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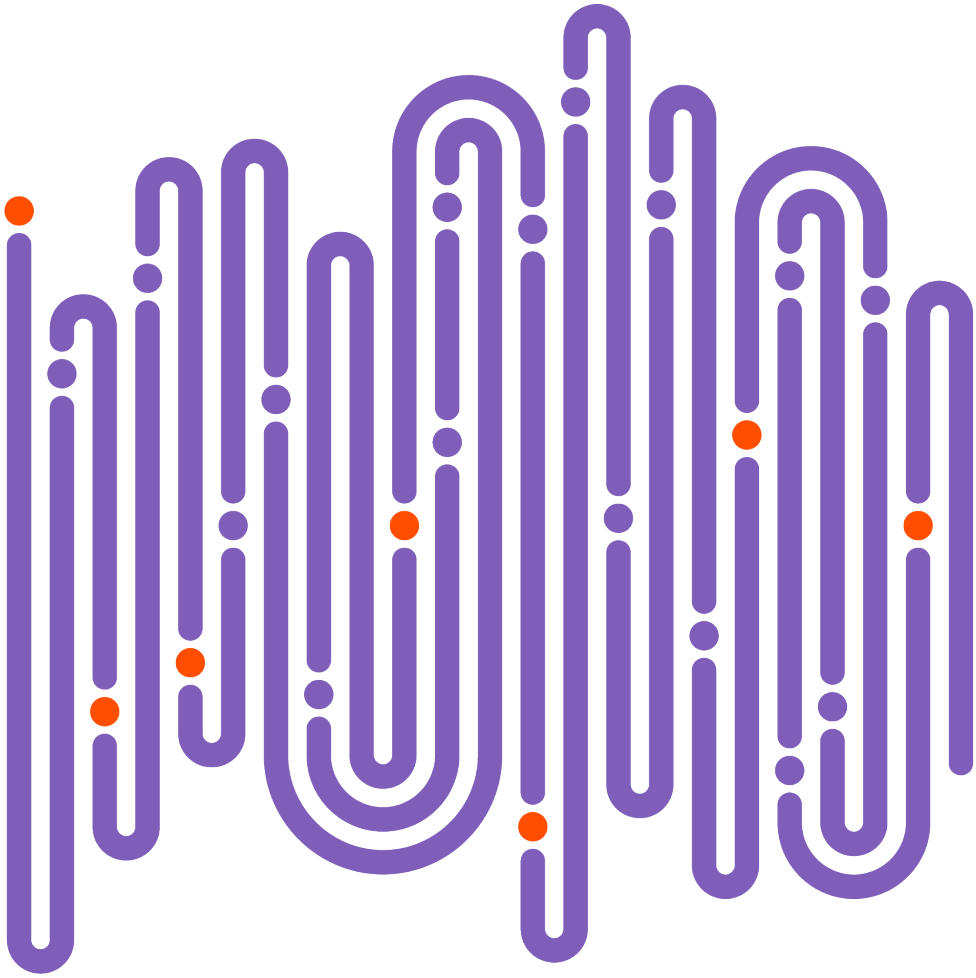
Ambulatory Practice Development Committee

Health System Specialty Pharmacy Limited Drug Distribution and Payor Network Experience Survey Report

Pharmacy Network

February 2021



Primary authors

Ashley McCracken, PharmD, MBA
Clinical Pharmacy Project Manager
Johns Hopkins Home Care Group

Scott Canfield, PharmD, CSP
Assistant Director, Clinical Program Development
Johns Hopkins Home Care Group

Workgroup contributors

Rebekah Hanson Anguiano, PharmD, BCPS, BCACP
Clinical Coordinator, Specialty Pharmacy Services
University of Illinois Hospital and Health Sciences System

Stephanie Barrus, PharmD
Pharmacy Supervisor
University of Utah Health

Michaela Heysler, PharmD, CSP
Manager, Specialty Pharmacy
The University of Vermont Medical Center

Jacob Jolly, PharmD, MMHC
Principal Consultant, Blue Fin Group
Previously Director of Market Access and Strategy at Vanderbilt University Medical Center

Sarah Lorenzen, PharmD, BCACP, CSP
Specialty Pharmacy Manager
The University of Toledo Medical Center

Matthew Rim, PharmD, MS
Associate Director of Specialty Pharmacy Services
UI Health, University of Illinois at Chicago
Previously Manager at University of Utah Health

Regina Schomberg, PharmD, BCPS
System Director II, Retail and Specialty Pharmacy Services
Wake Forest Baptist Health

Rushabh Shah, PharmD, MBA, AAHIVP, CSP
Pharmacy Director Associate, Specialty Pharmacy Services
UK HealthCare

Patrick Sorgen, PharmD, CSP
Manager, Specialty Pharmacy, Melvin and Bren Simon Cancer Center
IU Health

Martha Stutsky, PharmD, BCPS
Manager, Ambulatory and Specialty Clinical Pharmacy Services
Yale New Haven Hospital

Autumn Zuckerman, PharmD, BCPS, CSP
Program Director
Vanderbilt University Medical Center

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Rationale for Vizient member survey

As specialty drugs continue to enter the market, manufacturers and payors have developed strategies to balance patient access and safety along with cost, revenue and reimbursement. One strategy commonly employed by manufacturers within the specialty pharmacy space is the use of limited distribution drug (LDD) networks. LDD networks refer to a distribution model in which the manufacturer only provides drug access to a select number of pharmacies. The requirements and rationale for such networks vary by manufacturer, and the rationale for why a given LDD network is in place for a specialty pharmaceutical is often unclear. Potential reasons for pharmacies to pursue inclusion within a manufacturer LDD network include the desire to provide a consistent level of pharmacy service, improving the patient experience, maintaining internal integration, as well as revenue enhancement.

A similar strategy utilized by payors for cost containment involves restricting their pharmacy network for patients within their health plan, which often includes an emphasis on specialty prescriptions and requirements for members to obtain specialty medications from a single or a small network of preferred specialty pharmacies. Payors may utilize this strategy for reasons similar to manufacturer LDD networks, such as desire to control the consistency and quality of services provided as well as control cost and utilization. Increasingly, these restrictions result in networks in which the preferred or single specialty pharmacy is directly owned by or affiliated with the payor.

As competition and vertical integration continue to increase within the specialty pharmacy industry, specialty pharmacies within health systems face growing pressure to increase or maintain access to both LDD networks from manufacturers and restricted specialty pharmacy networks from payors.

The Ambulatory Practice Development (APD) Committee chartered a project to evaluate the current state of LDD and payor network navigation within health system specialty pharmacy practice. This document provides the synthesized data obtained from specialty pharmacies across the consortium.

