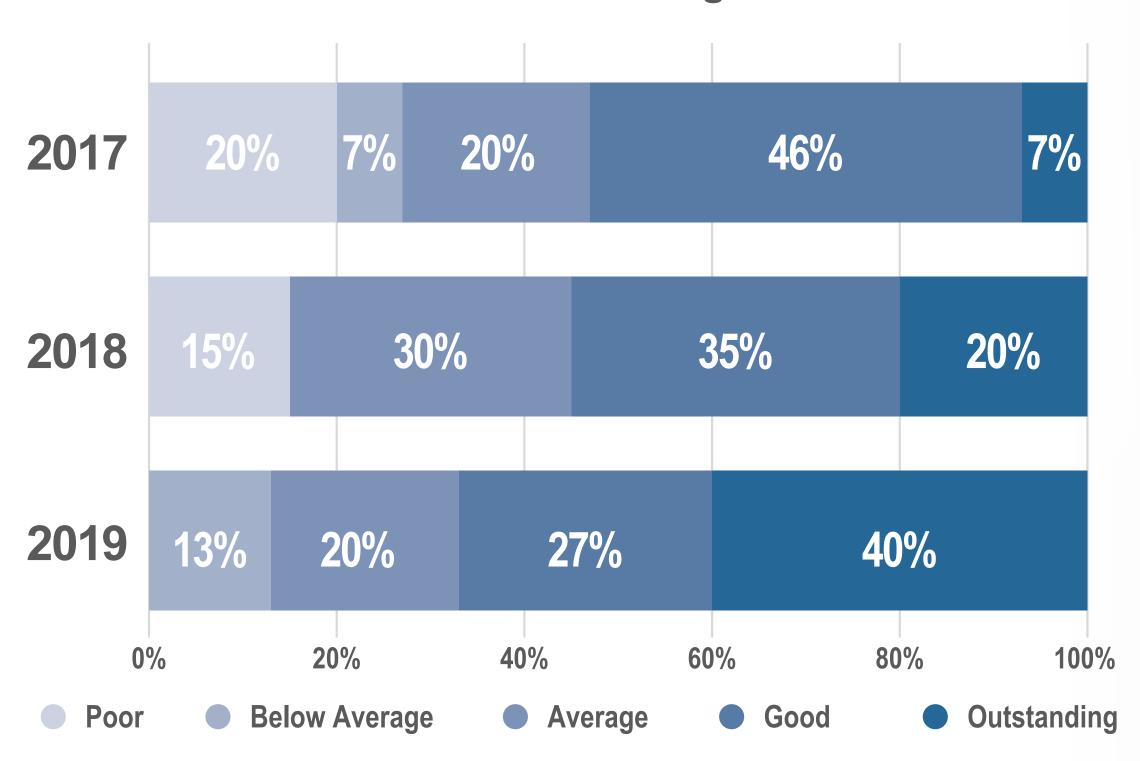
The Specialty Pharmacy Patient Census Grows by 27% Each Year





### Patient Utilization of Specialty Services is Rising

#### **Perceived Success at Driving Patient Utilization**



### Improvement in Physician Referral Processes Reduces Patient Leakage

Health systems have increased the utilization of in-house specialty pharmacy services by their patients. Since 2017, the proportion of health system executives reporting "outstanding" performance at increasing patient utilization of specialty pharmacy services has grown by nearly 600%. Over the same period, the proportion of health systems reporting "poor" performance has diminished to 0%. This perception of increased utilization is also indicative of decreased patient leakage to specialty pharmacies outside of the health system.

In 2019, 80% of health system executives indicated that the percentage of employed providers prescribing to their in-house specialty pharmacy has "increased over the past year." This signals an improvement in how health systems work with employed physicians to increase patient referrals to in-house specialty pharmacy services. As health systems continue to operate their own specialty pharmacies, their processes for self-referral are expected to improve and patient leakage is expected to decline.



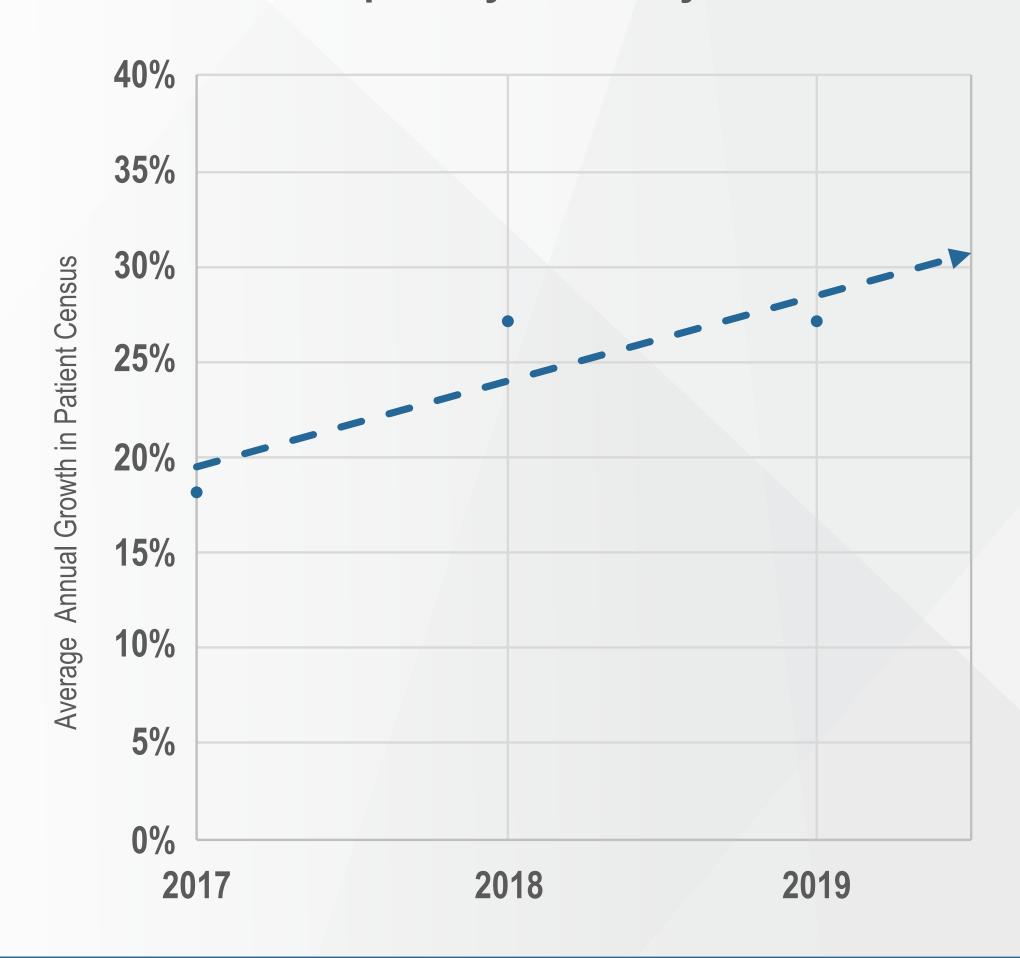
### Specialty Pharmacy Patient Census is Growing

