Visante®

BUSINESS OF PHARMACY™ FORUM

2018 | CHICAGO

IN PARTNERSHIP WITH BD

Introduction

The American healthcare system is under extreme pressure to produce important changes for patient care; however, financial and regulatory burdens put immense pressure on healthcare organizations. Today, medications are the primary treatment modality for 80% of patients and are the fastest growing component of healthcare costs. Medications are central to effective medical care; therefore, pharmacy leaders must play an essential role in reshaping the US healthcare delivery system.

Visante founded the Business of Pharmacy Forum in 2018 to bring together industry leaders to collaborate with peers who face similar challenges and have a broad understanding and distinctive knowledge of the business of pharmacy in the wider context of healthcare.

The Forum's mission is to develop innovative strategies to advance the business of pharmacy in the healthcare marketplace through collaboration among some of the industry's most respected and knowledgeable pharmacy executives.

This Forum was co-sponsored by Becton Dickinson (BD) Hazardous Drug Safety Business, whose mission of advancing the world of health, relies on active collaborations with pharmacy leaders. In addition, new regulations designed to protect healthcare workers and patients as well as expectations for financial and clinical outcomes are adding complexity to the practice of pharmacy. BD was honored to co-sponsor the Business of Pharmacy Forum. The insights provided by these leaders will help BD design solutions to some of the daunting challenges that face pharmacies.

The second Business of Pharmacy Forum brought together 22 pharmacy executives from leading integrated delivery networks (IDNs) across the US for two days of deliberations on solutions to common challenges. The small group sessions allowed extensive candid discussions about urgent problems and potential solutions.

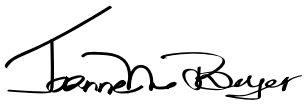
A key element of the small group structure is the ability to network with other leaders who face similar challenges and who understand the realities of working in similar institutions. Participants shared their experiences in small group discussions that allowed in-depth consideration of real-world solutions and the creation of alliances for future mutual exchanges.

A series of polling questions with immediate feedback guided the discussions in each session. The sessions focused on four topics:

- Sterile and non-sterile compounding: patient and healthcare worker safety
- Measurement and management
- Leadership development and succession planning
- Managed care strategies

These discussions have certainly been valuable to the pharmacy executives participating in the Forum, and we hope that this summary report will be a useful resource to executives who were not able to participate.

James Jorgenson
CEO
Visante



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The Business of Pharmacy™

Executive Summary

The Business of Pharmacy Forum's mission is to support development of innovative strategies focused on the unique challenges faced by multi-hospital systems to advance the business of pharmacy in the healthcare marketplace through collaboration among some of the industry's most respected and knowledgeable pharmacy executives. The second Business of Pharmacy Forum brought together 22 pharmacy executives from leading integrated delivery networks (IDNs) across the US for two days of intense and focused small-group discussions on solutions to common challenges. A hallmark of the Forum is the opportunity for networking among leaders who share insights, experiences, and best practices. The sessions, led by Visante Executives, focused on four topics:

- Sterile and Non-Sterile Compounding: Patient and Healthcare Worker Safety
- Measurement and Management
- Leadership Development and Succession Planning
- Managed Care Strategies

Session 1: Sterile and Non-Sterile Compounding

By December 1, 2019 pharmacies that do compounding must be in compliance with the significantly expanded requirements of new standards, including USP <795> for non-sterile compounding, USP <797> for sterile compounding, USP <800> for handling hazardous drugs, and USP <825> for radiopharmaceuticals.

Whether an institution only mixes two liquids together in a week or prepares thousands of chemotherapy doses, all the USP compounding requirements apply. As many as nine agencies, from Centers for Medicare & Medicaid Services (CMS) to The Joint Commission (TJC), may conduct compliance audits with a range of potential interventions. Participants assessed their readiness for compliance and monitoring on the new standards, and described hurdles they faced to meet the December 1, 2019 deadline.

Session 2: Measurement and Management

Participants defined the pharmacy areas that require metrics and discussed their strategies for capturing and presenting metrics for different stakeholders. These metrics fell into three categories: volume (how much is pharmacy producing?), productivity (is the pharmacy workforce effectively meeting this demand?), and outcomes (clinical outcomes, patient satisfaction, and process performance). Participants stressed the need to tease out pharmacy's specific contributions to organizational outcomes and the importance of communicating these outcomes to stakeholders, including the C-suite.

Session 3: Leadership Development and Succession Planning

In a session devoted to executive organizational structures, strategic planning, leadership development, succession planning, and creating a culture of safety, participants assessed where their organizations are on the journey to becoming high reliability organizations.

TJC defines a high reliability organization as: "all people always experience the safest highest quality, best value healthcare across all settings." In pursuit of this aspirational goal, the majority of Forum participants said they spend the greatest proportion of their time on strategic planning, integration, innovation, budgeting, and barrier removal. They stressed the importance of formal leadership development and succession planning for the benefit of their institutions.

Session 4: Managed Care Strategies

Health system pharmacy leaders are getting more actively involved in the management of the employee pharmacy benefit, and implementing strategies to fill more prescriptions in-house. Many Forum participants have been leading this trend and are actively involved in their employee prescription benefit program and demonstrating significant cost savings. Specialty pharmacies are an important element of the employee benefit program, and also an increasingly important financial contributor to health system bottom lines. Forum participants are also "leading by example" in working closely with their health system colleagues in Managed Care Contracting, as well as billing/reimbursement. Many Forum participants are leading another national trend through their high-level of involvement in population health and ACO strategies.

Sterile and Non-Sterile Compounding

The new USP standards due for implementation December 2019 represent major upgrades in attempts to protect patients from sterile compounding contamination and errors but also to protect healthcare workers from exposure to hazardous drugs. These enhanced requirements represent potentially millions of dollars of capital investments for many organizations and it is important to note that these standards continue to evolve every three to four years and move ever closer to Current Good Manufacturing Practice level standards. Participants discussed the need to consider not just the upcoming standards but to create a strategy for sterile and non-sterile compounding that will provide a compliant program that can last for at least the next 10 years without additional major capital investments.

The nation's health system pharmacies face a daunting challenge. Today drug shortages are a perennial problem for pharmacies, and there is strong trend toward in-house compounding to address this issue. However, by December 1, 2019 pharmacies that do compounding must be in compliance with the onerous requirements of newly revised standards, including USP <795> for non-sterile compounding, USP <797> for sterile compounding, and the new standards USP <800> for handling hazardous drugs, and USP <825> for radiopharmaceuticals.

Most institutions will invest millions of dollars to meet the USP compounding requirements to fund changes that span from facility alterations to personal protective equipment. In a session on sterile and non-sterile compounding and patient and healthcare worker safety moderated by Visante executives Greg Burger and Fred Massoomi, participants reviewed the requirements included in each of the new USP standards and discussed their progress toward readiness for the new standards and their concerns about compliance.

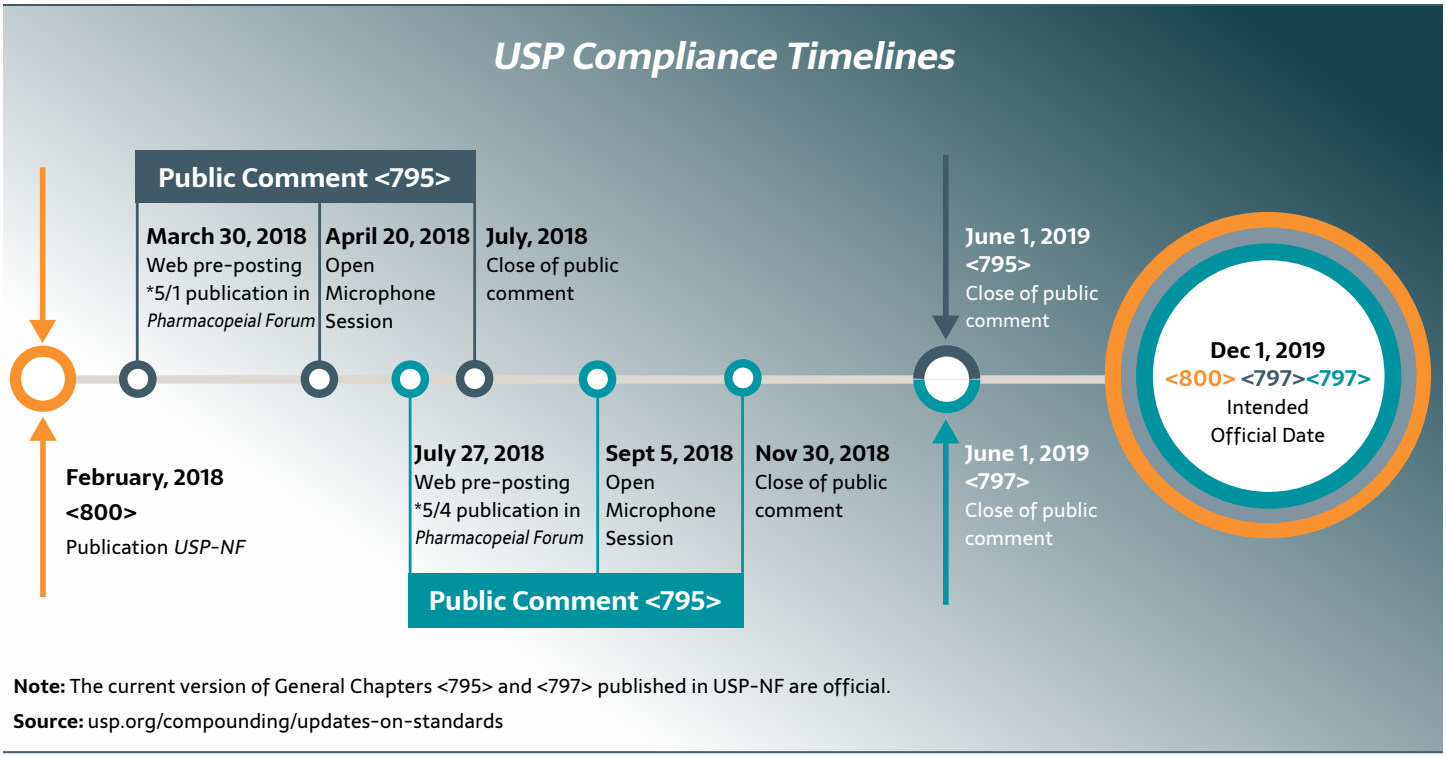
Dr. Massoomi pointed out a regulatory trend moving toward requiring current Good Manufacturing Practice (cGMP) standards, which assure proper design, monitoring, and control of manufacturing processes and facilities. CGMP standards include 124 provisions that differ from USP <797>, of which half of which relate to quality Dr. Massoomi noted. He suggested that facilities consider building toward cGMP compliance. Participants assessed their readiness for compliance and monitoring on the new standards, and described hurdles they faced to meet the December 1, 2019 deadline.

The New, Hidden Chapter

USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging is the newest chapter to USP. The handling of sterile radiopharmaceuticals was a section noted within 2008 USP <797>. The proposed 2019 USP <797> standards have removed this section to create its own chapter. Most IDNs noted unfamiliarity with the new chapter. Dr. Massoomi discussed the need for sites to review this chapter and examine how radiopharmaceuticals are managed within their facilities. Almost all IDN sites outsource these products, however, Dr. Massoomi noted that the burden of compliance with USP <795>, USP <797>, USP <800> and now USP <825>, resides with sites providing patient care. Sites should at a minimum examine how radiopharmaceuticals are handled. Examples of common practices in nuclear pharmacy that may be considered compounding by the USP standards:

Most institutions will invest millions of dollars to meet the USP compounding requirements to fund changes that span from facility alterations to personal protective equipment.

1. **Preparation of a radiopharmaceutical from a manufactured, non-radioactive, radioisotope kit with major deviations from the manufacturer's package insert.** Major deviations are defined as manipulations not included in the manufacturer's package insert (e.g., filtration, etc.), or the addition of other ingredients not included in the manufacturer's package insert (e.g., antioxidants, etc.);



Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

Source: usp.org/compounding/updates-on-standards

2. **Sub-division of a multiple-dose vial of a radiopharmaceutical into aliquots for storage and later use.**
3. **Preparation of non-FDA approved radiopharmaceuticals.** This includes radiopharmaceuticals no longer marketed for reasons not related to safety, radiopharmaceuticals during a shortage, and other situations involving extemporaneous compounding.

USP <795> Non-sterile Compounding

USP <795> non-sterile compounding is the least draconian standard; however, a pharmacy that mixes only two oral liquids together or two ointments/creams together in a day or week must adhere to all of the requirements of the standard. This imposes a burden on pharmacy to comply with requirements such as more stringent standard operating procedures (SOPs), pre-release testing of batched compounds, specific cleaning practices, and documentation, all of which add to workflow and costs. Most locations noted no budgetary assignment for compliance with UPS <795> for the expected compliance date of December 1, 2019. Participants observed that an expert would be needed to do compliance monitoring for USP <795>.

USP <797> Sterile Compounding

Compliance with USP <797> sterile compounding presents specific challenges. While 71% of participants said they were confident that their institutions would be in compliance with USP <797> requirements by the deadline, only 11% were currently meeting sterile USP and state board of pharmacy compounding standards. Others admitted, "We aren't anywhere near where we need to be with sterile compounding."

Under USP <797>, daily cleaning with detergent is required and "no quantity of residue should be visible on the equipment after cleaning procedures are performed." Participants' solutions to the need for high-tech cleaning varied from retaining an outsourced vendor, to using an insourced dedicated and trained technical cleaning crew, or relying on the hospitals' environmental services cleaning, which was considered least reliable due to frequent personnel changes.