Importance to Vizient members

The APD Committee's goal in compiling this survey is to understand the current state of specialty medication and payor network access across member organizations' specialty pharmacies, while helping member organizations learn and benefit from each other's strengths and best practices. The survey results are intended to provide guidance to the Vizient Consortium network members on potential areas of focus for LDD and payor network strategy development and highlight key areas of success for member organizations.

The data from this survey can provide members a current state benchmark to identify where their practices align or differ from peer experiences and assist in developing or modifying tactics used when pursuing access to LDD and restricted payor networks.

Survey methods

For this survey, specific committee members formed a project workgroup made up of leaders and clinicians within health system ambulatory and specialty pharmacy practice with experience in LDD and payor network navigation. Leveraging experience of the project workgroup, a 27-question survey was designed focusing on three specific themes: (1) specialty pharmacy demographics, (2) LDD experience and strategy, and (3) payor network experience and strategy.

The survey was built within Vizient's Qualtrics platform and was promoted for participation by Vizient's Pharmacy Network Community digital platform, containing 425 organizations, in January 2020. In February 2020, the survey was closed and data collated for workgroup summary and review. Responses were not anonymous, and any duplicate responses were reconciled and consolidated into one response through feedback of institution representatives. Respondents were not required to answer all questions.

Background

Demographics

Twenty-five health systems with established specialty pharmacies responded to the survey. The majority of respondents have a leadership position within health system specialty pharmacy practice. Geographically, respondents were located across the United States, including Southeast (11), Midwest (9), Northeast (8) and West (3). All specialty pharmacy programs were established between 2008 and 2018. Sixty-eight percent (17) of pharmacies reported current or in process URAC accreditation, with several sites having obtained or planned to obtain additional accreditation designations with Accreditation Commission of Health Care (16), The Joint Commission 16% (4), and Center for Pharmacy Practice Accreditation 4% (1).

Specialty medication access

When asked what percent of specialty medications they could fill themselves if their pharmacy received a referral first, most sites (84%) stated a range between 25-75% (Chart 1, page 6). When the pharmacy was unable to fill a specialty prescription, respondents estimated that 78% of the time it was due to payor network restrictions, 15% from product access or LDD restrictions, while the remaining 7% were due to other factors such as geographic location and licensing (Table 1, page 6).

Chart 1: Approximately what percent of specialty medications prescribed at your institution are you able to fill if your pharmacy receives the referral first?

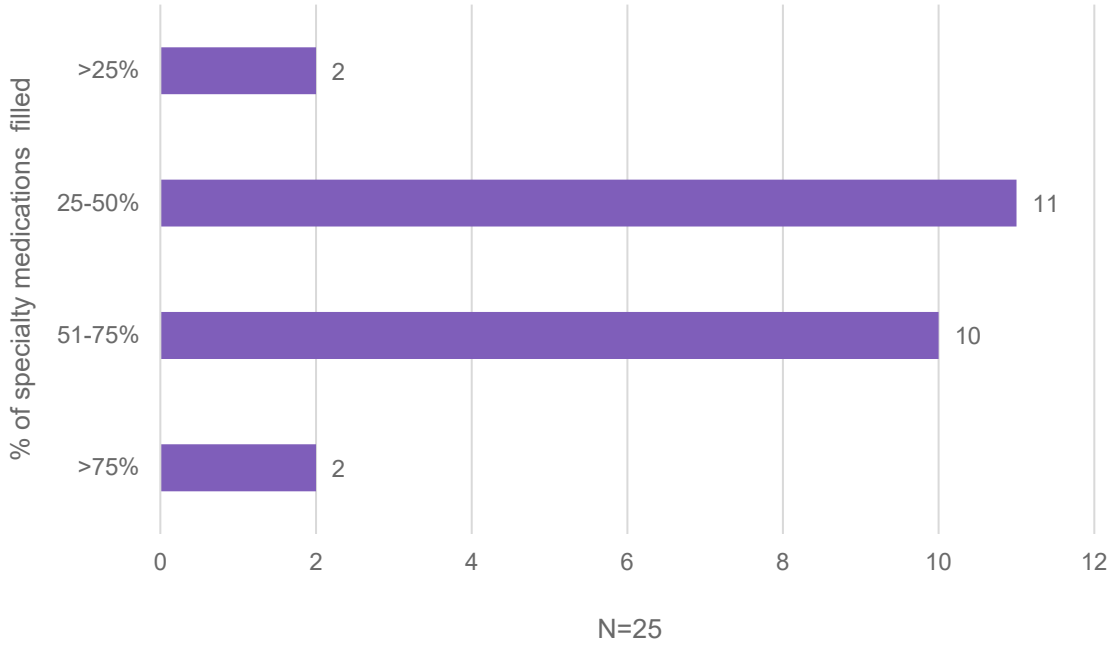


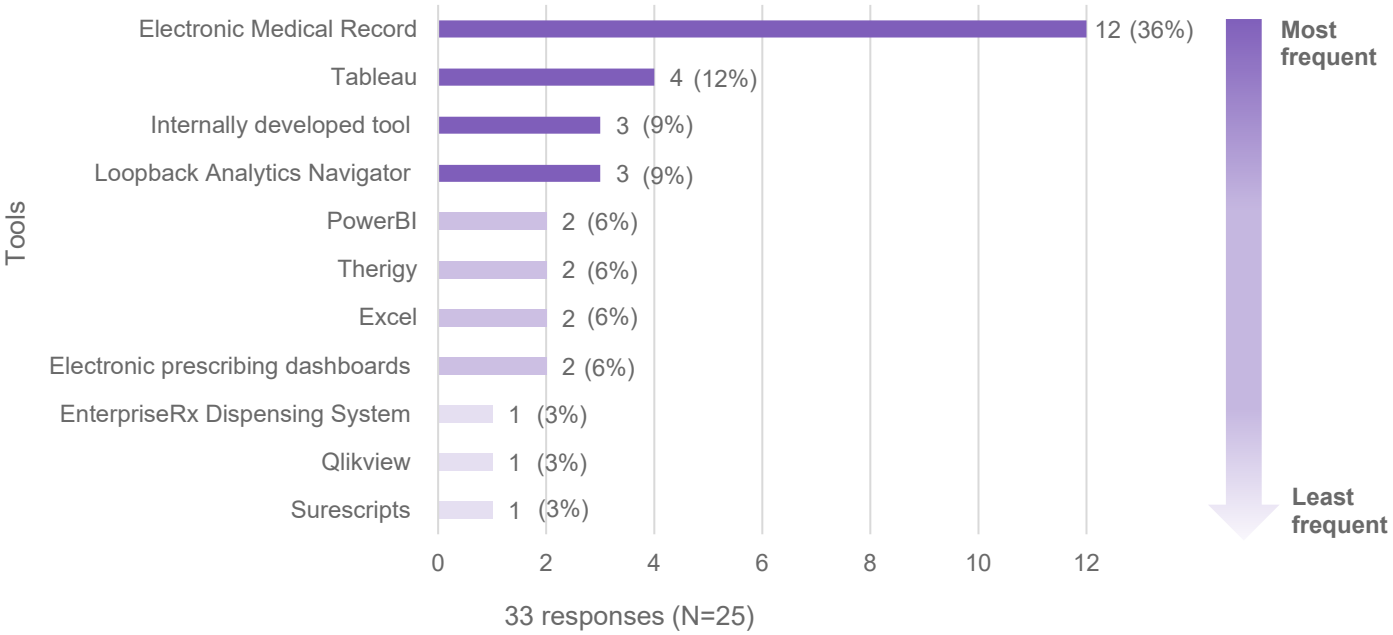
Table 1: For referrals where you are unable to fill specialty prescriptions at your institution, what % of cases are due to inability to purchase drug (e.g., LDD restriction) versus inability to dispense due to insurance restriction?