#### **In-House Specialty Patient Census Expected to Grow**

Reflective of the improvement in health systems' ability to drive patients to inhouse specialty pharmacies, health system executives report that their patient census is also on the rise. While the majority of respondents indicated 0-10% growth in 2017, most respondents indicated either 11-25% growth or 26-50% growth in 2018 and 2019. The average growth in patient census across all health systems was 27% from 2018 to 2019.

As health systems continue to increase the amount of services and drugs offered in their specialty pharmacies, it is likely that the patient populations they serve will continue to grow through 2020 and beyond.

#### **Growth in Specialty Pharmacy Patient Census**





### Referrals from External Institutions Remains Stagnant

### Health Systems are Successful at Driving Referrals to In-House Pharmacies Despite Competitive Market

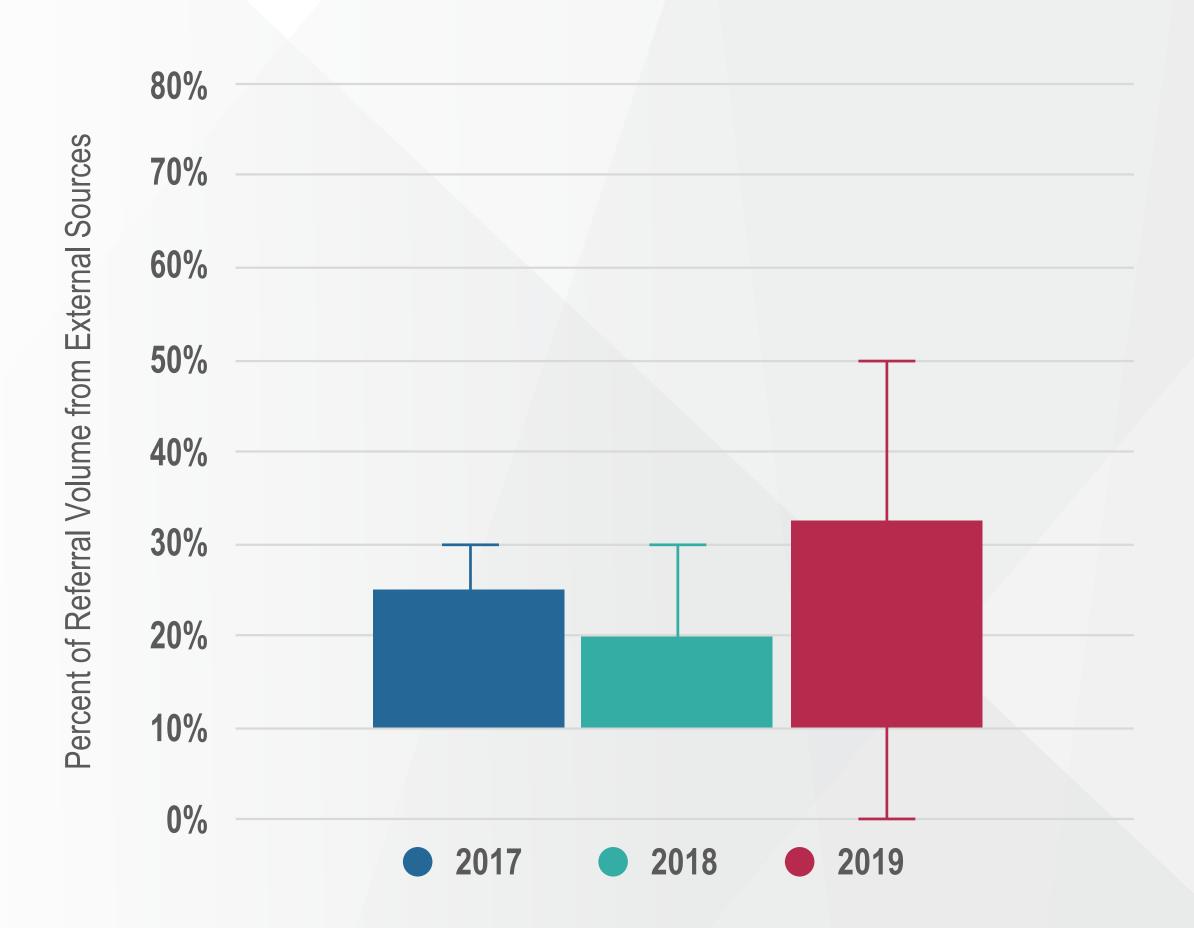
For the past three years, the proportion of referrals to health system specialty pharmacies from physicians outside of the institution has been stagnant, at approximately 20%, on average per year. There is wide variation among specialty pharmacies in the proportion of referrals coming from outside the health system, however, the middle 50% of executives indicate that 10% to 33% of referrals today are from outside institutions.

