Vizient University Health System Consortium

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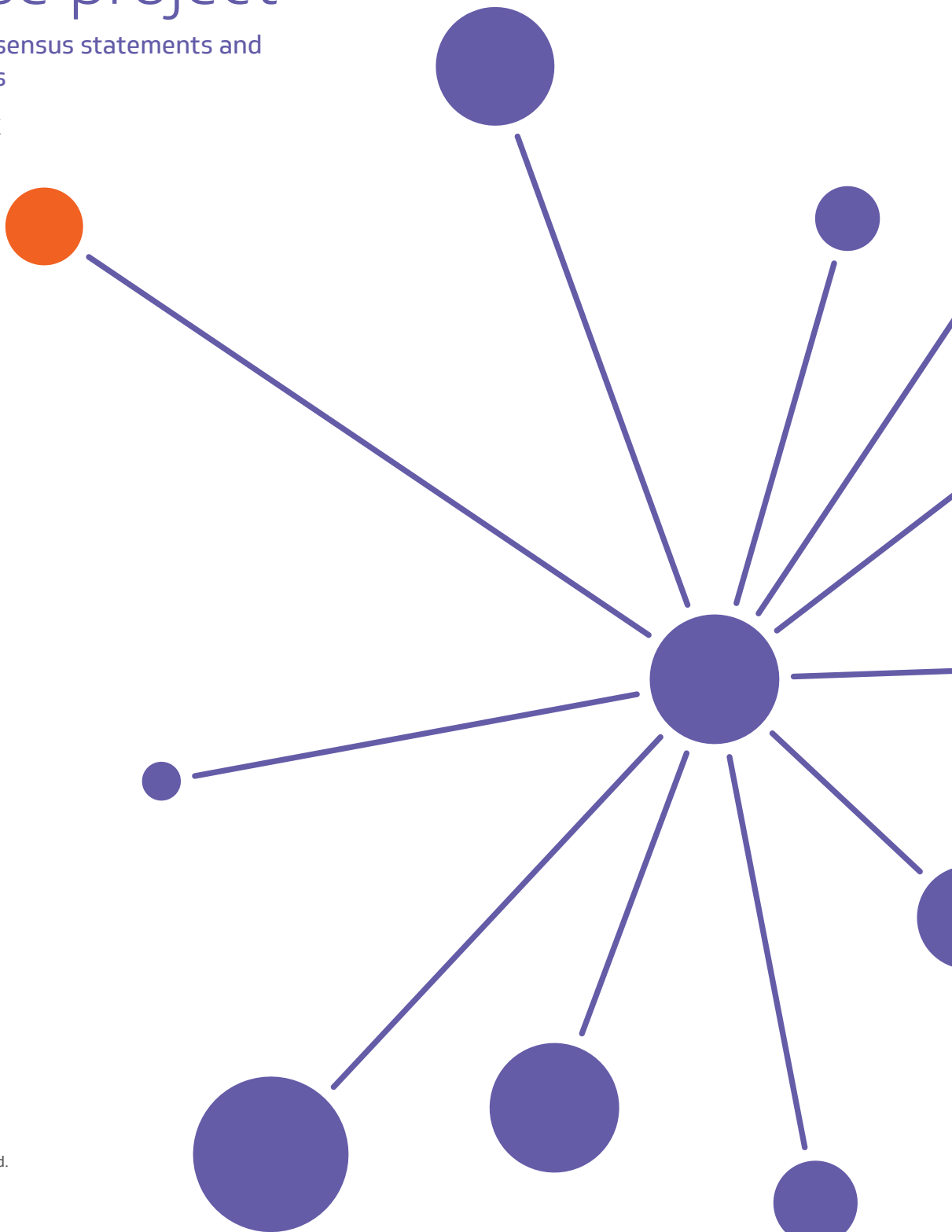
High-value pharmacy enterprise project

Literature review, consensus statements and performance elements

Pharmacy Network
December 2020



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Background

Project vision

Given the rapidly evolving health care landscape and focus on value-based care, the Vizient® University Health System Consortium Pharmacy Network Executive Committee determined the importance of developing a blueprint for the High-value Pharmacy Enterprise (HVPE) to preserve the core elements of pharmacy practice and advance the pharmacy profession to provide safe, effective and patient-centered medication management. The health care and pharmacy environmental drivers behind the project that underscore the need for the HVPE are outlined in the next section.

Over the past two decades, the High Performance Pharmacy initiative,[1] the Global Conference on the Future of Hospital Pharmacy,[2] the American Society of Health-System Pharmacists (ASHP) Pharmacy Practice Model Initiative[3] and the ASHP Ambulatory Care Summit[4] galvanized the advances achieved in the practice of pharmacy in the U.S. and internationally. The HVPE creates a new framework for the profession by defining eight domains that define both fundamental and aspirational elements of practice that should be established within the contemporary health system pharmacy enterprise by calendar year 2025. It is intended to be achievable and inspire health system pharmacies to attain the highest level of professional practice to meet the evolving needs of our patients and our organizations.