A crisis in compliance to USP <797> is occurring due to the lack of technicians trained and certified for sterile compounding.

A crisis in compliance to USP <797> is occurring due to the lack of consistent technicians trained and certified for sterile compounding. The Pharmacy Technician Certification Board (PTCB) announced 300 certifications for this skill. However, the discrepancy in salaries to intensity of work has left sites with a continuous challenge with retaining staff. This leaves compounding responsibilities in the hands of higher paid pharmacists, who may not be trained on the new requirements.

USP <800> Hazardous Drug Compounding

None of the participants said their system was 100% compliant with USP and state board of pharmacy hazardous drug handling standards; but the majority were at least three-quarters compliant. Complex standards under USP <800> for hazardous drug handling apply mostly to the Group 1 Antineoplastic Agents. However, it was noted that, for best practices, all investigational drugs should be deemed "hazardous" until proven otherwise with a manifest from the investigator demonstrating safety during handling.

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The standards define facilities, engineering, and environmental controls, practices for deactivating, decontaminating, cleaning, and disinfecting, extensive documentation and SOPs, as well as monitoring requirements.

For example, rigorous cleaning requirements include a four-step process of deactivation, cleaning, decontamination, and disinfecting, each process using a different solution. And the process must be repeated at a minimum at the end of every shift and between each differing drug preparation with proper dwell time observed.

USP <800> also applies to non-pharmacy locations, such as physicians' offices or hospital-based clinics, where infusions may be compounded by a nurse. This represents a risk for joint ventures between hospitals and off-site hospital infusion centers. The hospital pharmacy will be accountable for USP <800> compliance in those settings.

Devices to Support Compliance

Dr. Massoomi demonstrated two point-of-care rapid monitoring devices to help validate cleaning. Hygeina, which detects adenosine triphosphate (ATP) and present in living organisms, therefore point to bacterial, fungal, or viral surface contamination and alerts staff to reclean the work surface until acceptable levels are achieved. The HD Check provides staff with a validation of cleaning work surfaces by detecting hazardous drug residue (currently methotrexate and doxorubicin). The test takes less than 10 minutes and provides staff with information with regard to work surface contamination with HD residues. The two devices provide compounding locations with immediate and actionable information to enhance the safety of compounding sterile preparation for patients.

Participants also discussed their use of closed system transfer devices (CSTDs), which, under USP <800>, are required for HD administration and are recommended for pharmacy compounding. Most pharmacies and administration sites have adopted CSTDs. Participants debated the criteria for choosing a CSTD, noting that products with the most publications (third-party peer-reviewed studies) are most trusted, while studies funded by manufacturers leave them with questions of bias. Dr. Massoomi recommended that they review the study protocols and methodology to determine if the data are valid. In addition, Dr. Massoomi pointed out that CSTDs are "cleared," rather than "approved," as they are compared to the performance-tested predicate reference standard, BD PhaSeal™.

In some settings, CSTDs also have enabled drug vial optimization (DVO), which avoids waste of expensive drugs in single dose vials that require weight-based dosing by

extending the period of sterility of the drug vial content to the drug's chemical stability, so single dose vials can be used to compound doses for multiple patients, rather than be wasted. However, the FDA has not approved this approach and relies on the drug manufacturers' expiration dates noted within package inserts. TJC has issued a concurring statement.

Demand for Space

The new standards include requirements for pharmacy design, shelving, and space allocation for specific operations. But the standards are complex when applied to each pharmacy situation. Only Massachusetts has set specific room sizes for cleanroom suites in their standards. Pharmacy leaders are hard-pressed to compete for budget and space to meet these standards. "We need a reference to use as support to prove the space we need to meet the regulations," participants said.

Building projects need to anticipate upcoming standards that are not yet law.

Building projects need to anticipate upcoming standards that are not yet law, but it is a challenge to persuade architects and administrators to do so. They do not know the requirements for pharmacy. Details such as the not anticipating growth for storage needs, maxing out existing heating, ventilation, and air conditioning (HVAC) systems or undersizing HVAC systems, the use of wrong casters on carts, and/or, placement of sinks can violate the standards and lead to continuous challenges for departments.

Automation

Most of the hospitals represented use adjuvant automation, such as repeater pumps, thus requiring personnel to manually prepare product. Automation is used routinely in pharmaceutical companies for large quantity manufacturing and new automation can be scaled down for larger hospitals.

Automation has the potential to mitigate human error in hospital compounding operations; however, only a quarter of participants had implemented full sterile compounding automation.

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The group presented pros and cons for automation systems based on their experiences. Some robotic systems keep drugs in an ISO5 controlled environment throughout the process and compound drug into standard plastic syringes. Plastic syringes are not FDA cleared as storage devices, therefore glass syringes would be ideal. Currently, the transition from plastic to glass will add cost to each dose (estimated at $4 to $8 per dose), which makes this transition difficult to justify this early in the process. Furthermore, robotics must be thoroughly cleaned and decontaminated routinely to avoid cross-contamination of drug products. An advantage is that one technician can manage multiple robots, participants said. In a nationwide survey, robots were reported to either increase or produce no change in the number of full-time equivalents (FTEs) required in pharmacy.

Intravenous Workflow Systems

The Institute for Safe Medical Practices (ISMP) highly recommends the use of intravenous (IV) workflow systems, which can be used to compound anything from high-risk, high-cost medications to single-drug antibiotics and even oral medications through a combination of manual and automated steps. However, fewer than half of participants had adopted systems such as Pyxis™ IV Prep, DoseEdge, PharmacyKeeper, i.v.SOFT® Assist.

While many systems share common functionality, the implementation details and vendor approach to sterile compounding operations can vary widely. Participants discussed some of the workarounds that limit the effectiveness of IV workflow systems. Others reported that such systems had been acquired but were sitting idle. The lack of staff to customize and build systems was noted as resultant delay.

Outsourcing to 503B Entities

Almost all (94%) of participants currently use an outsourcing manufacturer to supplement sterile compounding; but only 12% expressed confidence in the current outsource manufacturing 503B market with regards to safety, while 59% were neutral. Participants cautioned that the pharmacy must drive the contract with the vendor to a required quality and delivery. They stressed the importance of vetting the backgrounds of the people running the business and setting clear expectations for the operation and relationship. From a legal and The Joint Commission perspective, hospitals are responsible for the services provided to patients from an outsourced vendor, they noted.

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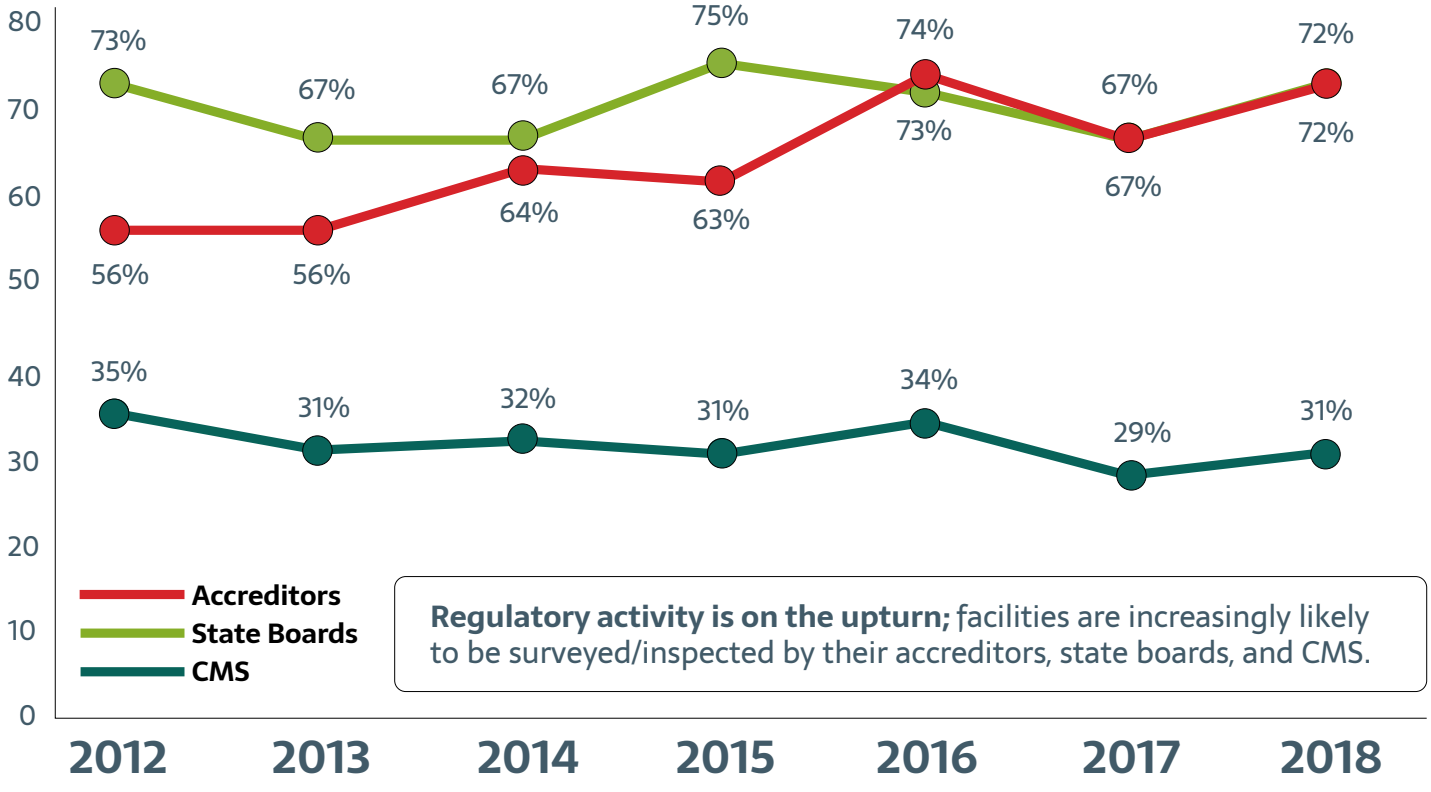
Ready-to-use Formulations

The pressure to ensure sterility and patient safety is driving many hospitals to source drugs in commercially available ready-to-use (RTU) formats, and this trend is likely to increase in the future. However, RTU drugs can be costly and have significant budget impacts. Frozen RTU drugs have to be labeled with beyond-use dating (BUD) when thawed. However, participants said it is easier to monitor these processes than to comply with the estimated 21 critical steps required for compounding a single sterile dose.

Regulatory Oversight

A plethora of agencies hold a stake in monitoring compounding compliance, creating challenges for IDN pharmacies.

Recent Regulatory Inspections



Regulatory activity is on the upturn; facilities are increasingly likely to be surveyed/inspected by their accreditors, state boards, and CMS.

Note: Does not include FDA investigations.

Compliance audits may come from:

- FDA: Food and Drug Administration
- State Boards of Pharmacy
- CMS: Centers for Medicaid and Medicare Services
- The Joint Commission
- Det Norske Veritas Healthcare, Inc. (DNV Healthcare)
- HFAP: AOA's Healthcare Facilities Accreditation Program
- ACHC: Accreditation Commission for Healthcare
- NABP: National Association Boards of Pharmacy
- PCAB: Pharmacy Compounding Accreditation Board

The FDA has taken a risk-based approach to facilities, so those with higher compounding volumes or with even minor violations may expect stringent scrutiny and repeated compliance audits. The agency also restricts the compounding of FDA-approved copies, driving pharmacies to use FDA-approved commercial products rather than compounding them in-house. It is important to note that this transition is a key safety expectation by FDA regardless of the costs.

Institutions with 503A compounding pharmacies are closely-monitored and may be forced into 503B compliance based on volumes and scope of services. With 503B compounding manufacturers compounding expectations differ from 503A, specifically the requirement that every concentration that is made must be validated and tested for sterility, stability and leachability of the storage device(s). 503B facilities are required to use cGMP used for pharmaceutical manufacturers, however, a new FDA guidance document is in the process to be finalized in 2018.

The uncertainty of FDA guidance documents may require increased capital outlay, operational, facility and product changes which may lead to shortages. These changes may lead to an increase in FDA 483 observations, warning letters, pushing existing 503B entities out of business, participants noted. IDNs and hospitals are exploring the development of 503B business entities and sites must be realistic to the expectations of FDA, where, greater than 50% of the staff must be devoted to quality control.

The FDA has asserted its enforcement authority and has partnered with State Boards of Health, who have adopted the USP standards for non-503B facilities. With increased enforcement and regulatory scrutiny over sterile compounding, IDN pharmacy leaders are reconsidering sustainable compounding models that can meet stakeholders' needs while protecting patients and healthcare workers. They reviewed the new regulations and examples of enforcement actions, which can be punitive.

Sites that have had the misfortune of a FDA inspection have noted high expectations of institutions for the day-to-day workflow, which makes compliance a daunting task. They noted that USP sets minimum standards, which change every three to five years. The complexity of USP requires at least one and maybe more FTEs to be assigned to compliance for compounding, pharmacy leaders concluded.

FDA has developed and published greater than 25 'guidance' documents with regards to sterile compounding since 2013. "FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required." One key guidance presented was the Insanitary Conditions at Compounding Facilities document, which clearly list "all" sites compounding sterile products. The governance for the safety of compounded drugs for patients resides with FDA and guidance documents should be incorporated into IDN compliance strategies for compliance and best practices.