Given the presence of competitors with significant market share in the specialty pharmacy space (e.g., CVS, Walgreens, and Express Scripts), an increase in health system referrals from outside the health system indicates that health systems are successful at competing in this space.

#### **Competitors Face Increased Pressure**

Based on historical data collected across different specialty pharmacy stakeholder groups, it is evident that independent specialty pharmacies are increasingly experiencing competition from health system specialty pharmacies when seeking access to manufacturer networks, patients, and payer contracts.

#### Referral Volume from Outside Health System



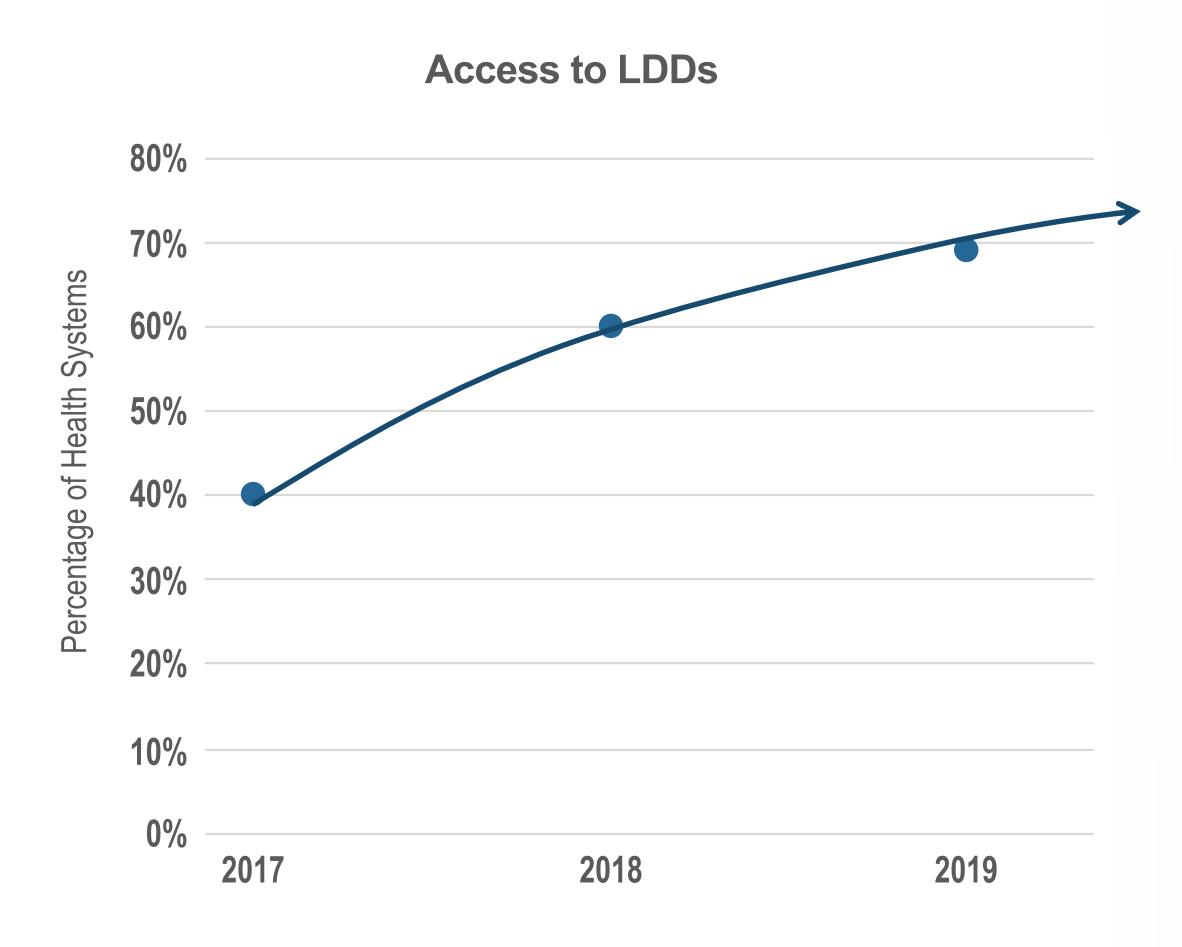
# II. Access to Specialty Drugs



Access to Limited Distribution Drugs (LDDs) is Increasing, with 69% of Health Systems Having Access to at Least One LDD by 2019



### Health System Access to LDDs has Improved



#### **Drug Manufacturers are Expanding Network of Partners**

Limited Distribution Drugs (LDDs) are specialty drugs that are only available to patients through a select group of specialty pharmacies, often selected for meeting rigorous clinical standards by LDD manufacturers. Securing access to LDDs remains a challenge for health systems as they continue to build out their specialty pharmacy operations.

Despite the challenge of securing access to LDDs, health systems are gaining traction in this area, with nearly 70% of health systems having access to "at least some LDDs" by 2019. This is potentially due to a large number of manufacturers increasing the number of partners to which they distribute LDDs and increasingly considering health system-owned specialty pharmacies for inclusion. Despite obtaining expanded access to LDDs, health system executives express that securing access to new LDDs is still a major challenge for them.

When considering partners for LDDs, drug manufacturers most often consider a specialty pharmacy's access to payers as the primary factor for their decision. Secondary factors include access, control, and data capabilities.