Reason	N=25	Average % of unable to fill	Range
Product access or LDD	25	15%	5-50%
Payor network restrictions	25	78%	30-90%
Other (e.g., geographic location, licensing)	18	7%	0-55%

Clinical services

Tracking and trending current specialty prescription trends and capture rates within health systems is important to delineate the scope and impact of pharmacy services. The survey identified that sites commonly utilize prescription tracking via an electronic medical record (EMR) (48%) with a variation of data tracking software (Chart 2).

Chart 2: What tool(s) do you use to track specialty prescription trends and capture rates within your health system? Examples include: Automatic tracking via EMR, ad hoc reporting, no standardized reporting, etc. (check all that apply)



Many of these manufacturer and payor restrictions have a multifaceted impact on institutions. Thus, it was important to identify from an institutional perspective what disease states are most impacted both clinically and financially by access barriers and restrictions (Table 2).

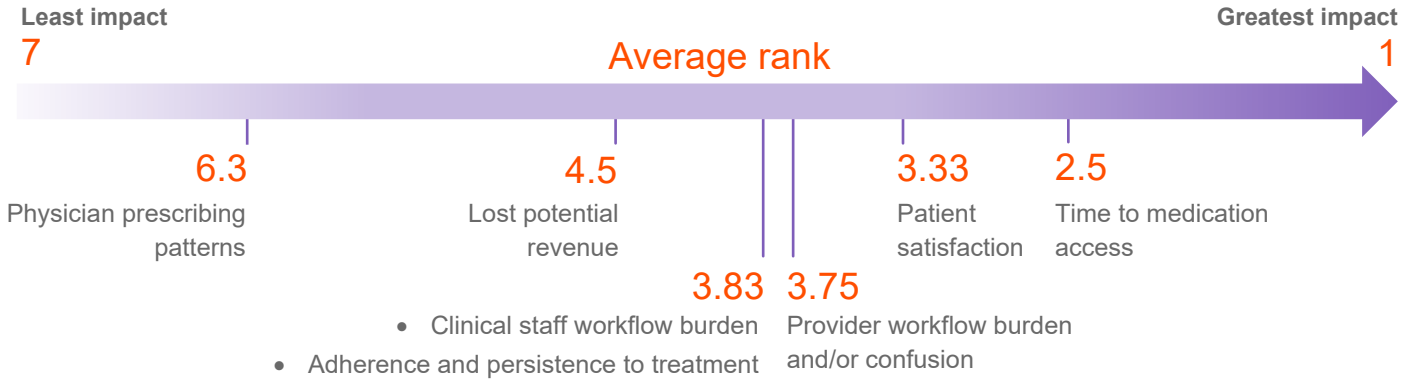
Table 2: Within which of the following disease states has lack of LDD and/or payor access had the greatest financial and clinical impact on your institution (check one)?

Clinical impact (N = 25)	Disease state	Financial impact (N = 25)
++++++	Oncology	$$$$$$
+++	Pulmonary Hypertension	$$$
+	Neurology (e.g., Multiple Sclerosis)	$
+	Cystic Fibrosis	$$
+	Inflammatory diseases	$
++	Ultra-orphan categories (e.g., genetic medicine)	
+	Other	

Key: + = 2 responses $ = 2 responses

When further assessing the clinical and financial impacts on an institution, surveyed pharmacies were asked to identify where their health system experiences the greatest impact when they are unable to dispense for a specialty patient due to either manufacturer restrictions or payor carve outs. Average ranking was calculated on a scale of 1 to 7, with one being the most frequently provided reason (Diagram 1).

Diagram 1: Rank the following regarding the impact your health system experiences due to the inability of your specialty pharmacy to dispense restricted medications due to either manufacturer restrictions or payor carve outs



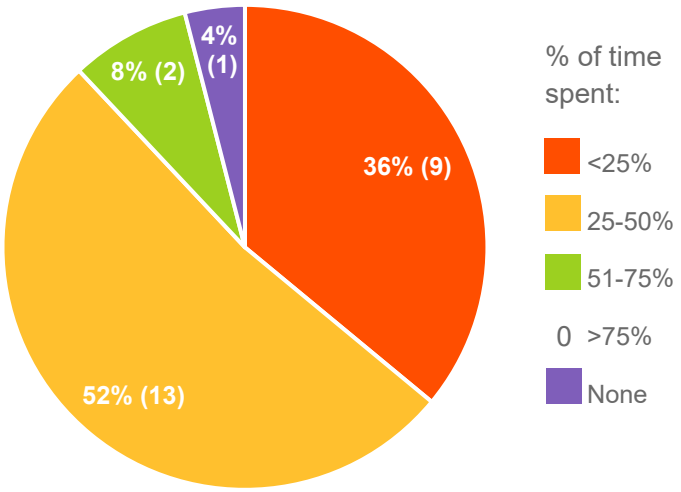
N=24

Due to manufacturer and payor restrictions, health system specialty pharmacies are unable to fill some prescriptions referred to their services. However, in many instances these integrated pharmacy programs provide support to patients and clinic team members even if they cannot fill the prescription. All pharmacies surveyed, 100% (N=22), continue to provide medication access and affordability navigation services regardless of ability to fill (e.g., prior authorizations, copay assistance navigation, etc.), 77% (N=17) provide initial patient education, and 45% (N=10) clinically manage and monitor these patients (Table 3). All of these clinical and financial services are associated with a significant amount of time (Chart 3, page 9).

Table 3: What kind of support does your specialty pharmacy provide to clinics and patients if your pharmacy CANNOT fill due to LDD and/or payor restrictions? (check all that apply question)

Support	N=22
Medication access and affordability navigation (e.g., Prior authorizations, manufacturer copay cards)	22 (100%)
Initial patient education	17 (77%)
Longitudinal clinical management and/or monitoring	10 (45%)
None	2 (9%)

Chart 3: Please estimate the amount of time, on average, specialty pharmacists within your institution spend on managing access, adherence, safety and efficacy monitoring for patients that do not have drug dispensed through your specialty pharmacy.