Key Documents Sites Must Review

- USP <795> Pharmaceutical Compounding—Non-Sterile Preparations (proposed): http://www.usp.org/compounding/general-chapter-795
- USP <797> Pharmaceutical Compounding – Sterile Preparations (proposed): http://www.usp.org/compounding/general-chapter-797
- USP <800> Hazardous Drugs—Handling in Healthcare Settings (proposed): http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare
- USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (proposed): http://www.usp.org/chemical-medicines/general-chapter-825
- FDA Guidance Document: Insanitary Conditions at Compounding Facilities—Guidance for Industry (NEW as of September 25, 2018): https://www.fda.gov/downloads/Drugs

Measurement and Management

Collectively the annual drug spend represented by the Business of Pharmacy participant organizations represented half a trillion dollars. Participants are managing operations that, if broken out of the larger health system and viewed as standalone entities, would be akin to midsized US corporations. Despite the magnitude of the pharmacy operations, participants noted that almost universally the essential data and analytics support to effectively understand and manage this business are lacking and there is no recognized metrics system that effectively trends and tracks volume, productivity and outcomes.

Hospital pharmacies have evolved from being inpatient, acute-care, cost centers to serving as a hub for complex operations that include outpatient services, retail and specialty pharmacies, and numerous clinical services that impact both clinical outcomes and system-wide financial outcomes.

Pharmacy leaders require reliable metrics to assess and report the performance of their organizations and the contributions of pharmacy activities to health system financial and clinical outcomes.

Pharmacy leaders have growing accountability for managing these multi-million-dollar operations where large staffs perform highly-regulated and complex processes. Ultimately, they are accountable for contributing to achievement of the clinical and financial goals of the health system, while facing increasing budgetary constraints.

Pharmacy leaders require reliable metrics to assess and report the performance of their organizations and the contributions of pharmacy activities to health system financial and clinical outcomes. These data provide the evidence for how pharmacy resources are allocated and what return on investment is generated. Furthermore, such metrics help identify opportunities for performance improvement or explain the clinical and financial rationale for adding new service offerings.

Data collection and analysis for productivity metrics pose substantial hurdles for pharmacy leadership, as most pharmacies must rely on system-generated "canned" reports. Most participants indicated that one or two FTEs are required to prepare performance metrics, but some said they need more than four. Pharmacy leaders are typically running multiple distinct business lines (e.g., inpatient, sterile products, clinical services, retail pharmacy, specialty pharmacy, mail order, health plan prescription benefits, etc.) that require data analytics for effective operational, clinical and financial outcomes tracking and trending.

The primary challenges in obtaining data for metrics include a lack of analyst resources and lack of data access. Even when analysts are on staff, they may have to access as many as 10 different data systems to obtain reports for key process metrics. "We are data rich but information poor," participants advised.

"We are data rich but information poor."

Some participants rely on electronic health record (EHR) systems, such as EPIC or CERNER, to capture retail-level pharmacy data. Healthcare institutions have invested substantially in EHR systems and want to leverage them as much as possible; however, these are not pharmacy-based systems and have limitations for tracking pharmacy applications. Most systems benchmarked key metrics both internally within the health system and externally (88%), while the remainder used only internal comparisons. Participants advocated that the Forum identify and publish what the validated, reliable metrics are for a high-performing pharmacy. They expressed a strong need for national benchmarking standards that they could reference, based on matching criteria to their institution.

Pharmacy Services Require Metrics

While participants acknowledged that outcomes are affected by many parts of their organizations, they stressed the need to measure and communicate pharmacy's specific contributions to important organizational outcomes. Participants defined the pharmacy service areas that require metrics, including:

- **Inpatient Operations**
  - Central
  - Decentral
- **Sterile Products**
  - Home infusion
- **Clinical Services**
  - Acute care
  - Ambulatory
  - Transitions of care
- **Outpatient Pharmacy Services**
  - Retail
  - Mail order
  - Specialty pharmacy

Pharmacy leaders also need access to metrics related to system-wide activities, including supply chain, regulatory compliance for controlled substances and diversion prevention, medication safety, education and training, credentialing and privileging, among others. Pharmacy metrics ultimately must be integrated into finance, billing, revenue cycle operations.

As an example, participants observed that finance departments often do not understand the nuances of pharmacy finance, especially within revenue cycle management and 340B programs, or perhaps they don't have the resource capacity, expertise or priority over other health system charge types. This lack of insight may cause profitable drug contracting opportunities to be overlooked. Pharmacy often does not have visibility to write-offs, billing, and reimbursement data, and this may reduce pharmacy and system revenue. In addition, other considerations must be factored into activities that affect system-wide measures, such as value-based purchasing, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), patient satisfaction surveys, population health, hospital-acquired infections, and readmissions, among others.

Finance departments often do not understand the nuances of pharmacy finance, especially within revenue cycle management and 340B programs, or perhaps they don't have the resource capacity, expertise or priority over other health system charge types.

Pharmacy leaders expressed frustration at not having access to essential data, facing substantial delays to get data, and having to access numerous (up to 10) systems to obtain system-generated reports for the key process metrics.

Access to data for key pharmacy metrics is an area of particular challenge. Pharmacy leaders expressed frustration at not having access to essential data, facing substantial delays to get data, and having to access numerous (up to 10) systems to obtain system-generated reports for the key process metrics.

The metrics that participants defined as essential fell into three categories:

1. **Volume**—How much is pharmacy producing?
2. **Productivity**—Is the pharmacy workforce effectively meeting this demand?
3. **Outcomes**—Return on the pharmacy investment: Clinical and financial outcomes, patient satisfaction, process performance.

Volume Metrics

The majority of participants had identified the key processes performed by pharmacy, focusing on those activities that constitute the major elements of pharmacy's

medication order/preparation and dispensing-related work which consume the majority of pharmacy resources, such as order verification, sterile product preparation and ADC restocking and management.

The majority reported that they had policies, procedures, and/or SOPs defined for most key processes, but only some of the processes were defined in a visual map. The frequency of review for these documents varied widely from three to 24 months. The discussants saw a clear distinction between policies and procedures. A policy is a more formal statement required for legal and regulatory purposes; however, policies must mirror practice, therefore, participants advised that policies should be very broad and open to accommodate different procedures. In contrast, SOPs define the step-by-step instructions to carry out complex pharmacy operations on a routine basis.

While 60% of participants had defined volume metrics for most of the key processes and most report these data monthly (76%) or quarterly (24%), the process of obtaining the data is challenging, relying on manual data collection, system-generated "canned" reports, or custom system-generated reports.

Volume metrics are primarily analyzed, trended and reported by higher-salaried, skilled professionals (versus an analyst).

A key concern is that volume metrics are primarily analyzed, trended and reported by higher-salaried, skilled professionals (versus an analyst), such as a pharmacy service area lead pharmacist, supervisor, or manager (29%), by a pharmacy assistant or associate director (35%), or by pharmacy-based analytics personnel (35%). An additional metric cited captures interventions; however, participants expressed concern about the reliability of these voluntary reports, as a lot of data is not reported.

Productivity Metrics

Productivity measurement, trending and benchmarking is a challenge because each institution varies in its size, structure, and services provided. Also, as noted above

There is a need for disease-specific and profession-specific productivity measures … The challenge is to create metrics that tease out pharmacy's contribution to patient and institutional outcomes.

the lack of volume metrics beyond the drug distribution process for other clinical, educational, research, and other department activities makes the formulation of productivity metrics challenging. As a result, more than 80% of participants had no or only some productivity metrics for key processes.

Participants noted that the increasing demand for direct patient care or clinical pharmacy confounds clinical volume and thereby productivity metrics. Often, pharmacists deliver clinically necessary services, such as home visits or medication management consultations, that may not be billable. Participants also differentiated what productivity means for a physician versus a clinical pharmacist. The physician's 15-minute visit looks like high productivity in reports, but a clinical pharmacist visit may last 30 minutes or more.

Outcomes Metrics

There is a need for disease-specific and profession-specific productivity measures, participants said. For example, a diabetes productivity measure could be the avoidance of an amputation; or, for a profession-specific measure, allocate two credits for a pharmacy office visit and one credit for a physician visit. The challenge is to create metrics that tease out pharmacy's contribution to patient and institutional outcomes. Examples of strategies to capture these nuances include:

- Comparing rates of length of stay or readmissions for patients seen by a pharmacist versus those not seen
- Using pay-for-performance incentives for high-risk patients managed by clinical pharmacists and tracking those outcomes
- Monitoring a specific lab value, such as international normalized ratio (INR) for patients in anticoagulation

clinics, tracking the number of pharmacist contacts, and the INR outcome.

Strategies such as these could provide outcomes data that would inform negotiations with payors and could reduce costs, participants advised.

There is a growing demand for pharmacist participation in clinical care teams. The pharmacist is the trusted adviser to the team on medication issues.

Participants observed that there is a growing demand for pharmacist participation in clinical care teams. The pharmacist is the trusted adviser to the team on medication issues. However, unlike specific measures for other doctors and nurses, pharmacists' impacts may not be reported in outcomes measures. In some cases, clinical services pharmacists report to a department chair and their activities are reflected in the hospital quality reports that get executive attention, but not in pharmacy or financial reports.

C-suite Communications

The majority of participants (83%) prepare dashboards to capture key pharmacy metrics including volume (27%), outcomes (36%), and financial (36%) data. Unfortunately, all respondents reported that—other than 'drug costs'—few, if any, of these key pharmacy metrics are included in executive dashboards. Importantly, the C-suite often fails to differentiate between outpatient drug spend (which can be revenue-generating) and inpatient drug spend, and this can lead to missed opportunities.

Unfortunately, all respondents reported that—other than 'drug costs'—few, if any, of these key pharmacy metrics are included in executive dashboards.

Conclusion

The leaders at the Business of Pharmacy Forum unanimously endorsed the value of a well-defined and organized pharmacy key process and metrics package, which would guide daily operations and help rationalize reallocation of resources or justify additional programs development. They said that such a metrics package would facilitate decision-making for the pharmacy leadership and inform communications with system executives.

The leaders at the Business of Pharmacy Forum unanimously endorsed the value of a well-defined and organized pharmacy key process and metrics package.

Leadership Development and Succession Planning

For any business the future is uncertain and those who fail to plan, plan to fail. While most participants indicated the presence of a strategic plan, there were wide variations and gaps in those plans when considering succession planning, business functionality, leadership development and continued progress toward high reliability and participants noted these represent major opportunities to enhance the effectiveness of the Business of Pharmacy.

Moderated by healthcare leadership expert Ron Small (Visante), this session examined how participants approached pharmacy executive organizational structures, strategic planning, leadership development, succession planning, and creating a culture of safety.

To establish the landscape for the discussion, participants responded to seven to eight polling questions related to the session topics. Most participants had a pharmacy strategic plan that covers the next three years, and a formal leadership development plan; however, fewer had formal succession plans for key pharmacy leadership positions.

Participants identified "leadership development" as a key written objective for 2019 and agreed that leadership development and succession planning should be given more attention during the next one to two years. Nearly all organizations conduct regularly scheduled surveys of the perceptions of employees related to a culture of safety, reflecting the importance of this focus.

Participants reported that their organizations are at various stages on the journey to become high reliability organizations (HROs), which TJC defines as: "all people always experience the safest highest quality, best value healthcare across all settings." Ron Small reminded the participants that the essential elements of HROs include:

- Leadership commitment to excellence, including zero patient harm
- A systematic approach to problem-solving and opportunity taking
- A high-performance culture of safety

Organizational Structures

An Array of Titles and Reporting Structures

Ron Small compared Forum participants' responses to an April 2017 nationwide Advisory Board survey of the pharmacy profession. There is no universal model for system-level pharmacy leadership, and participants held a variety of titles from vice president (VP) to director. Nationwide, directors or senior directors still predominate, with the chief pharmacy officer (CPO) title being used only 18% of the time, while 23% of pharmacy leaders are vice presidents. They reported to a variety of individuals, including SVP, CMO, CNO, VP operations, VP procurement, and CEO.

The majority of Forum participants serve in a system- or regional-level position and spend the greatest proportion of their time on strategic planning, integration, innovation, and budgeting. The Advisory Board survey noted that established reporting relationships may limit pharmacy leaders' effectiveness; for example, if the chain of command isolates them from financial leadership and access to revenue cycle data. More than 50% of these pharmacy leaders report to a system SVP/VP. A large number report to the CFO. Far fewer report to the COO or CMO.

The nationwide survey found that large, progressive organizations are establishing a dedicated system-level pharmacy leader. System-level pharmacy leaders are relatively new to the role, with two-thirds having fewer than five years' tenure in their current position. Participants observed that system-level pharmacy leaders' responsibilities differ from those of hospital-level leaders. The top responsibilities system-level pharmacy leaders cited as consuming the greatest proportion of their time included strategic planning, integration of operations and

Given the scale of IDN pharmacy operations, often operating on multimillion dollar budgets, business management responsibilities such as financial planning, business development, and measuring and reporting outcomes are essential functions.

innovative clinical services with best practice standards, budgeting, finance and revenue-generation activities, and leadership development, coaching and mentoring.

Pharmacy Support Roles

Given the scale of IDN pharmacy operations, often operating on multimillion dollar budgets, business management responsibilities such as financial planning, business development, and measuring and reporting outcomes are essential functions. However, the majority of the participants did not have a dedicated business manager or a position within pharmacy to provide financial oversight.