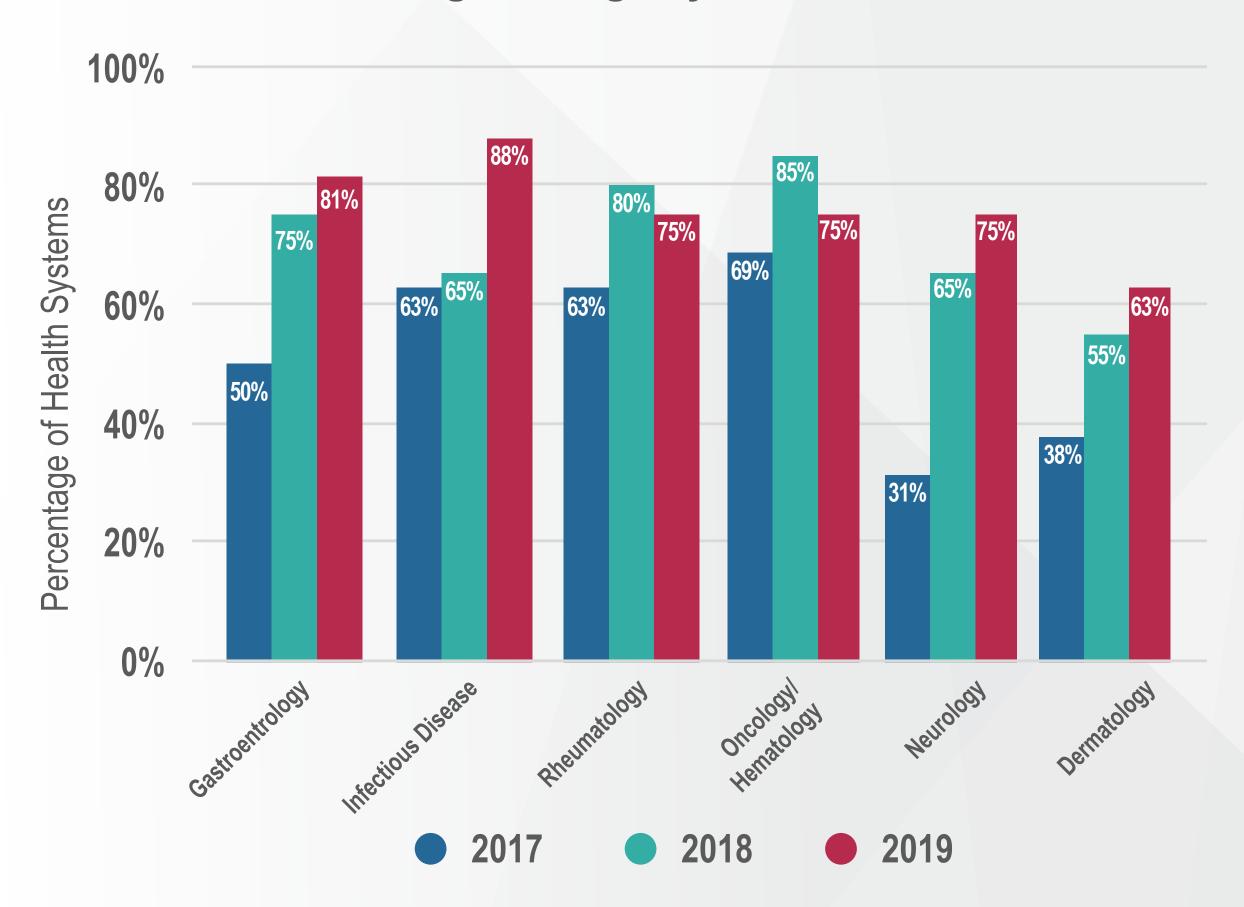
### Presence in Manufacturer Networks Has Expanded Offerings

### Health System Drug Offerings Have Expanded Across Multiple Disease States

As drug manufacturers increasingly consider health systems in their distribution networks, health systems are able to offer a larger array of drugs to their patients. The proportion of health systems offering drugs for a variety of disease states has grown over the past three years. Health systems cite patient need, increased access to specialty pharmaceuticals, and revenue opportunities as reasons for expanding disease state offerings.

In 2017 and 2018, oncology/hematology was the specialty most commonly served among the health system specialty pharmacies surveyed, whereas in 2019, infectious disease has become the most common, with 88% of health systems offering infectious disease specialty medications. Notably, since 2017, there has been a 142% increase in the percentage of health systems offering neurologic specialty drugs and a 66% increase in the percentage of health systems offering dermatologic drugs.

#### **Drug Offerings By Disease State**

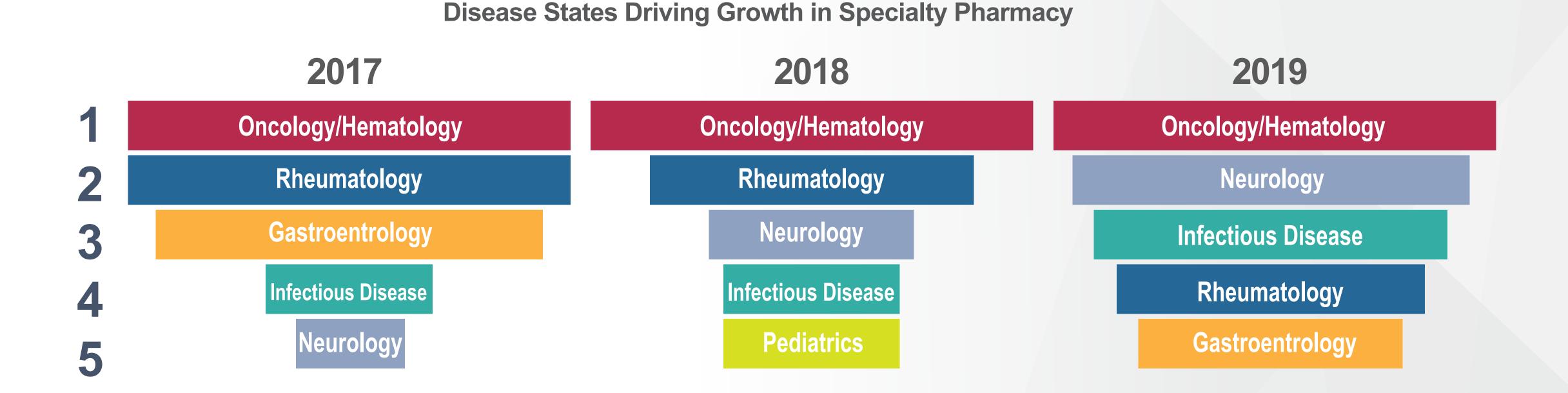




# Health Systems and Manufacturers are Aligned on Drivers of Growth

Over the past three years, health systems have consistently identified oncology/hematology specialty pharmaceuticals as the greatest drivers of growth in their specialty pharmacy markets. Similarly, manufacturers also indicate that the majority of LDDs offered fall into oncology/hematology as well. Consistent with substantial increases in the percentage of specialty pharmacies offering neurologic drugs, neurology went from being the fifth-ranked growth driver in 2017 to the second-ranked growth driver in 2019. Infectious disease drugs have also improved in ranking from 2017 to 2019.