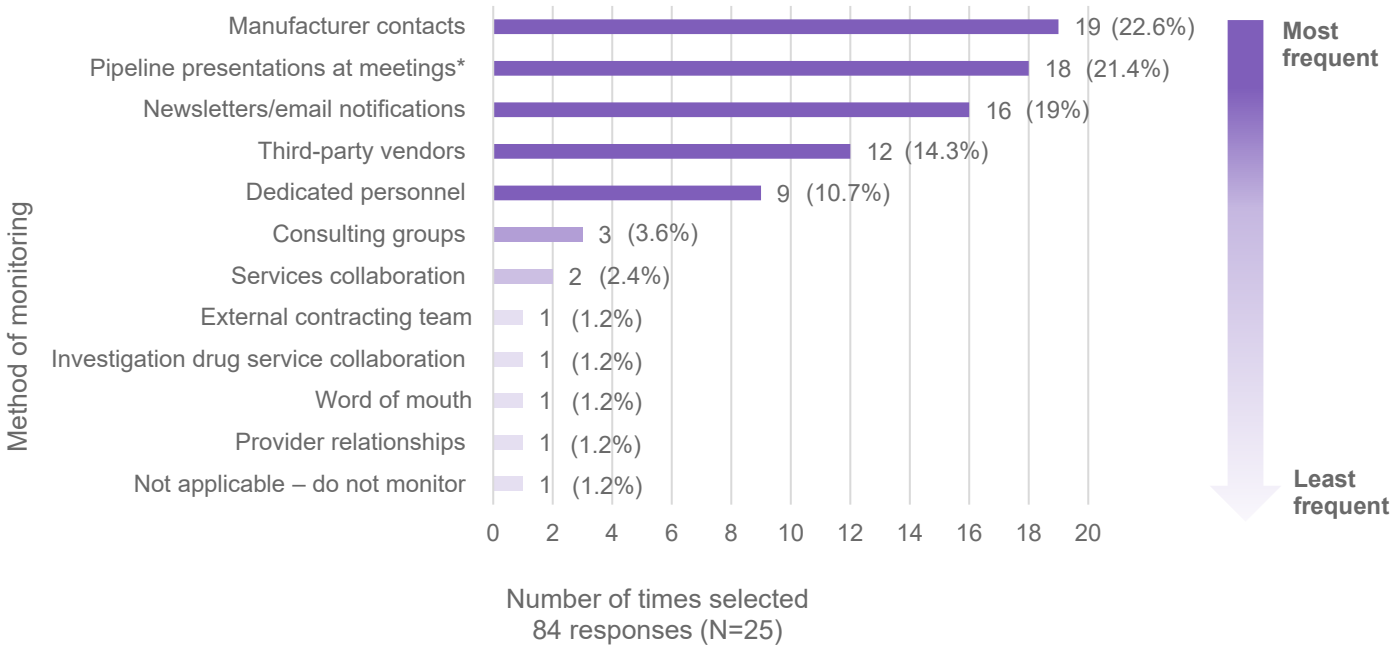
N=25

Pipeline tracking and trending

With the continued expansion and evolution of the specialty market, it is imperative that institutions stay up to date on the newest medications introduced to the market to ensure early discussions with manufacturers and payors. This proactive approach facilitates a seamless transition into operations once the medication is available. The top five methods institutions endorsed as the most beneficial to routinely monitor new/pipeline drug products and approvals include (Chart 4):

1. Leveraging manufacturer contacts
2. Attending pipeline presentations at meetings such as Asembia Specialty Summit, NASP, etc.
3. Newsletters and email notifications from manufacturers and market monitoring companies
4. Third-party vendors
5. Having dedicated personnel on staff

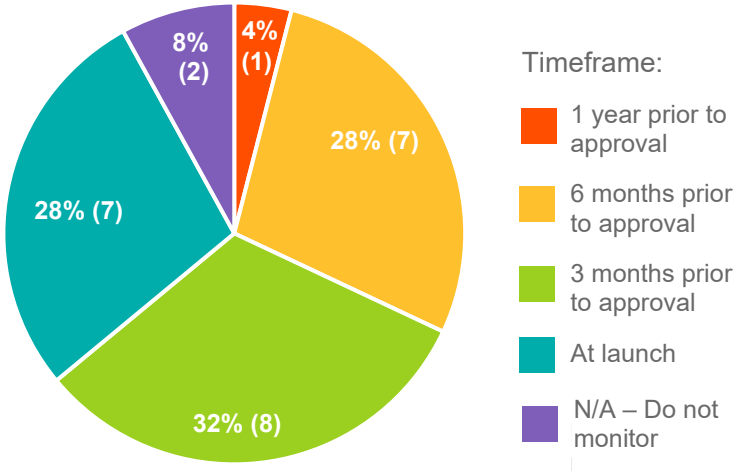
Chart 4: Which of the following does your institution use to routinely monitor new/pipeline drug products and approvals to determine the presence of limited distribution networks or restrictions? (check all that apply question)



* e.g., Asembia Summit, NASP

The period in which institutions monitor the pharmaceutical pipeline for new specialty drugs is summarized in Chart 5. The majority of institutions identified that they start evaluating pipeline products prior to FDA approval, with most evaluation occurring between 3 - 6 months prior to anticipated FDA action.

Chart 5: On average, what timeframe do you typically start evaluating new/pipeline drug products for potential inclusion within your pharmacy services?



N=25

Manufacturer LDD networks and manufacturer engagement

Obtaining access to dispense a wide variety of specialty products remains a high priority for many health systems. Within this section, we aimed to identify key trends within the intersection of manufacturer LDD networks and health system specialty pharmacy programs.

When asked about the top disease categories impacted by LDD therapies, 22 institutions responded, with 93 drug products or product categories listed (Table 4). Oncology LDD therapies were the most commonly listed, with 13 institutions (59%) listing at least one Bristol Meyers Squib (BMS), formerly Celgene, oncology product including Revlimid® (lenalidomide), Pomalyst® (pomalidomide) or Thalomid® (thalidomide). Pulmonary arterial hypertension and multiple sclerosis were also listed frequently, with 12 (54%) institutions including at least one drug from these categories in their responses. Additional impact from restrictions in cystic fibrosis and a number of other rare diseases are present, but a clear emphasis on the impact of restriction in the areas of oncology, pulmonary arterial hypertension and multiple sclerosis is noted.