Despite the complexity of projects within pharmacy, such as adding a new clinical service, most did not have a dedicated pharmacy project management office. Many collaborated with the organization's project management department to obtain these services, but they had to compete for the attention and saw frequent turnover as a problem.

The biggest challenges related to strategic planning were identified as sufficient time to develop the plan and the linkage to the organizational strategic plan.

Participants observed that projects often fail if they are led by the information technology (IT) department, because of competing priorities and IT's desire to streamline operations into limited software systems. Options were discussed for accessing financial and project management resources including affiliating with a local business school for support. System engineers from business or engineering schools could be valuable resources for pharmacy project management.

Strategic Planning

The majority of responders discussed a hybrid model of staff engagement that created a strategic plan based on vision and goals, although some said an "issues model" was used to create the strategic plan. Many participants had three-year strategic plans that were reviewed annually to realign new priorities or address issues. Elements of the plans not yet completed were rolled forward. The biggest challenges related to strategic planning were identified as sufficient time to develop the plan and the linkage to the organizational strategic plan. Often, the overall system strategic plan is adapted to drive pharmacy goals and implementation.

Getting Ownership/Buy-in on the Strategic Plan

Participants stressed the importance of engagement and a sense of ownership among all stakeholders throughout the entire process related to strategic plan development and

It is essential that everyone has a voice to contribute to the strategic plan.

implementation. It is essential that everyone has a voice to contribute to the strategic plan, they said. Some systems have a multi-day leaders' retreat to define the strategic plan. An innovative option was a Stakeholder Summit held twice a year that includes all service line leaders, the CMO, and HR leaders, who review and provide input into the strategic plan.

Others have used crowd sourcing techniques such as the Delphi process where everyone comments. In some settings, input for the strategic plan is collected

throughout the year to identify issues. Then work groups are established to address these issues, composed of those who are passionate about the issue and motivated to see the plan implemented. This "bottom-up" approach was seen to be effective and the optimal approach to creating "ownership" of the strategic plan rather than a top down approach and the need to generate "buy-in" for the plan.

Participants agreed that ownership always takes them further than buy-in and is worth the extra effort.

Monitoring Progress on the Strategic Plan

Recognizing that strategic plans are living documents that need to evolve, leaders discussed their approach to monitoring their plans. One participant reported that monitoring is supported by the project management office, which creates a dashboard for monthly review indicating deadlines and using a stoplight system (green, yellow, red) to represent progress. Weekly or monthly dashboard reviews provide information for the pharmacy's annual report in some systems. This can be used as a gateway to get resources allocated to meet objectives. Participants noted that competing priorities can derail progress on a strategic plan and the dashboard report keeps leadership informed about progress.

Some systems create metrics for each strategy and make one person accountable for each goal in the plan.

Some systems create metrics for each strategy and make one person accountable for each goal in the plan. They observed that some financial incentives may not be aligned with the strategic plan, and they stressed the importance of developing performance objectives that tie strategic accomplishments to the individual's annual performance appraisal.

Annual Reports

The annual report can be a principal advocacy tool for the pharmacy. The pharmacy annual report captures performance information for internal and external markets. When pharmacy is operated as a business, annual reports play an essential role in communicating outcomes to the C-suite and explaining the value that pharmacy brings to the system. The report can demonstrate alignment and integration with system-wide strategies and objectives. Few of the participants provide annual reports to their C-suites, and some involve residents in developing their annual reports.

When pharmacy is operated as a business, annual reports play an essential role in communicating outcomes to the C-suite and explaining the value that pharmacy brings to the system.

However, leaders noted that pharmacy sees changes in technologies, drugs (such as high cost therapies like CART) or regulations (such as those affecting 340B hospitals), long before the C-suite is aware. Such advances can dramatically alter the services pharmacy offers and impact the financial models that make sense. Annual reports provide a forum where such changes can be anticipated and their impacts on budget and revenue can be explained in a format that gains C-suite attention.

Leadership Development

Leadership of a large IDN pharmacy organization requires knowledge across many disciplines from business management, including finance and human resources, strategy, planning, and budgeting, to clinical and organizational insight that enables leaders to anticipate changes in the health system landscape.

Despite these herculean challenges, most pharmacy leaders were not trained in any systematic approach to problem solving and depended upon organizational resources.

Addressing Skills Gaps

Forum participants identified skill gaps when starting their careers, including lack of knowledge about organization culture and communication flows, strategic planning, business acumen, processes to get things done, and

people/communication skills. Emotional intelligence and the ability to manage staff more effectively were cited as key concerns. This suggests areas of opportunities to support the next generation of pharmacy leaders.

A Training Needs Assessment or Analysis (TNA) is a structured approach for understanding the who, what, why, and how of a system's training efforts.

Ron Small reported that these needs could be met through a training needs assessment or analysis (TNA), which is a structured approach for understanding the who, what, why, and how of a system's training efforts. It helps identify training that will successfully address any knowledge gaps and allows leaders to survey skills that employees already have, as well as those that they need. In the TNA process, first, the appropriate data are gathered to identify the "who" at the organizational, task/role and individual levels. Then, any performance gaps in the skills needed in those roles are identified, and this information is used to define specific training needs. Finally, the training that is required is prioritized.

Primary Functions of Pharmacy Executive Leadership

Participants said their primary functions as executive leaders in pharmacy are related to organization integration, strategic planning and barrier removal. The importance of education and influence, including the C-suite, was discussed. Executive leadership team functions identified included speaking with a consistent voice, overcoming barriers to innovation and improvement, captivating investors and communicating the return on investments. An essential role is providing evidence to the C-suite that pharmacy is an asset which can be revenue-generating, rather than a cost center. In one system, pharmacy leaders generated data to prove to leadership that "pharmacy is one of our three most strategic assets." They commented, "We weren't doing something new, but they knew what we were doing."

Ron Small suggests using the "Leaders SERVE" model to assess and develop leadership in your organization:

Great leaders SERVE others.

S	See the future
E	Engage and develop others
R	Reinvent continuously
V	Value results and relationships
E	Embody the values

A serving leader's actions are far-reaching because they are passed onto others.

Blanchard, K. & Miller, M. (2003). *The secret: What great leaders know and do.* San Francisco, CA: Berrett-Koehler Publishers, Incorporated.

Common Mistakes of Leadership

When discussing the most common mistakes that leaders make, participants cited not having the right person in the right job as a major concern, which may result from lack of focus and involvement in the recruitment process. Furthermore, they criticized themselves for delaying too long or distrusting their assessment of an individual not suited for a position. This lack of confidence could undermine their decision-making.

A key mistake of leadership is lack of consistency—saying one thing and doing another—which can destroy trust. Ineffective leaders rarely provide clarity of direction or purpose; they do not set challenging goals or objectives, and give no coaching or mentoring. Finally, leaders who do not seek input or listen to input show little or no interest in ideas from their direct reports, and this will limit their effectiveness.

In contrast, participants identified the traits and characteristics of a successful leader as including emotional intelligence, curiosity, engagement, determination, loyalty, openness and trust.

Succession Planning

Some organizations have leadership development plans to assist in the efforts to ensure leadership continuity. However, the vast majority did not have a succession plan for the pharmacy enterprise and acknowledged that it was difficult to fit this in given the priority list of issues and challenges. The majority of responders said this area of leadership development lacks the commitment and planning that it needs. Most responders acknowledged that succession planning is poorly-managed in their systems, and often is not considered until a leader's anticipated departure triggers its discussion.

Succession planning can be defined as a purposeful and systematic effort made by an organization to ensure leadership continuity, retain and develop knowledge and intellectual capital for the future, and encourage individual employee growth and development.

Ron Small offered that succession planning can be defined as a purposeful and systematic effort made by an organization to ensure leadership continuity, retain and develop knowledge and intellectual capital for the future, and encourage individual employee growth and development. He noted that this should be based on a gap analysis.

Participants discussed an approach to succession planning that starts with identification of the key pharmacy positions where training and support are required, especially business planning and financial aspects of the business, which get little in-depth coverage in most pharmacy training programs. They recommended identifying positions where people are likely to change roles and the timeframe required to cross-train people to prepare them to take over these positions. Established career paths are an effective way to guide personnel through a step-by-step progression of learning the skill sets necessary for pharmacy leadership positions.

Established career paths are an effective way to guide personnel through a step-by-step progression of learning the skill sets necessary for pharmacy leadership positions.

Strategy versus Execution

When asked whether strategy or execution was more important, many responders felt execution was more important than strategy. However, they could also see that a high-performing organization most likely is the result of an excellent execution of a strategic plan to achieve organizational goals and objectives. Participants recognized the interdependency of the two. They noted that if you fail to execute on your strategy, you lose the confidence from the C-suite and other stakeholders; therefore, it's important not to over-promise but to set attainable goals, they said.

The importance of having a commitment to an excellent strategy and the dedication/culture required to drive its execution … most participants felt culture was more important.

There was considerable discussion on the importance of a commitment to an excellent strategy and the dedication/culture required to drive its execution. In a related question, when asked which is more important strategy or culture, most participants felt culture was more important. Again, discussions were held regarding the importance of executing a high quality strategic plan to achieve a high performing culture.

Managed Care Strategies

With medications as the primary treatment modality for more than 80% of patients, managed care strategies such as retail/specialty pharmacy, infusion, PBM and population health management truly represent a significant business opportunity for health systems and really emphasize the "Business" aspect of this Business of Pharmacy Forum. Combined, the elements discussed by the participants can significantly contribute to creating new revenue, enhancing current revenue and reducing expenses and this can be worth hundreds of millions of dollars annually for larger systems.

This session, moderated by Visante Executives and Managed Care experts, Paul Foley, Kristin Fox-Smith, and Tammy Zukowski, focused on issues related to pharmacy benefit management (PBM) contracting, reimbursement, and strategy, along with specialty pharmacy, accountable care organizations (ACOs) and population health models infusion services (both in clinic and home), and on finance payment models, billing, compliance, and reimbursement challenges.

Retail Pharmacy

Among the Forum participants, most have outpatient/retail and specialty pharmacies, but at different levels of maturity, while only half had mail order pharmacies for traditional retail medications. All were aware of chains, such as Walgreen's, proposals to provide outsourced retail pharmacy or to engage in joint ventures. Some noted that chains had appealed directly to hospital C-suites and Boards of Directors; however, most systems represented at the Forum had rejected these approaches.

Specialty Pharmacy

Specialty pharmacy is definitely a focus for all participants and is seen as an important financial contributor to organizations, offering opportunities for revenue optimization. Several systems had long-standing URAC-accredited programs that were housed in the outpatient/retail pharmacy. Several health systems had a specialty pharmacy program that retains all prescriptions in-house, including employee scripts.

The ability to triage prescriptions and provide concierge support to patients was the driver to making this a best practice within health systems. This process provides clinical services integrated with the patient care team, as well as all aspects of billing, prior authorization, and copayment support for patients specialty medication needs.

Specialty pharmacy is definitely a focus for all participants and is seen as an important financial contributor to organizations, offering opportunities for revenue optimization.

Leaders with established programs advised that revenue projections and margin contribution made a compelling story to get FTEs allocated to support prior authorizations. They stressed the importance of finding a medical group champion to advocate for the program. Their message to clinicians is, "We want to be able to capture those patients for whom we can be reimbursed, so we can take care of more patients." Use a dashboard to show what you write off every month and what could have been reimbursed, if adequate staffing was available to follow up on denials, participants recommended.

"We want to be able to capture those patients for whom we can be reimbursed, so we can take care of more patients."

When all scripts are captured in-house, integrated data can be used to determine which interventions improved patient outcomes and reduced total costs. These data can be a bargaining chip with payor networks and contract negotiations, leaders observed. For example, in one system, outcomes data from patients with diabetes treated

with a specific drug showed a significant decline in HbA1c, and these data were part of the narrative that persuaded the payor to enter a contract.

However, others noted that many payor networks have their own PBM programs and want to drive the prescription revenue to the PBM. As hurdles are created by PBMs to narrow networks, health systems continue to rise to the challenge to meet these requirements. Other systems are just beginning to establish specialty pharmacies and described the challenges to put standards, policies, systems and processes in place that meet standards for accreditation. Policies and procedures are one facet of accreditation, and operations and process redesign are often critical for accreditation success.

Specialty pharmacy programs create much more than financial benefits to the health systems. Physicians are often important advocates for in-house specialty pharmacy services, because they see improved patient care and patient satisfaction as clinical pharmacy support is fully integrated with the health care team.

Mail Order/Home-Delivery

Half of Forum attendees have mail/home-delivery, but sometimes focused just on employees.

Employee Prescription Benefit

Until recently, many health systems employee pharmacy benefits were managed by Human Resources (HR), with little or no involvement by pharmacy. In the HR silo, there is often no awareness of the potential cost savings available for employee prescriptions. Involving the pharmacy department in employee pharmacy benefits is a recent phenomenon with most progress in the past one to two years. Because decision-making processes often operate in silos, politics and "turf battles" were barriers to pharmacy involvement in employee pharmacy benefits. But all participants reported that those barriers quickly evaporated once pharmacy and HR began working together.

An employee pharmacy benefit program can save millions of dollars for a system.

The moderators observed that recently a number of health systems have requested Visante's advice in redesigning their employee pharmacy benefits to bring more responsibility in-house. Participants reported varying levels of involvement in design and management of the employee pharmacy benefit. Half of Forum participants (significantly more than the national average) said pharmacy was deeply involved, while one-quarter reported they still had not been consulted.