The consistency in perceptions of growth drivers across stakeholder groups not only signals alignment in the specialty pharmacy market, but also highlights health systems' response to growing patient needs.



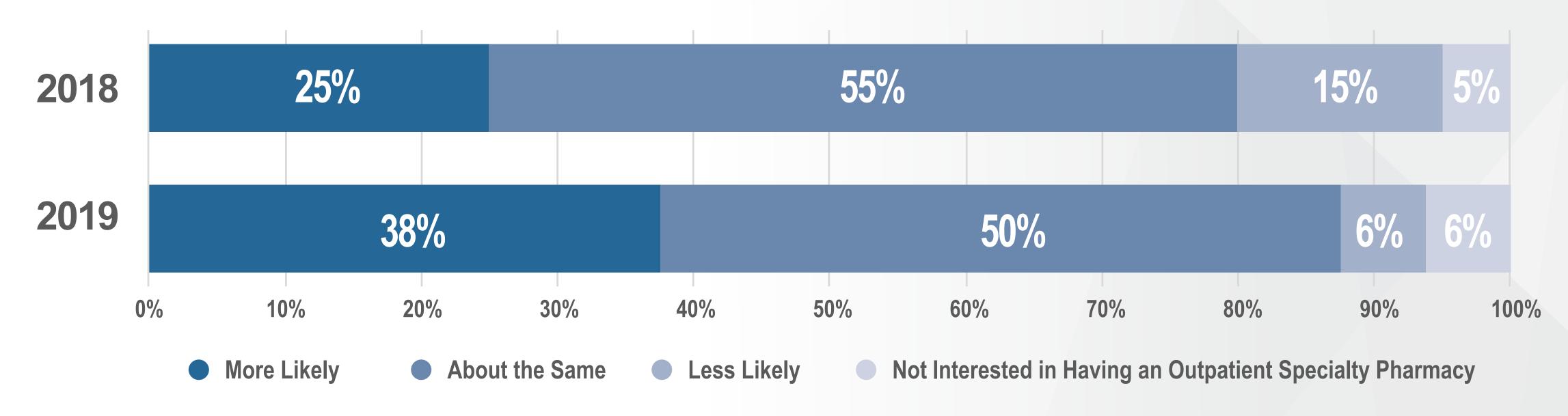


### Health Systems are Not Deterred by 340B Changes

#### Political Climate May be a Contributor to Growth in Specialty Pharmacy

Proposed legislative changes to Section 340B of the Public Health Service Act aim to cut discounts allotted to eligible hospitals when purchasing drugs from manufacturers. Despite these potential changes on the horizon, health systems are still poised to move forward with expanding their specialty pharmacy programs. The proportion of health systems that responded as being "more likely to expand outpatient specialty pharmacy" increased by 13 percentage points from 2018 to 2019. The increase in likelihood to expand specialty pharmacy programs across health systems may be due in part to the Democratic Party regaining control of the House of Representatives in the fall of 2018, making it less likely that Congress will pass legislative changes to discount rules for the 340B Drug Discount Program.

#### Likelihood to Expand Outpatient Specialty Pharmacy in Light of Proposed 340B Changes



# III. Payer Contracting

Payer Contracting is an Obstacle for Operating Specialty Pharmacies, with 56% of Executives Indicating Access to Payer Contracts as the Top Challenge





### Access to Payer Contracts is the Greatest Challenge

### Payer Contracting Continues to be the Greatest Challenge

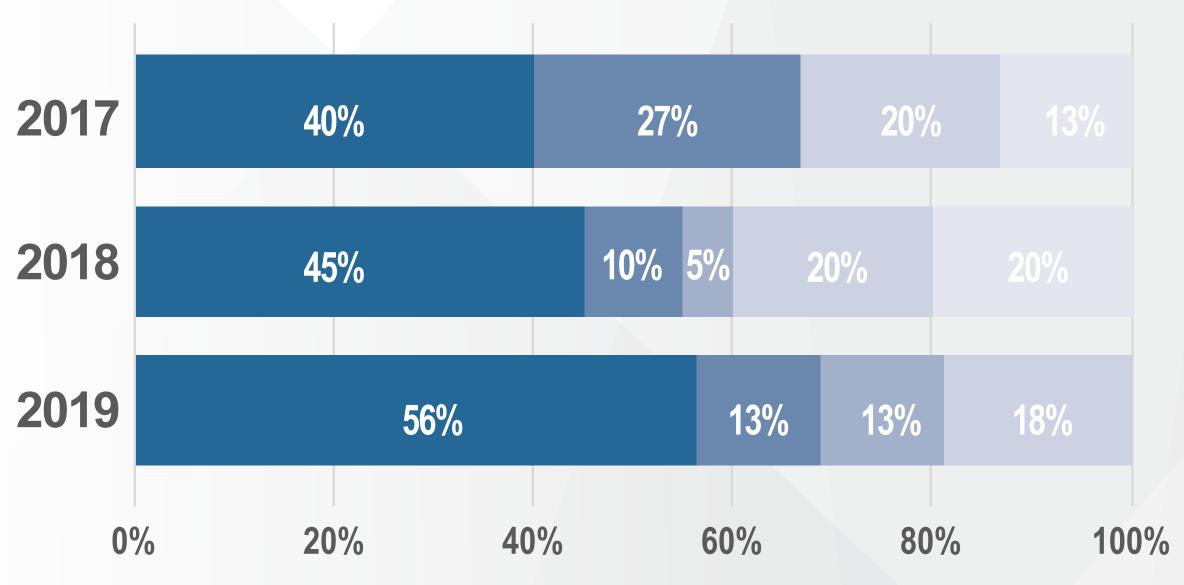
Due to the high costs of specialty drugs, payers seek to control expenditures by creating narrow and 'preferred' networks. This makes it particularly difficult for health systems that are seeking to secure new contracts with payers and thereby increase their own market share.