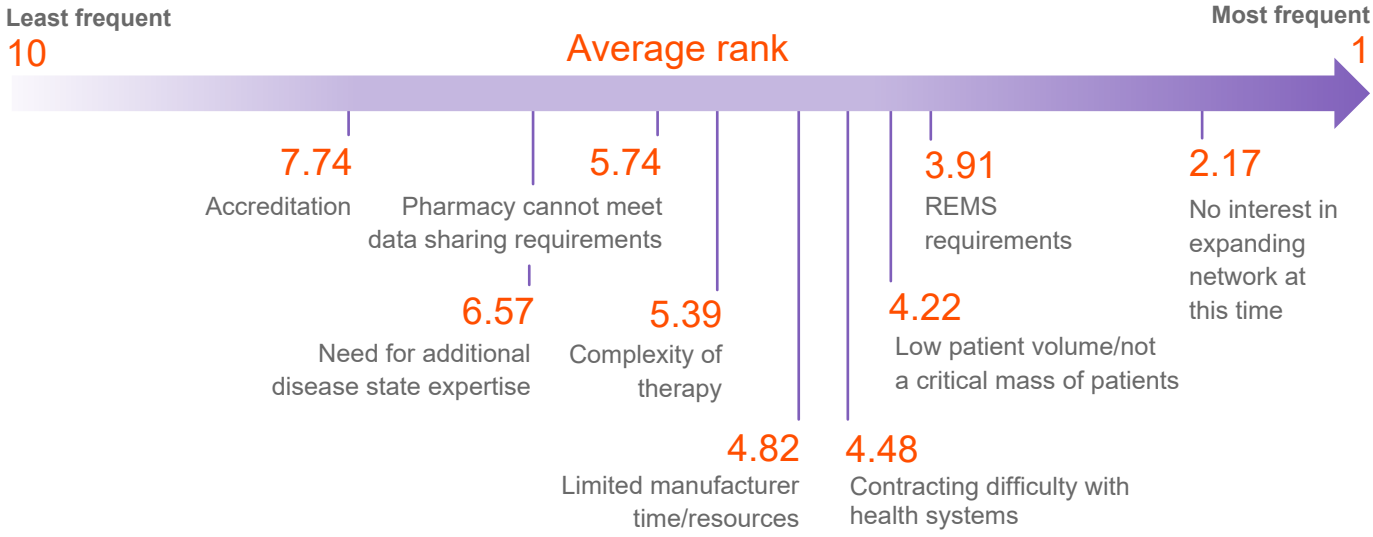
Table 4: What are the top five limited distribution therapies that your pharmacy has not been successful in obtaining access to that have the greatest impact on your institution?

Disease categories and products submitted	Frequency of product listing (N=22) 93 responses
Oncology (Revlimid®, Pomalyst®, Thalomid®, Ibrance®, Lysodren®, Nerlynx®, Venclexta®, Vitrakvi®, Xospata® or Xpovio®)	31
Pulmonary Arterial Hypertension (Adempas®, Letairis®, Opsumit®, Remodulin®, Tracleer®, Tyvaso®, Uptravi®)	23
Multiple Sclerosis (Ampyra®, Aubagio®, Mavenclad®, Gilenya®, Mayzent®, Plegridy®, Tecfidera®, Tysabri®)	18
Cystic Fibrosis (Trikafta®, Orkambi®, Cayston®, Symdeko®, Kalydeco®)	9
Other (Acthar®, Crysvita®, Jynarque®, Natapara®, Ocaliva®)	6
Sickle Cell Anemia (Oxbryta®)	2
Inflammatory Conditions (Kineret®)	2
Parkinson's Disease (no specific therapy listed)	1
Hereditary Angioedema (Haegarda®)	1

Respondents to the survey listed up to five products or disease categories.

For products where health systems have been denied access, we asked institutions to identify and rank some of the common reasons manufacturers provided when communicating a denial of requested access. Twenty-three institutions responded, and the average ranking was calculated on a scale of 1 to 10 with one being the most frequently provided reason (Diagram 2). The most common reason identified was “No interest in expanding network at this time” with an average rank of 2.17. REMS requirements and small patient volume were the second and third most frequent reasons for denying network access. Other less frequent reasons included pharmacies being unable to meet data sharing requirements, not having specific disease state expertise or lack of applicable specialty pharmacy accreditation. Accreditation was likely ranked as less frequent as all institutions who responded to the survey had already achieved specialty accreditation through at least one accrediting body.

Diagram 2: For LDD products where you have attempted to gain access but HAVE NOT yet been successful, rank the following reasons in terms of the frequency at which you are told the following explanations by drug manufacturers for your lack of network inclusion?