Participants commented that an employee pharmacy benefit program can save millions of dollars for a system. Most systems (62%) offer a copay incentive for employees to fill prescriptions at in-house pharmacies.

Chronic Care Clinics

While most (76%) of the participants' systems are 340B covered entities and fill prescriptions for employees, only a few (22%) have a "chronic care clinic" for employees. Many participants see potential opportunities with chronic care clinics. However, they emphasized the importance of rigorous compliance with 340B rules and regulations, which require that the chronic care clinic must deliver and document full clinical services to employees, including clinical examination, diagnosis, patient medical records, wellness services and coordinated care. Maintenance of the patient's medical record is critical documentation.

Many participants see potential opportunities with chronic care clinics.

Managed Care Contracting

An expanding trend is increased pharmacy involvement in contracting processes with payors and health plans for pharmacy services, particularly specialty pharmacy and/or infusion services. Almost half of participants said they are intimately involved, while the remainder reported that contracting is handled by others, with little involvement by pharmacy. In some cases, pharmacy reviews the fee schedule but not the contracts, which limits pharmacy's effectiveness, participants said. While pharmacy involvement in contracting has been limited in the past, participants say they are getting more support

An expanding trend is increased pharmacy involvement in contracting processes with payors and health plans for pharmacy services …

for their inclusion and have seen important benefits from a stronger pharmacy role. Pharmacy has the most information about drug costs, reimbursement, and "site-of-care" reimbursement, particularly for high-cost, specialty infusion drugs. By sharing this information with hospital contacting departments, systems can avoid unpleasant surprises in managed care reimbursement.

"Specialty pharmacy contracting" was seen as a problem for 59% of respondents, particularly for inclusion in PBM or health plan networks. Often, a "standalone specialty pharmacy" will have difficulty gaining entry into PBM pharmacy networks. However, when the specialty pharmacy is negotiating within the larger context of health plan/health system contracting process, this may facilitate access to specialty pharmacy networks, participants reported.

Home Infusion Services

As attention to "site-of-care" reimbursement grows among payors, health systems are considering site optimization strategies to better manage costs and profitability. While many hospitals providing home infusion care in the past suffered from low revenue and high contractual adjustments and bad debt," today's reimbursement models are causing systems to rebuild these services.

Pharmacy Services Administrative Organizations (PSAOs)

PSAOs are designed to perform administrative functions for pharmacies in order to achieve administrative efficiencies, including contract and payment efficiencies for both pharmacies and third-party payors or their PBMs. Many Forum participants (47%) have been members of the PSAO affiliated with their wholesaler for two or more years. Forum leaders with PSAO participation reported that they did not derive much benefit from them. Visante reported that some PSAOs have begun denying membership to closed-door health system pharmacies.

Participants observed that health systems can benefit most from a PSAO when they are creating a new pharmacy service, as it is difficult to go from "zero" PBM/health plan pharmacy network contracts to the 100+ network contracts required to serve all patients under all the different payor/PBMs. The PSAO can immediately deliver access to these pharmacy network contracts, dramatically reducing start-up contracting efforts.

Health systems can benefit most from a PSAO when they are creating a new pharmacy service.

Billing and Reimbursement

The majority of participants (89%) have good visibility to accounts receivable and reimbursement rates for retail and specialty pharmacy services, either by directly managing these processes within the pharmacy department, or by working closely with finance, revenue cycle, and/or patient accounting department(s).

For infusion services, billing and reimbursement is typically managed by normal hospital finance processes, and very few pharmacies get insight into denials and write offs. When a separate ambulatory-clinic or a home-care group did billing for infusion services, most participants reported working closely with these units.

In the remaining 11% of systems, pharmacy has little or no involvement in billing and reimbursement. "We throw the pharmacy charges over the wall, and hope the billing

Hospital billing will write off $500 without even blinking, while retail pharmacy billing will work for every nickel.

people take care of it," they said. Participants agreed that hospital finance or patient accounting typically does a poor job of optimizing reimbursement for prescription claims, so optimally billing and reimbursement should be managed by the pharmacy department. Hospital billing will write off $500 without even blinking, while retail pharmacy billing will work for every nickel.

Population Health versus ACO Strategies

Discussants reflected on the differences between Accountable Care Organizations (ACO) and population health strategies. Participants noted that there are definite similarities and overlap between the two, including the emphasis on bundled reimbursement, total cost of care, outcomes, and value-based reimbursement. Both models use clinical pharmacy services in the ambulatory environment to better manage medication therapy for chronic diseases. Most Forum participants' institutions have both initiatives, but more participants (61%) are actively involved in population health strategies, while fewer (39%) are involved in developing ACO strategies.

Population Health

"Population health" is a broader initiative than ACO, and applies the concepts of bundled reimbursement, total cost of care, outcomes, and value-based reimbursement to many different patients from many different payors, with an emphasis on chronic diseases such as diabetes, heart disease, or hypertension. In some systems, these bundled "cost of care" programs are managed by the pharmacy. For example, one participant described a program where four pharmacists support 36 clinics focused on diabetes, hypertension, and other high risk chronic diseases. These clinics have excellent outcomes metrics, in part, because pharmacists have more patient contact and are effective in getting patients to continue in the chronic care program, he explained. In another system, 500 medical groups are served by 14 pharmacists in a central hub who provide care for high-risk patients. These advanced practice clinical pharmacy practitioners are physician extenders, like physicians assistants, and have prescribing authority.

There are definite similarities and overlap between the two, including the emphasis on bundled reimbursement, total cost of care, outcomes, and value-based reimbursement. Both models use clinical pharmacy services in the ambulatory environment to better manage medication therapy for chronic diseases.

Population health is expected to expand in the next two years and will require funding for more pharmacy FTEs.

Population health is expected to expand in the next two years and will require funding for more pharmacy FTEs. However, the cost/revenue equation needs to be properly framed for finance. Finance knows that Nurse Practitioners or Physician Assistants bill for their time, while pharmacists typically do not. In traditional models, pharmacist revenue was tied to dispensing a drug. Today, pharmacists are delivering services that create revenue, improve outcomes, reduce costs and increase patient convenience and satisfaction. Forum participants are actively building evidence that revenues go up and costs come down when pharmacists are on the team.

ACO Strategies

In contrast, "ACO" applies the principles of bundled reimbursement, total cost of care, outcomes, and

Today, pharmacists are delivering services that create revenue, improve outcomes, reduce costs and increase patient convenience and satisfaction.

value-based reimbursement to a smaller subset of patients enrolled in the particular health system's ACO. Participants noted how important it is for ACOs to consult with pharmacy in order to meet their goals and earn incentives.

Most systems have clinical pharmacists working in various chronic care clinics as active partners in the health care team with physicians, nurses, and other clinicians. In fact, Forum participants appear to be more advanced in these services than the average health system in the US today

Physician recruiting is always a challenge for any health system. Many physicians are now joining our system because we have clinical pharmacists in their clinics.

Physician recruiting is always a challenge for any health system. Many physicians are now joining our system because we have clinical pharmacists in their clinics. Forum participants also reported on their positive experiences in working with physician champions, first welcoming and then demanding more clinical pharmacists in the clinics. They also reported significant progress in the past couple years in developing the business case (i.e., financial return on investment) associated with clinical pharmacists in ambulatory chronic care clinics.

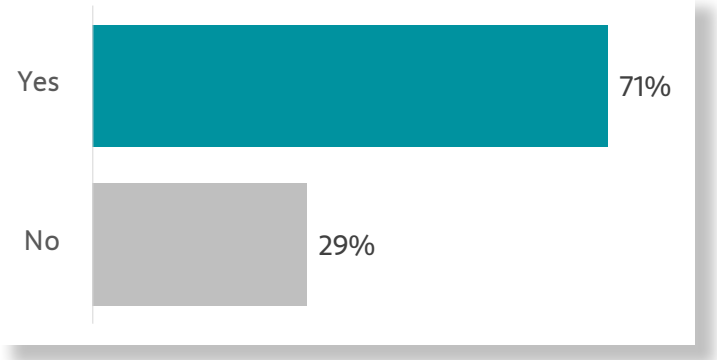
Participants observed that when a pharmacist is fully-integrated into the care delivery model, improvements in quality of care and patient satisfaction can improve the system's STAR ratings.

Appendix: Group Discussion Polling

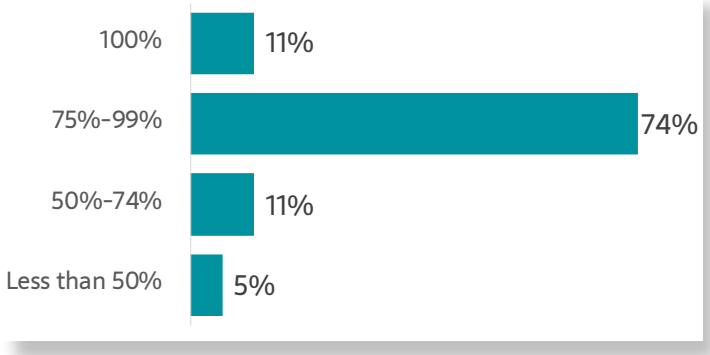
During each session, polling questions were asked of each small discussion group of seven to eight participants. Each participant responded anonymously and, after all responses were received electronically, results were displayed to the group for a focused discussion.

Sterile and Non-Sterile Compounding

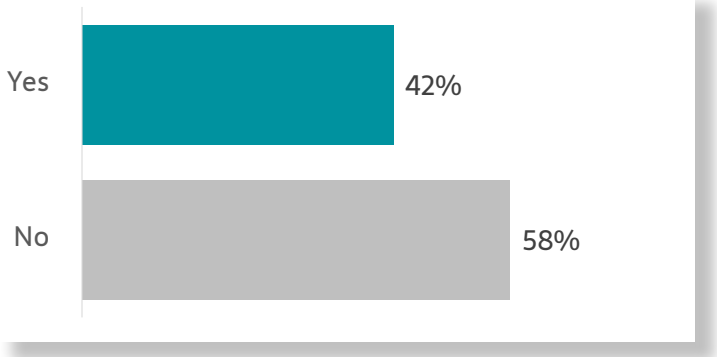
Q1. Are you confident that your facilities and practices will be compliant with USP <795>, USP <797> and USP <800> by December 1, 2018?



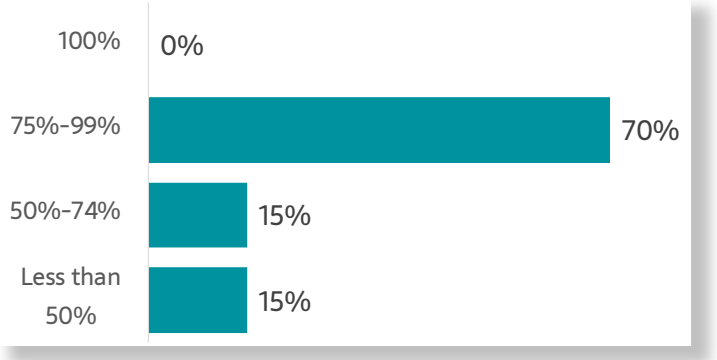
Q2. How compliant do you feel your hospitals are with regards to sterile compounding standards, specifically USP <797> and your state board of pharmacy requirements?



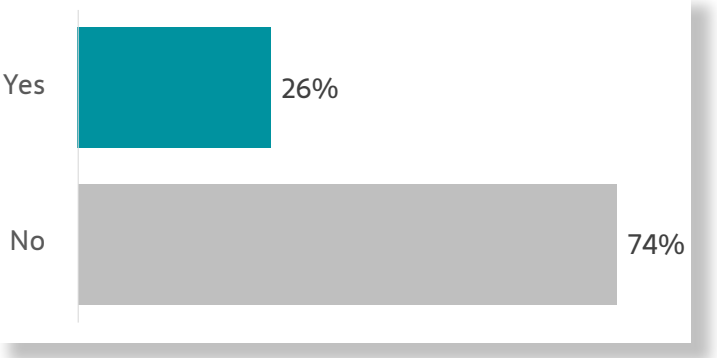
Q3. Does your facility have an IV efficiency system in place?



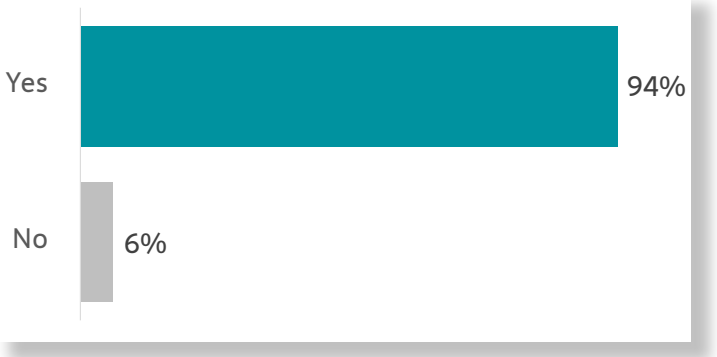
Q4. How compliant do you feel your hospitals are with regards to hazardous drug handling standards, specifically USP <800> and your state board of pharmacy requirements?



Q5. Has your site(s) implemented sterile compounding automation?