As health systems improve physician engagement, drive volume into their specialty pharmacies, and expand access to a wider array of specialty drugs and LDDs, they continue to struggle with securing access to payer contracts. 56% of respondents indicated that "access to payer contracts" is their greatest challenge, and this number is on the rise. Similarly, independent specialty pharmacies also report access to payer contracts as their greatest challenge.

#### **Staffing Presents a Secondary Challenge**

As the portfolio of drugs and services offered by health system specialty pharmacies continues to grow, health systems are faced with an emerging challenge around insufficient staffing available to handle these growing operations. Furthermore, over 60% of respondents feel that the low national unemployment rate in 2019 has further impacted their ability to fill specialty pharmacy roles.

#### **Top Challenges to Specialty Pharmacy Growth**

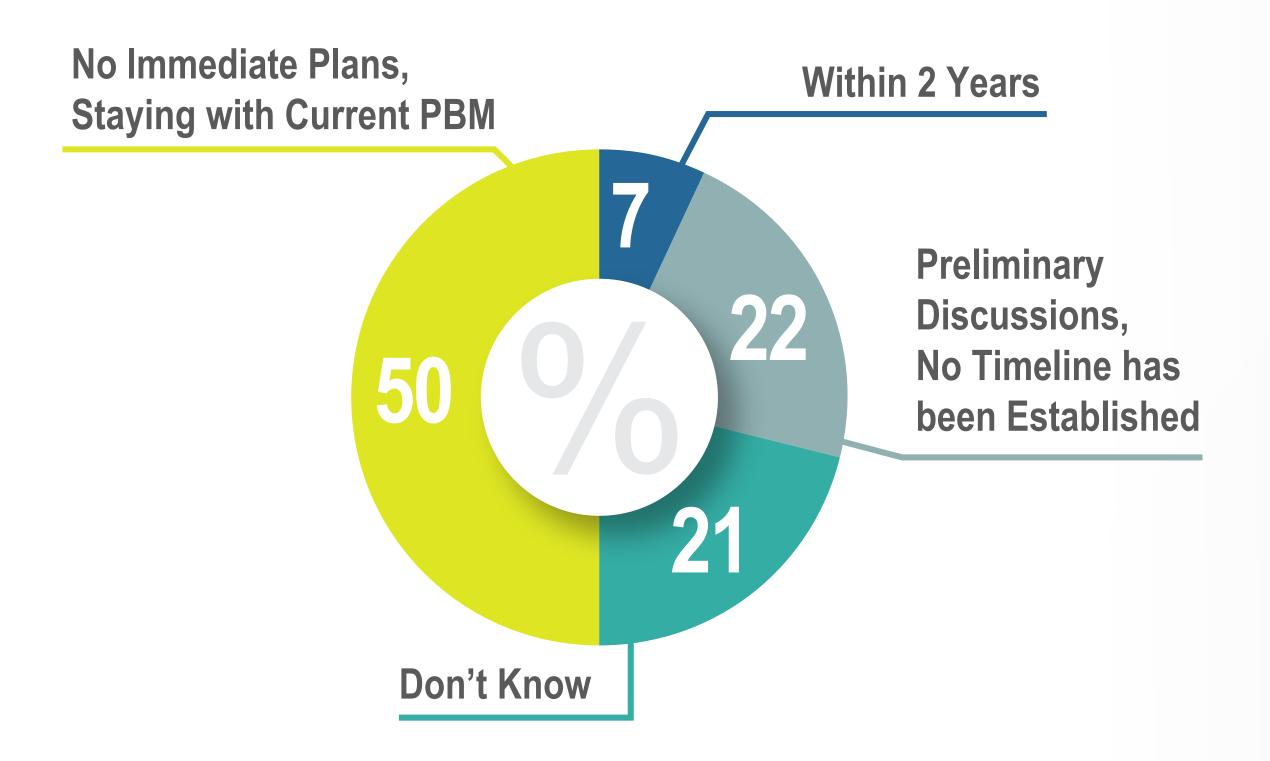


- Access to Payer Contacts
- Access to Specialty Medications
- Having Enough Staff to Handle Growth
- Health System & Physician Engagement
- Other