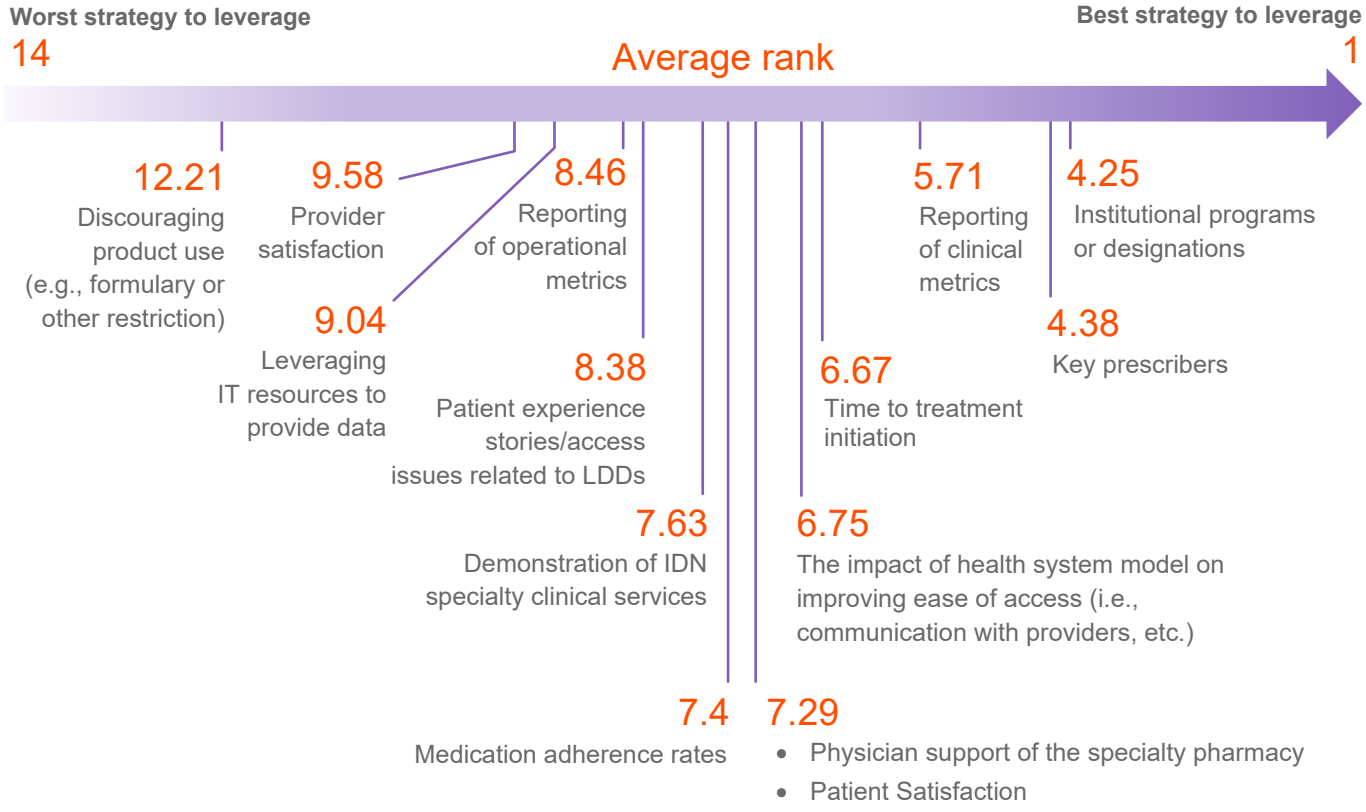


Other (free text) and unranked responses included:
lack of home health capabilities (1 response)

N=23

Twenty-four institutions ranked their top five strategies that pharmacies should leverage to gain access to LDD products. An average ranking was calculated on a scale of 1 to 14 with one being the most frequently provided reason (Diagram 3).

Diagram 3: Rank the top five strategies or data that specialty pharmacies should leverage to gain and maintain access to LDD products



Other (free text) and unranked responses included: demonstrating the impact of health system models on improved outcomes (1 response)

N=24

Respondents reported heavy participation in health system specialty networks and third-party data aggregators such as Asembia, Acentrus and Excelera to support data aggregation requirements within their specialty pharmacy programs (Table 5). A total of 22 institutions (88%) had at least one affiliation with one of these third-party programs surrounding data aggregation, with 3 (12%) respondents reporting multiple affiliations.

Table 5: What external or third-party specialty program helps with data aggregation?

Program	Total institutions (N = 25)
Acentrus alone	10
Asembia alone	8
None	3
Multiple – Excelera + Asembia	2
Excelera alone	1
Multiple – Acentrus + Asembia	1

With the high volume of new specialty medications continuously entering the market, health systems must utilize additional time and resources to track, monitor and strategize access requests. Institutions were asked to estimate the amount of time dedicated to securing access and engaging manufacturers (Table 6a).

Table 6a

Amount of time	Responses (N = 25)
Estimated number of hours per month that an institution dedicates to attempt access to LDD products – median (range)	12 (5 – 160)
Number of institutions with team member(s) responsible for actively engaging with manufacturers with a focus on outpatient/specialty products – no. (%)	17 (68%)

The 17 institutions that endorsed responsible team member(s) for manufacture engagement in Table 6a were also asked to complete the following questions to detail specific resource time by measure of full-time equivalents (FTE):

Table 6b

Amount of time	Responses (N = 17)
As multiple team members may partially contribute time to this task, what would you estimate is the total FTE allotment across team members (e.g., 0.5 FTE, 1 FTE) – median (range)	0.5 (0.1 – 2)
Of the total FTE allotment, what percent of that time comes from individuals outside of your pharmacy management team? (e.g., separate contracting team, purchasing team, consulting groups) – median (range)	5% (0% – 100%)

The payor contracting and engagement experience

Despite the commonly discussed challenges of manufacturer-implemented LDD networks, health system respondents cited payor network restrictions as the primary reason for lack of access to serving patients. Within this section we aimed to identify key trends regarding payor engagement.

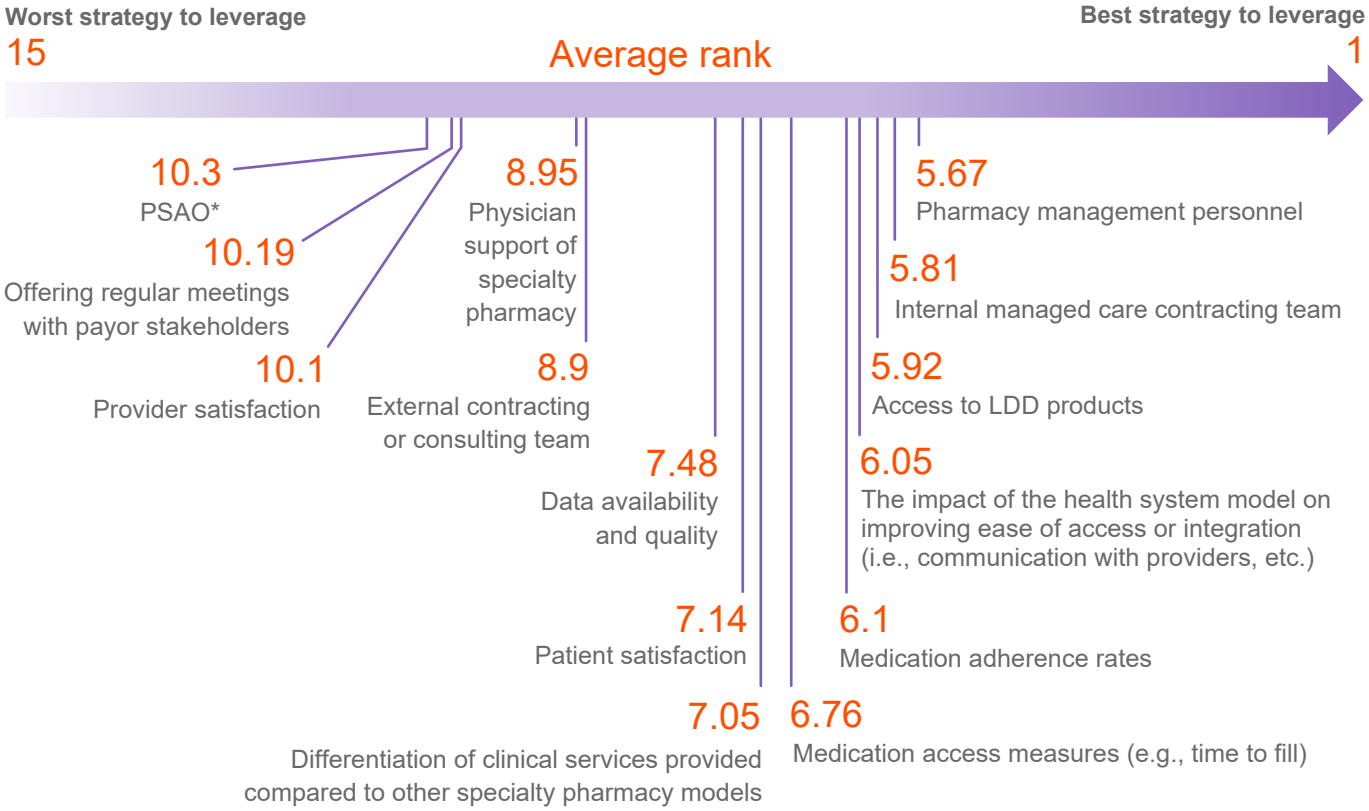
When institutions were asked if they have been successful in obtaining acceptance to formal specialty pharmacy payor networks where they were previously restricted from accessing, 72% (18) indicated at least one instance of successful network inclusion. Of these 18 institutions, 89% (16) noted that data sharing was a requirement to maintain this network access. Payor required data can be challenging to assimilate, report and share as it often requires aggregating data (which may or may not be discretely documented) from multiple systems utilized by the health system specialty pharmacy. Additionally, payors, and manufacturers, may require data to be reported up to multiple times per day or in "real time." Institutions that endorsed data sharing were asked the best mechanism to help share this information as a part of the payor agreement (Table 7).