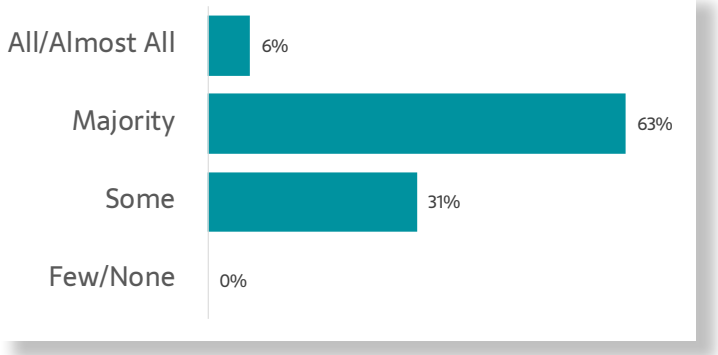


Q6. Does your site currently use an outsourcing manufacturer to supplement sterile compounding needs?

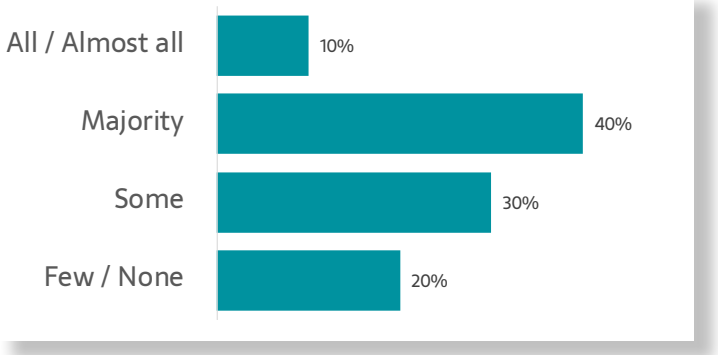


Measurement and Management

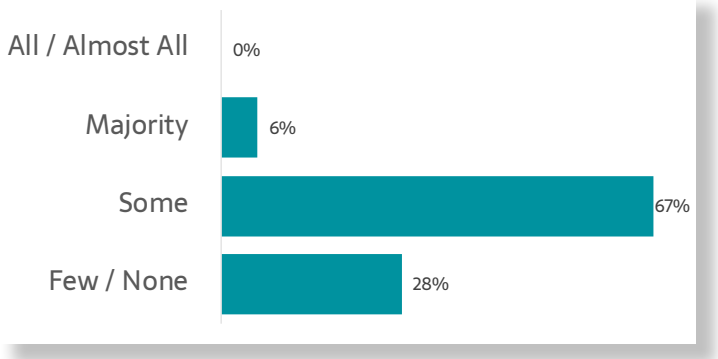
Q1. Have you identified key processes in each of your major pharmacy service areas?



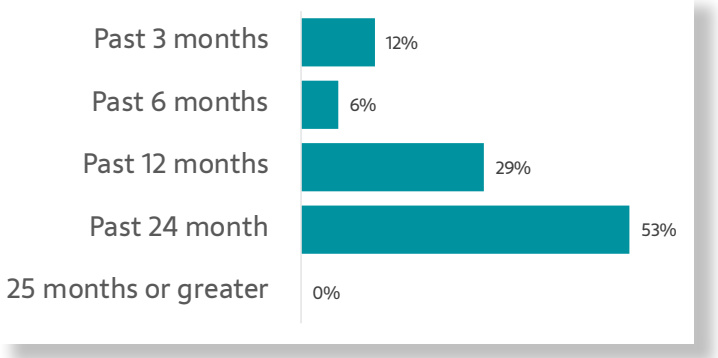
Q4. Does each key process have an associated SOP?



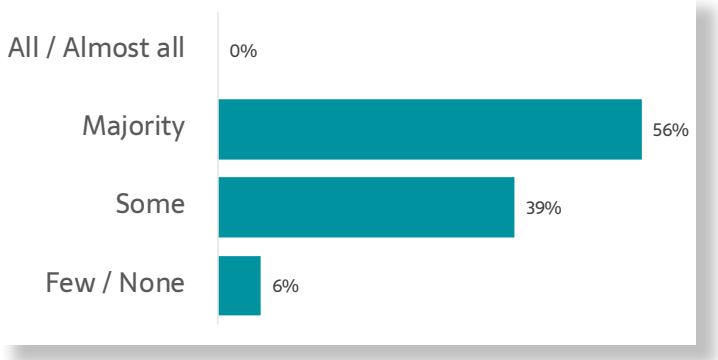
Q2. Does the pharmacy have visual process maps for your identified key processes?



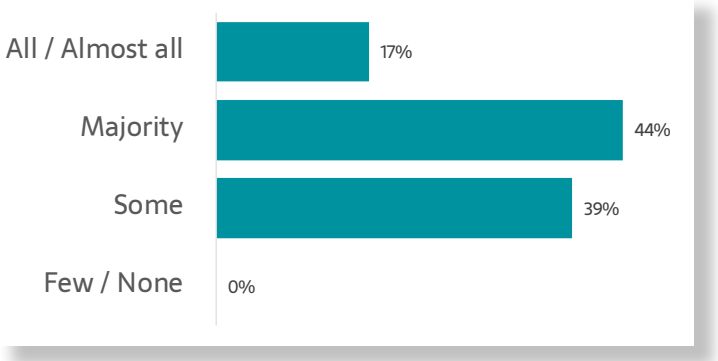
Q5. How recently have your process maps, P&P and/or SOPs been reviewed and updated?



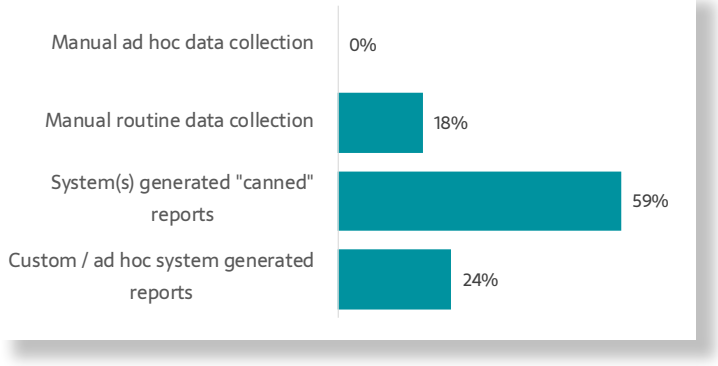
Q3. Does each key process have an associated P&P?



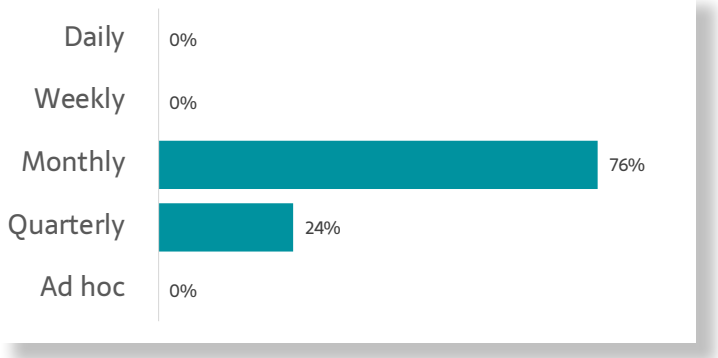
Q6. Does the pharmacy have volume metrics for each of the identified key processes?



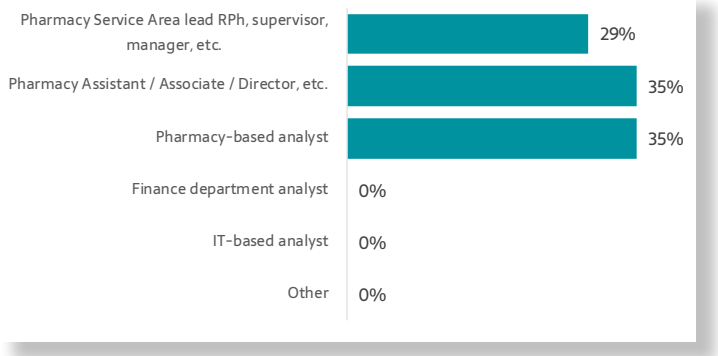
Q7. How are most of your volume metrics data elements collected or obtained?



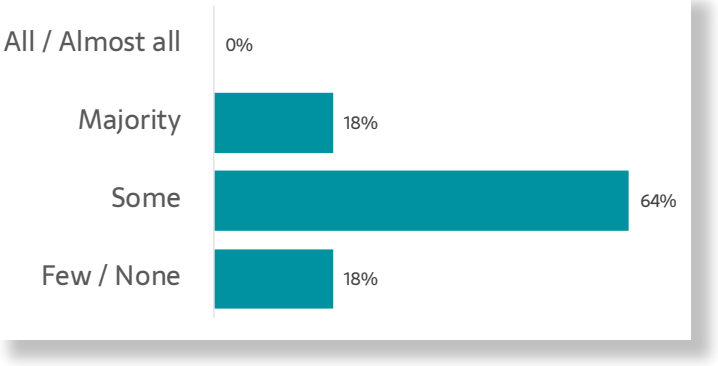
Q8. How frequently are your volume metrics collected and reported?



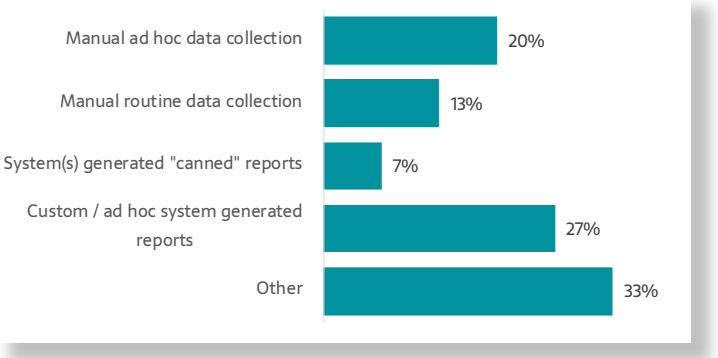
Q9. Does the pharmacy have productivity metrics for each of the identified key processes?



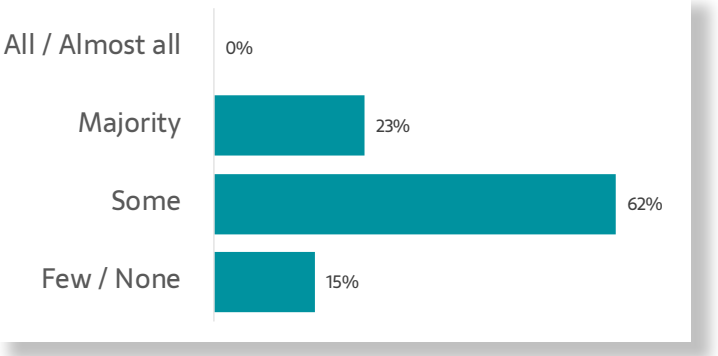
Q10. Does the pharmacy have performance metrics (process, outcome, satisfaction, etc.) for each of the identified key processes?



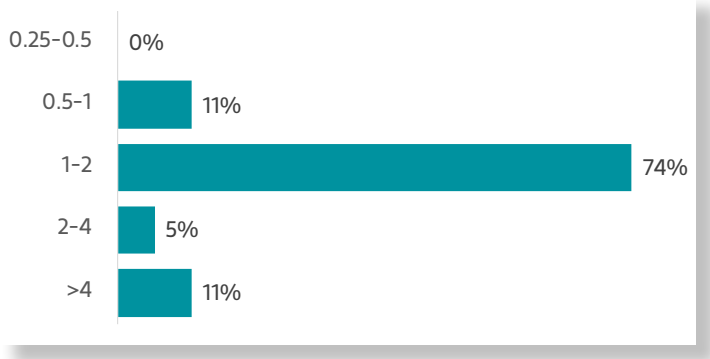
Q11. How are most of your productivity data elements collected or obtained?



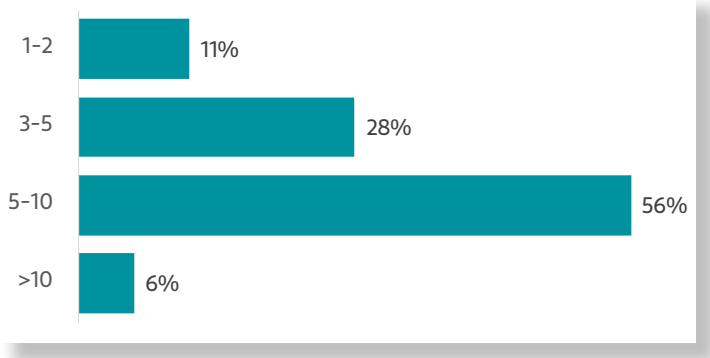
Q12. Who primarily analyzes, trends and reports your volume metrics?



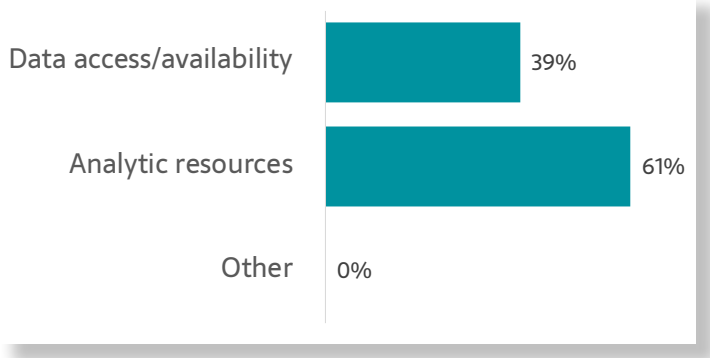
Q13. What would be a reasonable FTE estimate for personnel time utilized to prepare your performance metrics?