### Few Health Systems Plan to Open In-House PBM

#### **Plans to Start Own PBM**



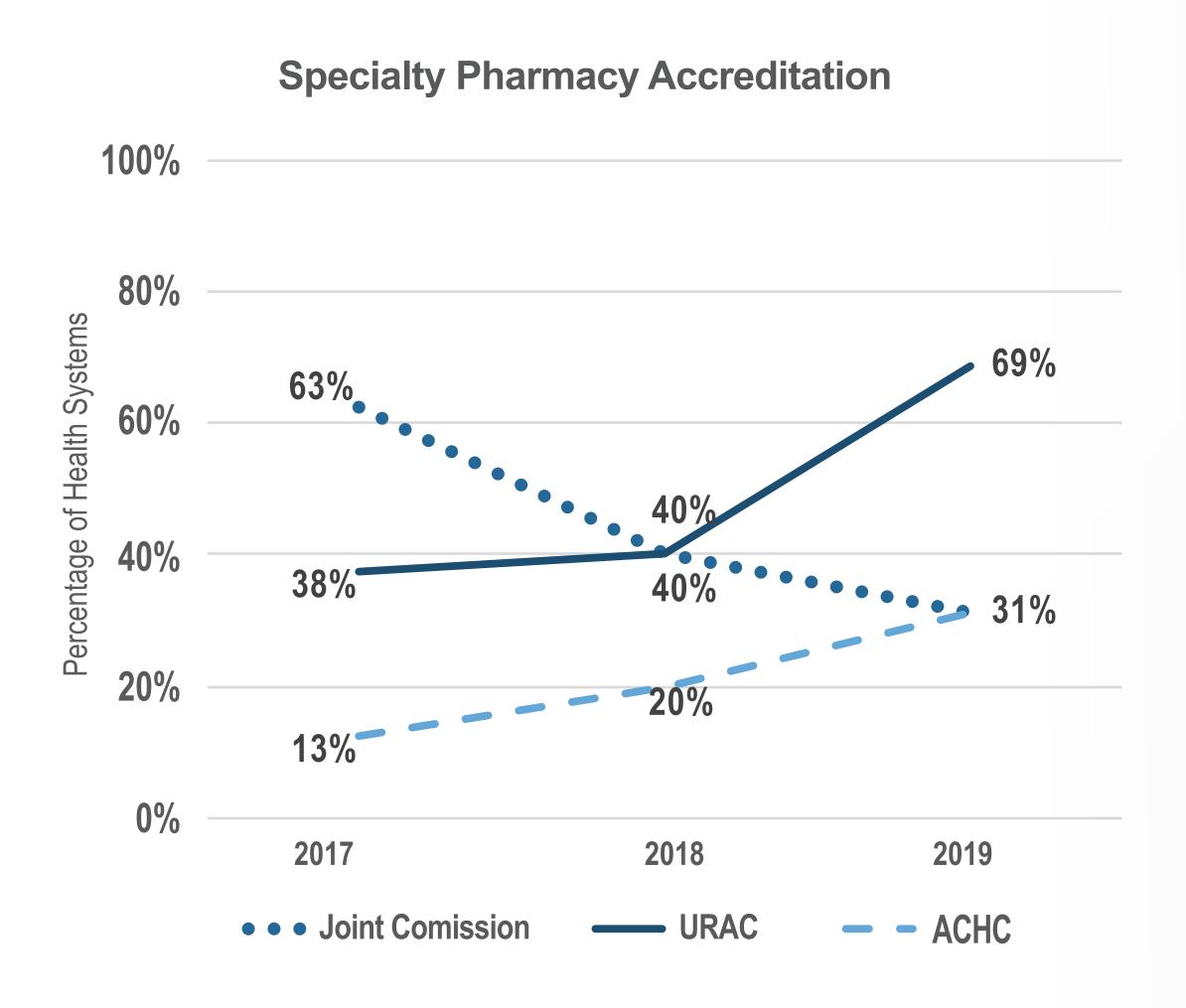
#### **Majority Plan to Stay with Current PBM**

Despite the challenges health systems face with securing payer contracts, relatively few health systems have plans to open an in-house Pharmacy Benefit Manager (PBM) as a means to improve access to payer contracts or secure access to lower cost specialty drugs. Specifically, half of health system specialty pharmacies surveyed plan to stay with their current PBM, with programs across CVS Caremark, Express Scripts, Navitus, MedImpact, and regional Blue Cross and Blue Shield programs among those cited.

Approximately one-quarter of respondents are unsure of their PBM strategy moving forward, while one-quarter are having exploratory discussions around opening an in-house PBM with no formal timeline set in place. Only one responding health system has plans to open an in-house PBM within the next two years.



### Accreditation is a Key Influence in Payer Contracting



### **URAC Replaces Joint Commission as Top Accreditor**

The percent of responding health systems reporting specialty pharmacy accreditation through the Utilization Review Accreditation Commission (URAC) increased to 69% in 2019, while those accredited through the Accreditation Commission for Health Care (ACHC) increased to 31%. The percentage of responding health systems reporting specialty pharmacy accreditation through the Joint Commission decreased from 63% in 2017 to 31% in 2019, on average.

Accreditation is an important factor that payers consider when contracting with health system specialty pharmacies. Three-quarters of 2019 respondents indicate that the primary reason for selecting an accreditor is that it is a requirement by a payer or PBM with which they are seeking to contract.