Table 7: What mechanism(s) do you utilize to share data with the payor as part of your agreement?

Mechanisms	# of times selected N=16
Automated data sharing between pharmacy and payor	11
Manual collection of data by pharmacy collated and sent to payor	5
Other (Free text: Data aggregator)	1

A primary aim of this survey was to provide institutions with a better understanding of how to overcome restricted access to medications and patient lives. The survey listed 15 strategies and asked participants to rank (1 being the best strategy and 15 being the worst) what strategies were most helpful to leverage in payor conversations. The results identified that participants found that there was no single best practice strategy, but a consensus that leveraging one or more may be beneficial when approaching payors. (Diagram 4).

Diagram 4: Rank the top five strategies or data that specialty pharmacies should leverage to gain and maintain access to payor restricted specialty networks



*Pharmacy services administration organization

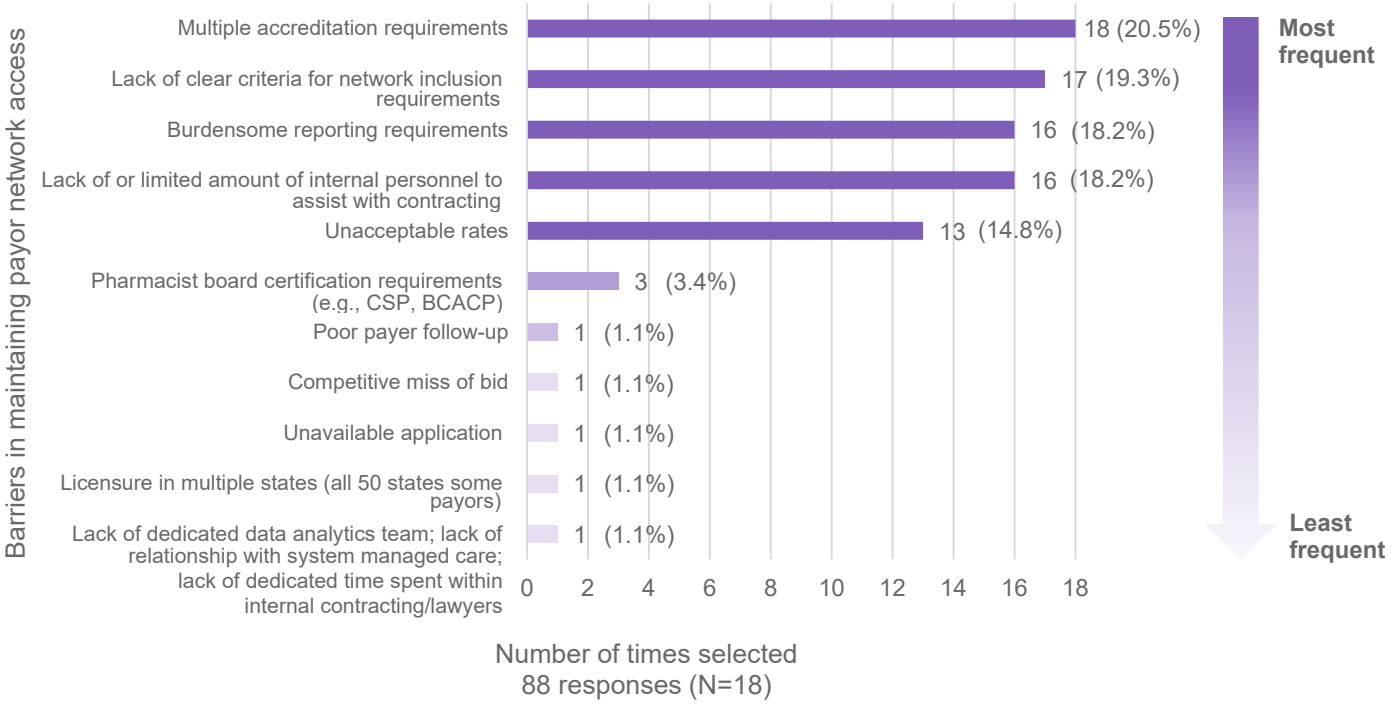
Other (free text) and unranked responses included: cost savings (3 responses)

N=24

Diagram 4 notes that one of the top strategies for obtaining these contracts is having dedicated pharmacy personnel. When sites were asked how much time per month is utilized to secure these payor and manufacturer contracts, a median of 16 hours (range 2-160 hours) was collated from 22 surveyed pharmacies.

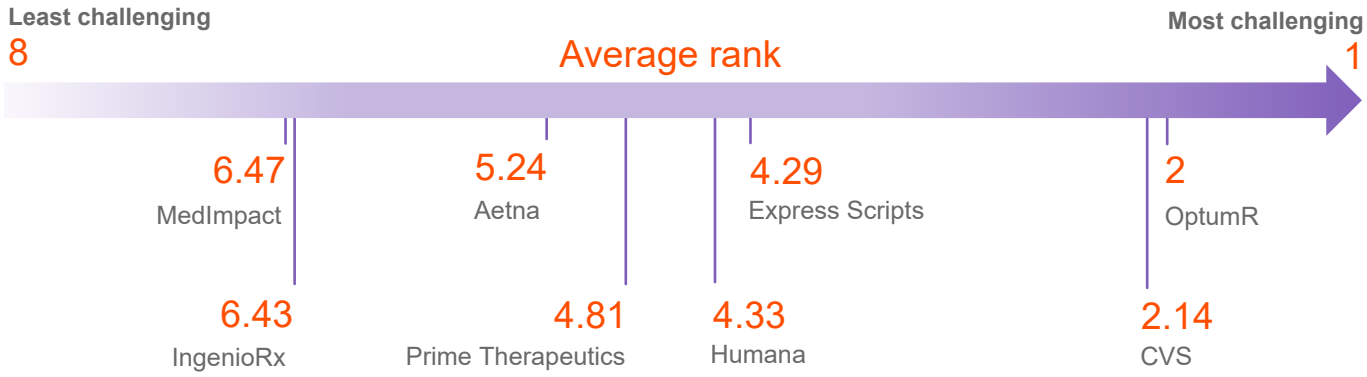
When asked what are the top five barriers in maintaining payor network access, 18 sites reported the number one barrier was multiple accreditation requirements followed by lack of clear criteria for inclusion, burdensome reporting requirements, and lack of or limited amount of internal personnel to assist with contracting (Chart 6).