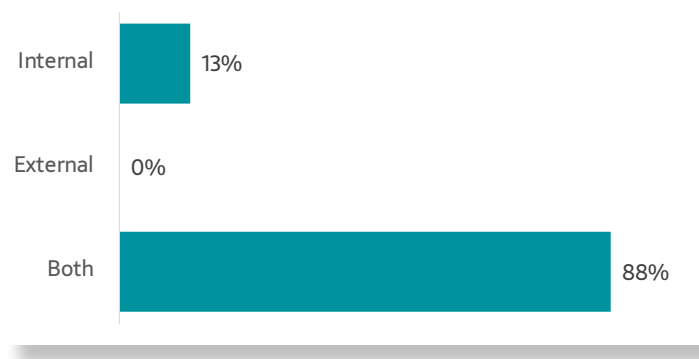
Q14. How many systems do you need to access in order to obtain system generated reports for the key process metrics you collect?



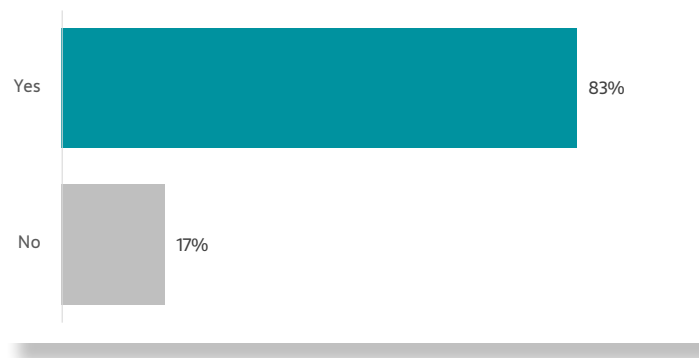
Q15. What are the primary challenges in obtaining data for metrics?



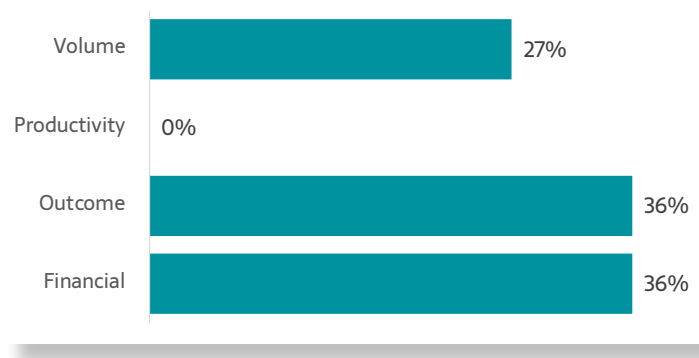
Q16. Are your key metrics benchmarked internally within your health system, externally or both?



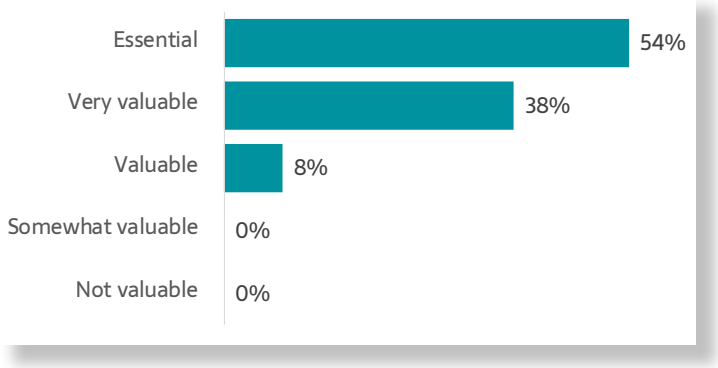
Q17. Do you prepare and report pharmacy service area or department dashboards within the hospital pharmacy department or health system pharmacy program?



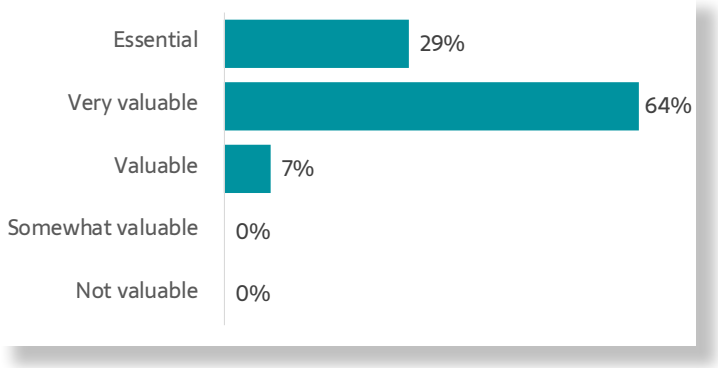
Q18. Which of the pharmacy key metrics types are utilized in the executive dashboard?



Q19. How valuable is a well-defined and organized pharmacy key process and metrics package in the day to day operation and reallocation of current resources and/or justification of additional programs needs for a pharmacy service area supervisor/manager/assistant/associate director of pharmacy or system level pharmacy VP/CPO?

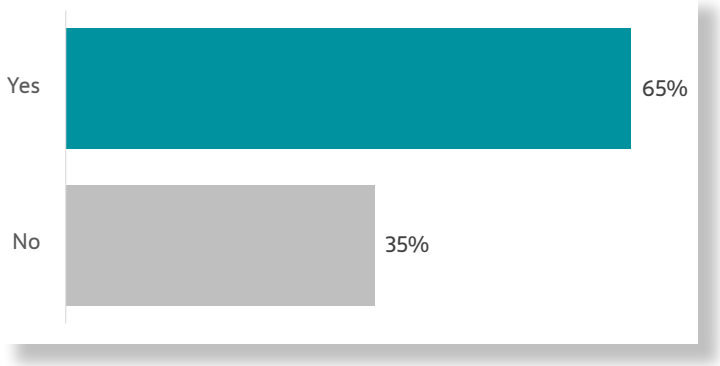


Q20. How valuable is a well-defined and organized pharmacy key process and metrics package in the day-to-day operation and reallocation of current resources and/or justification of additional program needs for a pharmacy department or program at the hospital or health system executive level?

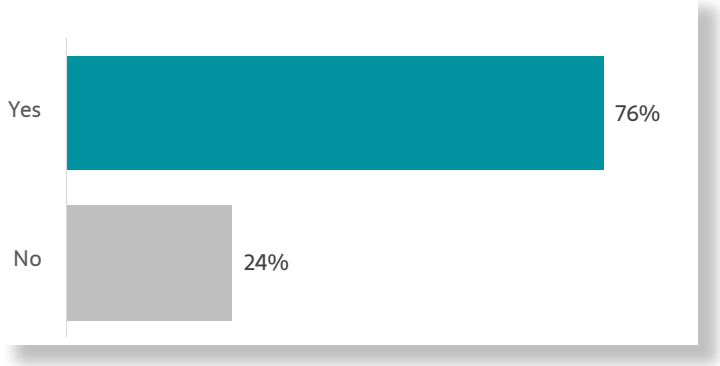


Leadership Development and Succession Planning

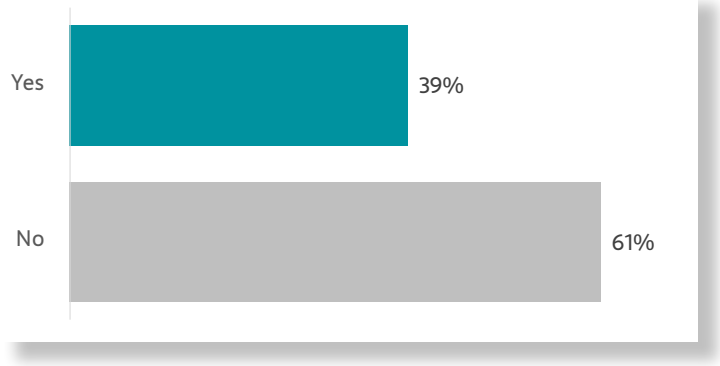
Q1. Do you have a personal Mission and Vision Statement?



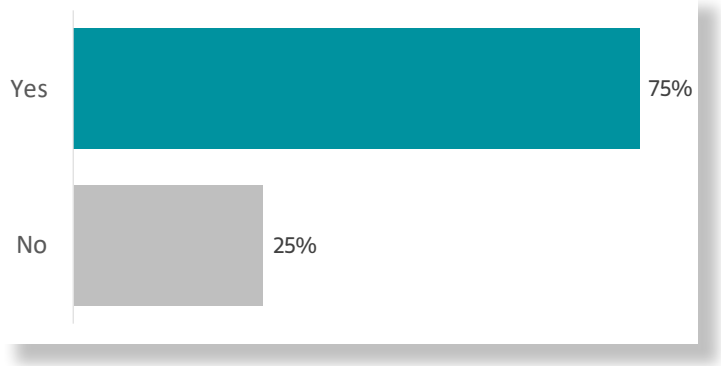
Q2. Do you have a formal Pharmacy Strategic Plan that covers the next three years?



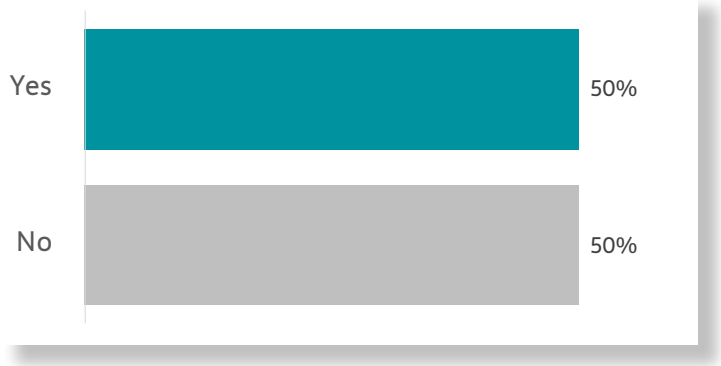
Q3. Do you have a formal Succession Plan for key pharmacy leadership positions?



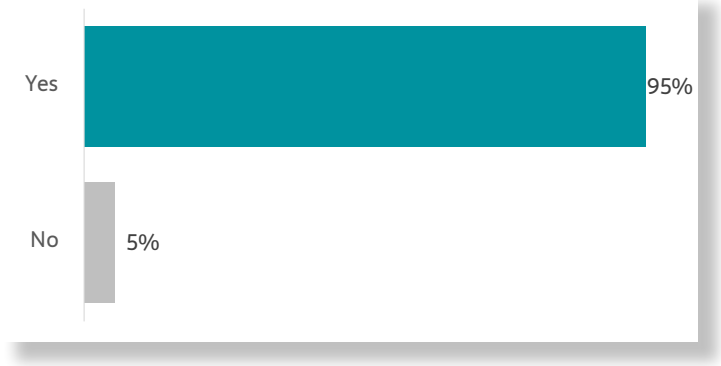
Q4. Does your organization have a formal Leadership Development Plan?



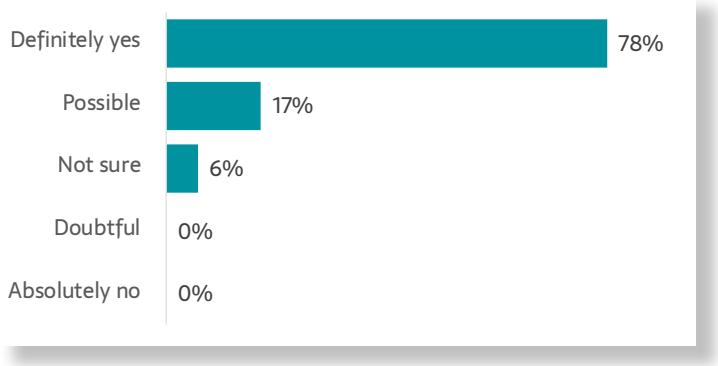
Q5. Does your organization have a formal Leadership Succession Plan?



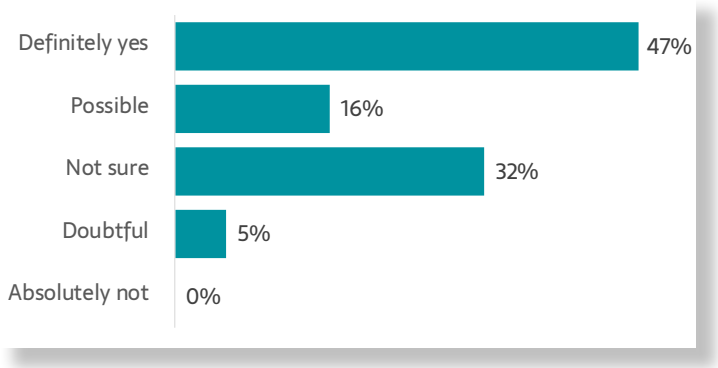
Q6. Does your organization conduct regularly scheduled surveys of the perceptions of employees related to a Culture of Safety?



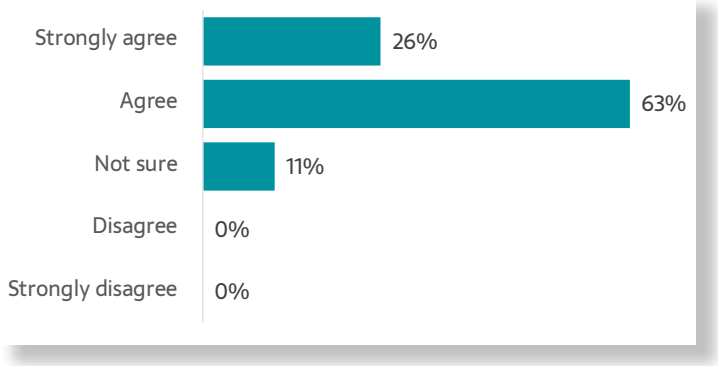
Q7. "Leadership development" will be one of my Top 10 written objectives for 2019.