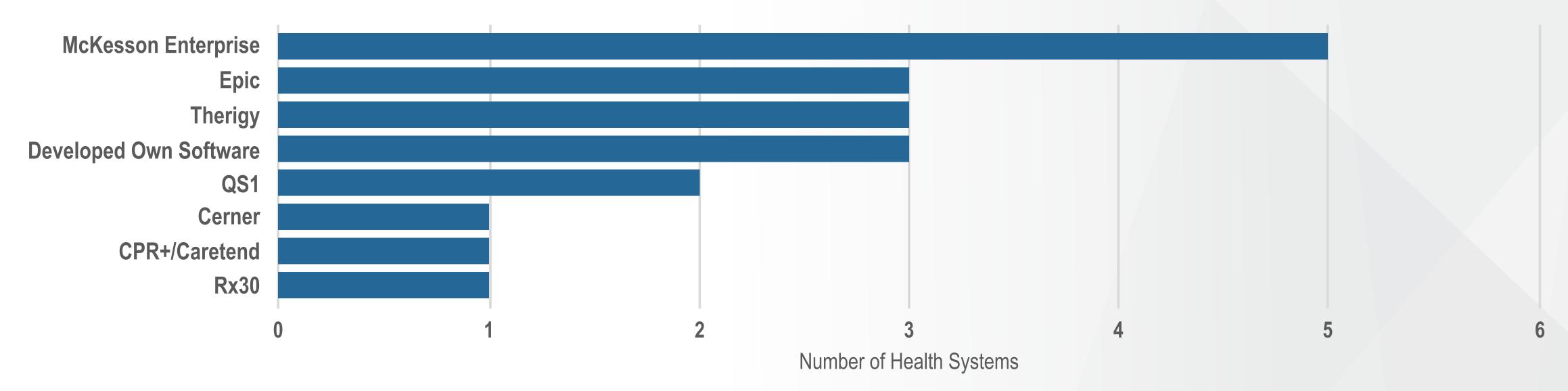


### Diversity in Software Suggests an Unmet Need

#### Data Infrastructure and Software Programming are Essential to Securing Payer Contracts

The use of robust data infrastructure and software programming are essential criteria that both manufacturers and payers use to evaluate the strength of a health system's specialty pharmacy program. These IT systems make it possible for health systems to provide patients with sufficient monitoring and support, while also tracking metrics like medication adherence, overall cost of care, and clinical outcomes. All health systems surveyed report the use of at least one software product within their specialty pharmacy that is used for dispensing, operations, clinical care, and billing. Among respondents, McKesson Enterprise is the most common product utilized. However, the diverse array of different products used indicates that there is an unmet need for a single platform that does everything a specialty pharmacy needs.





### Informed Practices for Leading Health Systems

Trends identified across three specialty pharmacy stakeholder groups indicate that health systems have improved their competitive advantage in the market over the past three years. In order to continue to be successful in this space, health systems may consider the following practices when strengthening their specialty pharmacy strategy.

#### Strengthen physician engagement and buy-in from external partners

Trends indicate a stagnant increase in referrals from outside institutions, signaling a need for increased physician engagement and stakeholder buy-in from outside institutions. Health systems should be prepared to continue to strengthen these efforts in order to improve specialty pharmacy patient census over time.

#### Demonstrate credibility through step-ladder approach to disease state expansion

Over the past three years, health systems have slowly expanded services offered by their specialty pharmacies and established their credibility one disease state at a time. Depending upon the pipeline of specialty pharmaceuticals developed over the next 3-5 years, health systems should be prepared to expand to additional disease states in order to meet demand.

# 3

#### Use data and analytics platforms to gain leverage with manufacturers and payers

In order to gain access to payer contracts and LDDs from manufacturers, health systems should bring data on patient adherence and clinical outcomes to the table and demonstrate their value against to independent specialty pharmacies.

# About this Project

Methodology, The Academy, and CSI Specialty Group

### Methodology

In March and April of 2019, The Health Management Academy and CSI Specialty Group co-administered a quantitative survey among pharmacy executives across multiple stakeholder groups regarding their specialty pharmacy programs. Stakeholder groups included health systems, pharmaceutical manufacturers, and independent specialty pharmacies. Respondent roles included Chief Operating Officers, Chief Pharmacy Officers, Directors and Managers of Pharmacy, and other pharmacy staff.

Historical data for 2017 and 2018 were provided by CSI Specialty Group. While the data presented in this study are reflective of national averages, one limitation is the lack of a consistent sample of respondents across all three years of the survey.

#### **Project Team**

Sanjula Jain, Ph.D., Executive Director, Research & Advisory

#### **Study Authors**

- Matt Devino, Senior Analyst, Research & Advisory
- Jackie Risco, Associate Director, Research & Advisory

#### Research Support

Anita Wang, Data Analyst, Research & Advisory

#### **Production**

Anthony Casini, Senior Graphic Designer

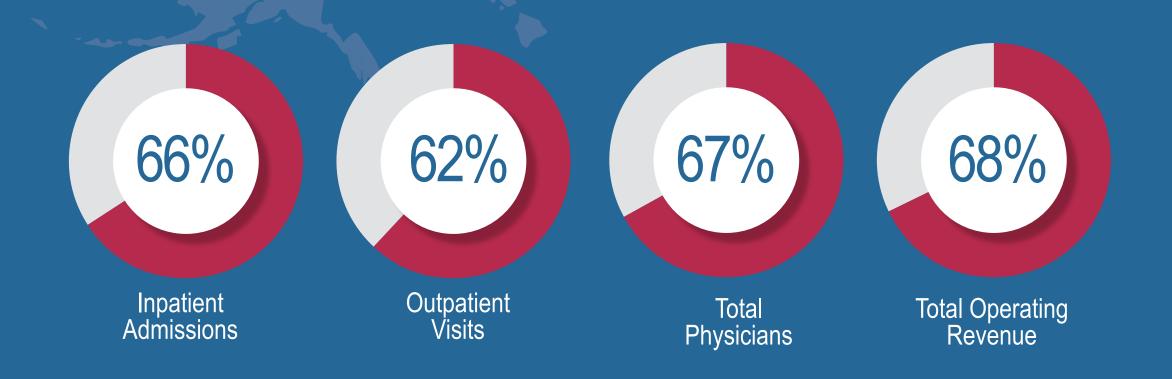
# The Academy The Health Management Academy

The Health Management Academy (The Academy) brings together health system leaders and innovators to collectively address the industry's biggest challenges and opportunities. By assisting member executives to cultivate their peer networks, understand key trends, develop next-generation leaders, and partner to self-disrupt, they are better positioned to transform healthcare.



500+ C-suite Executives

2,000+ Health System Leaders



### **CSI Specialty Group**

The Academy extends its appreciation to CSI Specialty Group for their collaboration on this project.

CSI Specialty Group is a globally recognized leadership consulting firm dedicated to delivering solutions that continually elevate the specialty pharmacy and manufacturing industries. By providing innovative consulting, workforce planning, and talent acquisition solutions, CSI Specialty Group uniquely tailors their service offerings to help clients drive sustainable, accelerated growth. The industry-leading consulting group is at the forefront of pioneering concepts to meet the changing needs of specialty pharmacy, home infusion, mail order/PBM, health systems, manufacturing, and pharmacy/biotech clients across the USA and throughout Europe. Each year, CSI publishes an annual State of Specialty Pharmacy Report. The report describes trends, opinions, and predictions for the future of specialty pharmacy, with key findings segmented by manufacturers, health system specialty pharmacies, independent specialty pharmacies, and payors.

Click here for a copy of the **2019 report**. For more information, please visit CSIgroup.net.