Chart 6: In terms of obtaining or maintaining payor network access, select the top five hurdles or barriers your institution has recently encountered?



For contracts requiring specialty Pharmacy Business Manager (PBM) credentialing or contracting, survey participants were asked to rank PBMs from 1 to 8 (1 being the most challenging and 8 being the least challenging). Results identified OptumRx and CVS as the most challenging PBMS (Diagram 5).

Diagram 5: For contracts requiring specialty PBM credentialing or contracting, which has presented the most challenges in obtaining or maintaining network access?



N=21

Section summaries and lessons learned

Commentary on LDD findings

A number of specialty products remain challenging for health systems to access due to manufacturer LDD networks, with product restrictions in oncology, pulmonary hypertension and multiple sclerosis being the most commonly experienced. The most frequent reasons for denying network access communicated by manufacturers to health systems included a lack of interest in expanding distribution partners and individual health systems not achieving a critical mass of specific specialty patients. Other more publicly cited reasons manufacturers provide for utilizing LDD networks — such as ensuring appropriate disease expertise, data collection and operational complexity — were not identified as occurring as frequently.

The majority of IDN specialty pharmacy programs are now dedicating some degree of pharmacy resources to actively engage with manufacturers, although the allotment for these activities is typically less than one FTE. Given the robust specialty pipeline and increasing complexity of navigating specialty distribution networks, health systems desiring to gain access to such products should consider evaluating resource needs in this arena. Additionally, health systems are heavily participating with third-party data aggregators and specialty networks, which may provide additional support for manufacturer engagement surrounding limited distribution drugs.

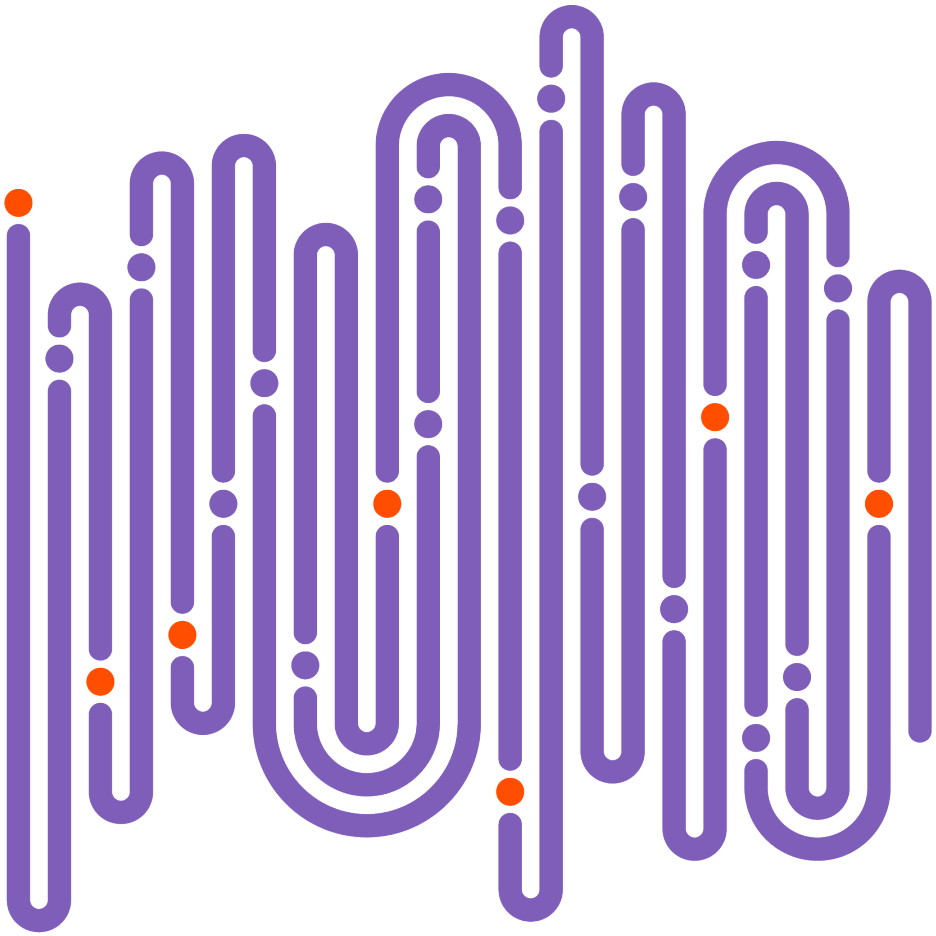
Commentary on payor contracting findings

Despite the challenges identified, many health systems indicated at least one instance of successfully accessing a restricted specialty pharmacy network with a payor. Payor network access appears to often require data sharing, which may be supported by data aggregators. Respondents indicated that leveraging pharmacy management and internal managed care contracting teams were the best strategies to employ when evaluating and negotiating for payor network inclusion. We suspect that these responses indicate a new but growing focus within health system specialty pharmacies on leveraging internal leadership outside of pharmacy for negotiation with payors around specialty pharmacy, while also dedicating pharmacy personnel to help educate, manage and oversee such endeavors. Additionally, we suspect that as continued health system infrastructure is established in this area, strategies such as leveraging the impact health systems have on the ease of navigation, patient access, clinical outcomes and patient/provider satisfaction may become more highly ranked.

Requirements for multiple specialty pharmacy accreditations were consistently identified as a barrier to health system entry into restricted payor networks. This appears to be an active strategy payors utilize to retain use of restricted networks, although the operational or quality improvement benefits of obtaining multiple accreditations are not clear. Alongside the requirement for multiple accreditations, respondents highlighted a lack of clear network requirements and limited resources to review and perform burdensome contracting or data requirements as major challenges to payor network access.

vizient®

Vizient, Inc.
290 E. John Carpenter Freeway
Irving, TX 75062-5146
(800) 842-5146



For more information, contact Karl Matuszewski at (312) 775-4120 or karl.matuszewski@vizientinc.com or Sybil Thomas at (312) 775-4436 or sybil.thomas@vizientinc.com.

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