Q8. Creating a "succession plan" will be one of my Top 10 written objectives for 2019.

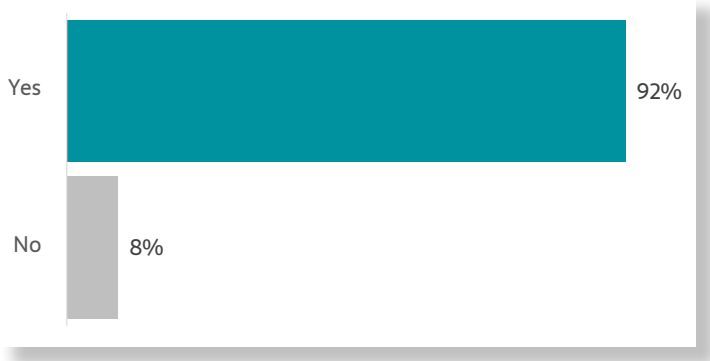


Q9. In my organization, leadership development and succession planning should be given more attention during the next one to two years.

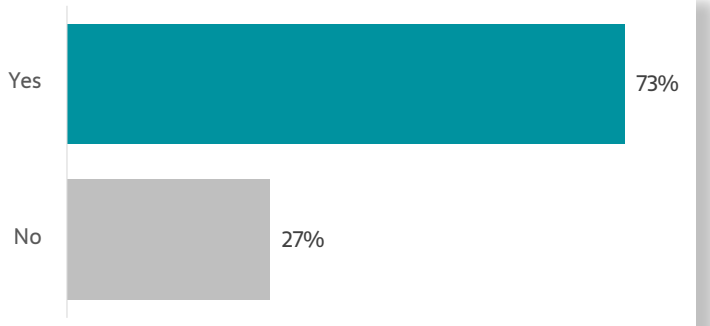


Managed Care Strategies

Q1. Do you have your own outpatient/retail pharmacies?

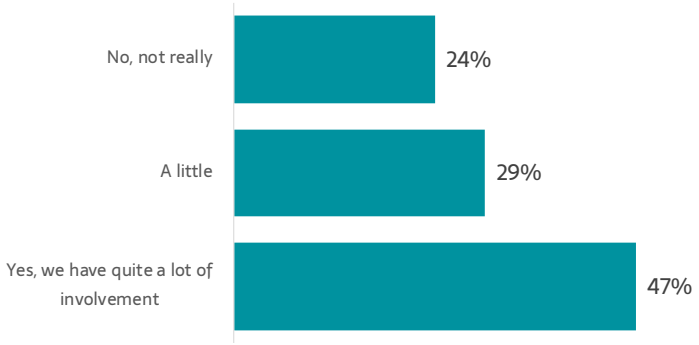


Q2. Do you have your own specialty pharmacy?

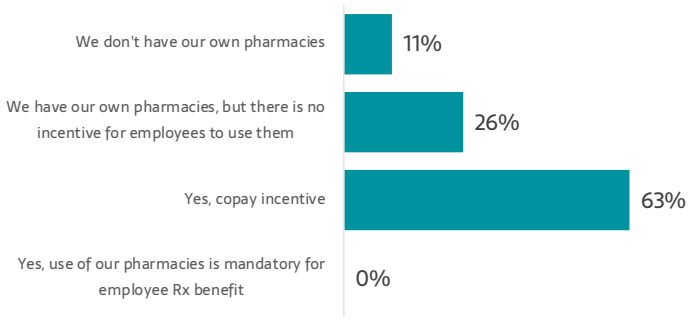


Q3. Do you have your own mail order pharmacy? (i.e., for traditional retail medications, not specialty)?

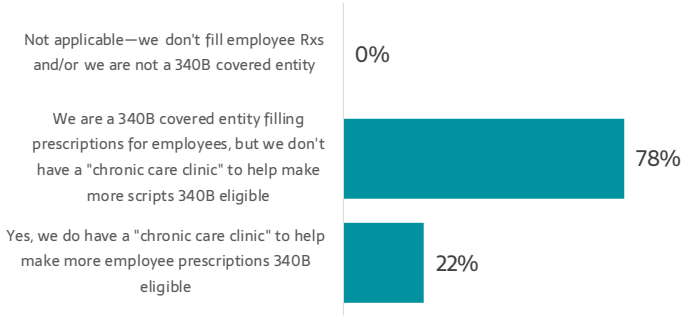
Q4. Is "pharmacy services" involved in design and management of the pharmacy benefit for employees?



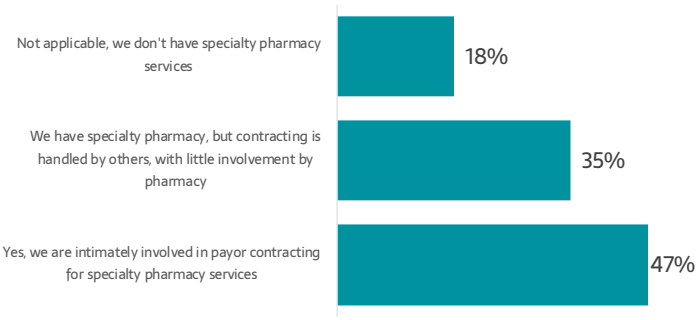
Q5. For the pharmacy benefit for your employees, is there a copay incentive or other incentive (e.g., mandatory) for employees to fill prescriptions at your pharmacies?



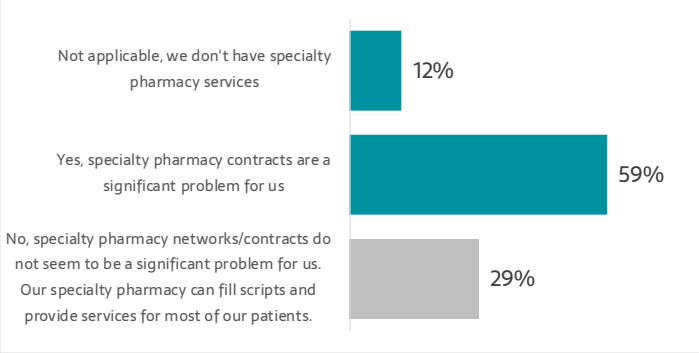
Q6. Do you have a "chronic care clinic" to increase the number of employee prescriptions eligible for 340B (e.g., employees seen in the chronic care clinic, have a medical record, prescription written by health system prescriber)?



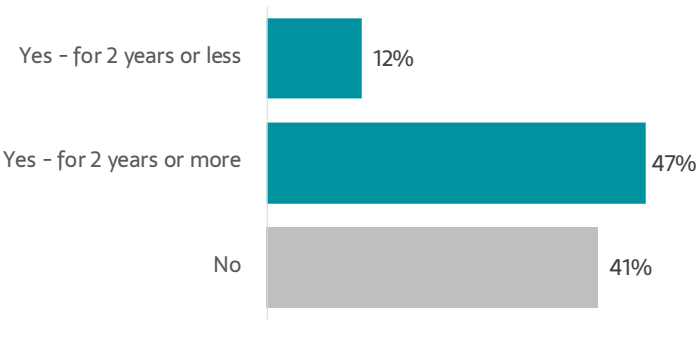
Q7. Is pharmacy involved in your contracting processes with payers/ health plans for pharmacy services (particularly specialty pharmacy and/or infusion services)?



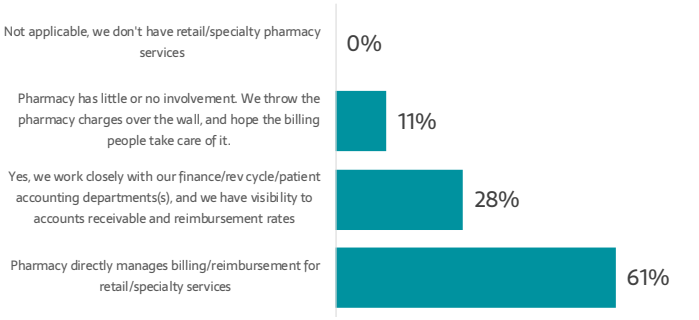
Q8. Is "specialty pharmacy contracting" seen as a problem for your health system, particularly inclusion of your specialty pharmacy in various PBM or health plan networks?



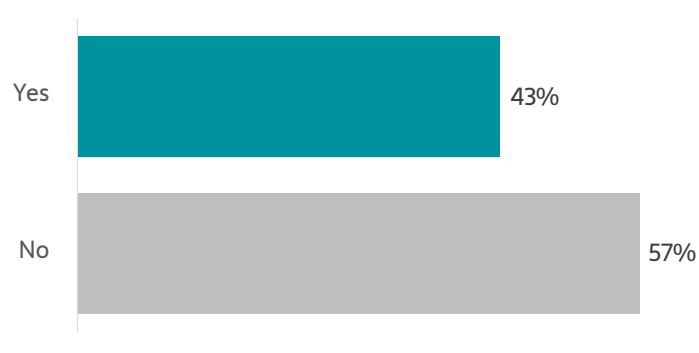
Q9. Are you currently enrolled in a PSAO? If so, how long have you been in the PSAO?



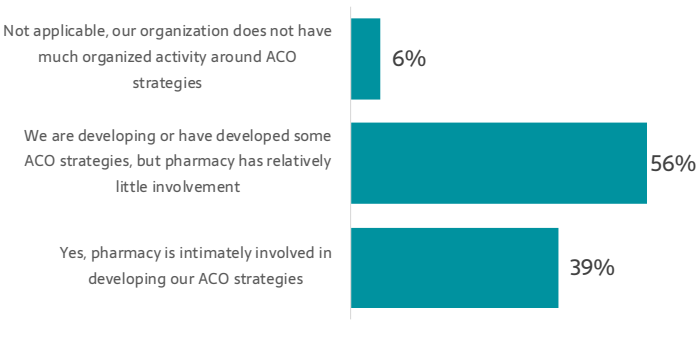
Q10. Is pharmacy involved in billing/reimbursement for retail/ specialty pharmacy services?



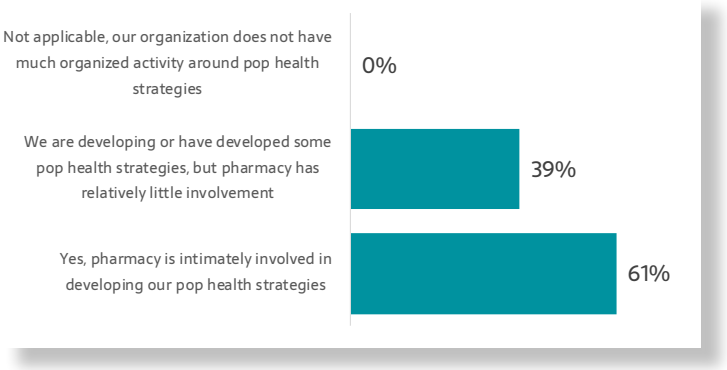
Q11. If you are currently involved in Home Infusion, is pharmacy involved in billing/reimbursement?



Q12. Is pharmacy involved in your organization's ACO strategies?



Q13. Is pharmacy involved in your organization's population health strategies?



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About BD

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Hazardous Drug Safety

Anyone who handles hazardous drugs during transportation, preparation, administration or waste disposal may be at risk of exposure. They need and deserve to be protected. Various industry organizations such as NIOSH, ASHP, NAPRA, ONS, ISOPP and USP all recommend a comprehensive safety program to prevent hazardous drug exposure, including the use of closed-system drug transfer devices (CSTDs) in preparation and administration.

BD hazardous drug safety offers a comprehensive portfolio of best-in-class products—including two closed-system drug transfer devices (CSTDs) and one innovative rapid detection system—to help protect healthcare workers from hazardous drug exposure and to detect hazardous surface contamination. This is backed by our clinical expertise and experience to provide a tailored solution that best fits their healthcare facility's needs for safety, efficiency, compliance and costs.

Twenty years ago, the BD PhaSeal™ system pioneered the category of CSTDs to help protect healthcare workers from the risks of hazardous drug exposure. It is an airtight and leakproof CSTD that mechanically prohibits environmental contaminants from entry and drugs or vapor concentrations from escape. The BD PhaSeal system was the first CSTD to be clinically used. Today, it's also the most widely published CSTD in the world, supported by more than 25 independent published studies.

Customers can also choose the Texium™ system with SmartSite™ VialShield™, an end-to-end leak-free CSTD that provides a flexible, simple and cost-effective safety solution to help protect healthcare workers from exposure. The pre-assembled components of the Texium system seamlessly integrate with SmartSite valve technology and Alaris™ Pump infusion sets, aiding workflows and enabling healthcare facilities to maximize their existing investments.

BD's latest innovation in hazardous drug safety is the BD™ HD Check system—the first and only rapid detection test for select hazardous drugs. Using conventional methods to test for surface contamination can take weeks for results, delaying the ability to take immediate action and making routine monitoring a challenge. But the BD HD Check system detects hazardous surface contamination on-site, in less than 10 minutes. Its handheld design makes routine testing simple and convenient. The results are quick, reliable, easy-to-read, enabling immediate corrective action to be taken.

Along with these world-class products, BD brings its vast clinical expertise and experience to partner with customers in balancing their needs for efficiency and cost with the need to keep their workers safe from the risks of hazardous drug exposure. From expert clinical support and ongoing training programs to clinical workflow tools, BD helps healthcare facilities make the most of their investments in protection and detection. All so we can help our customers protect their greatest assets—their healthcare workers—with a solution that meets everyone's needs.