Health care environmental drivers

- There will continue to be tremendous payer pressure on health systems to reduce costs and measure quality.
- Organizations are increasingly taking on financial risk from payers (i.e., shifting to value-based and full-risk payment models).
- Health care marketplace mergers, acquisitions and disruptions will redefine how patient care is delivered.
- Rising drug costs are the new norm due to the increasing release of biologics and immunomodulators to treat a growing number of chronic and orphan diseases.
- Drug shortages have significantly increased costs for generic drugs, particularly injectables.
- Aging of the population and the prevalence of chronic diseases requiring complex drug regimens will continue to increase health care expenses.
- Focusing on the management of patients across the continuum of care (transitions of care) will continue to be a high priority, emphasizing the need to reduce readmissions and costs.
- Post-acute and non-acute sites of care (e.g., home care, skilled nursing facilities, ambulatory care, ambulatory infusion centers, etc.) represent areas of growth associated with lower costs of care.
- Unexpected global and national events such as the recent COVID-19 pandemic will put significant financial pressure on health systems, drive new ways of providing health care and may result in significant downsizing.
- The creation of nursing-sensitive indicators and the Magnet Recognition Program have created standards of excellence for nursing services, serving patients well by assuring safe nurse-to-patient staffing ratios. Similar efforts are needed, yet absent, in pharmacy.

Health system pharmacy drivers

- How pharmacy services are provided and how value is quantified vary widely across health systems.
- While pharmacy staff salaries have risen over the past decade due to the previous pharmacist shortage, these are expected to soon be a target for health system cost reductions.
- Although multiple organizations have developed advanced technician roles, many continue to use pharmacists to perform work that can be performed equally well (or better) by properly trained technicians at a much lower cost. Thus, opportunities exist to improve skill mix and further leverage technicians to support health system and pharmacy needs, and to build the pharmacy technician workforce necessary to support this.
- Ambulatory pharmacy services, which encompasses retail, employee prescription benefit management services, specialty pharmacy and ambulatory clinical pharmacy services are critical to health systems for a number of reasons: they support employee and population health programs by managing utilization and drug costs; they support quality and safety for specialty pharmacy patients while generating revenue; and they improve patient outcomes through pharmacist-run clinics as modeled by the Veterans Administration's national program and Geisinger Health.
- Evolving pharmacy models for telehealth in ambulatory care and remote acute care may become standard practices resulting from the recent pandemic.
- Vertically integrated mergers of payers and pharmacy benefit managers are disrupting the ambulatory care environment, including infusion programs, cancer centers, and retail and specialty pharmacies, creating challenges for patients in terms of access to care, quality and safety, while also negatively impacting health system financial performance.
- Pharmacy transitions of care services support patient care needs but are not consistently provided due to resource limitations. These services are essential to achieve organizational population health goals, and data demonstrate superior outcomes when these services are provided.
- Regulatory requirements in the areas of controlled substances and sterile compounding are expected to continually increase, making the provision of high-performing pharmacy services more costly and complex.

- The shortage of pharmacy staff trained to manage traditional central pharmacy functions presents a growing challenge due to the focus on clinical pharmacy over the past several decades. Currently, national pharmacy organizations and schools of pharmacy are not focused on addressing this challenge.
- While technology has improved many outcomes such as safety, efficiency, speed of operations and remote work capabilities, it has increased the complexity of pharmacy operations and the resources required to manage them.
- Metrics to demonstrate the effectiveness of pharmacy in demonstrating value are not well understood nor standardized across health systems.
- A large and growing body of evidence exists that demonstrates the value provided by a well-run pharmacy enterprise, yet payers and health system administrators are largely unaware of this positive association.

Methods

It was recognized that to develop the elements of an HVPE, an evidence-based and expert opinion-based approach was required. This well-established methodology is used by the National Academies of Sciences, Engineering, and Medicine (formerly known as the Institute of Medicine) to address critical national health topics, including preventing medication errors, the future of nursing and pain management, and the opioid epidemic. The cochairs (i.e., project leaders) of the initiative identified eight proposed domains as critical for the HVPE project, and a diverse panel of strategic contemporary pharmacy leaders was recruited to serve as domain authors. In preparation for an in-person meeting with all project panelists, each author was responsible for performing a thorough review of the literature and supporting professional guidance documents pertaining to their assigned domain. Based on this review and their personal experience, they were then responsible for writing a paper containing proposed evidence-based best practice consensus statements and performance elements, including a synthesis of the evidence, for full group review and debate.

Each author was encouraged to engage a pharmacy resident to support their work and participate in the in-person meeting. An experienced and respected facilitator was selected to support the process and guide the in-person meeting.

For each domain, the co-chairs developed questions to stimulate authors in developing their initial papers, consensus statements and associated performance elements. Authors were provided with written feedback on their draft papers, which were subsequently revised prior to the in-person meeting. Two reactor panelists, well-respected for their extensive contributions to the profession, were selected to provide feedback at the meeting. The draft papers were provided to all panelists for review and reaction prior to the in-person meeting, and each panelist was assigned as a lead reviewer for a paper they had not authored. The in-person meeting lasted two days, during which the panelists debated all draft consensus statement recommendations and reached an agreement on amended statements and performance elements within each domain. The meeting was made possible by a grant from Vizient.

Following the meeting, each paper was revised by the lead author and further edited by the project co-leads to achieve aspirational and consistently structured content, until an acceptable final paper was produced. Given the broad nature of the domains, there is redundancy in some of the performance elements and papers; however, editors observed that for the most part, the elements were described from different perspectives and/or the importance of the element warranted reinforcement in more than one domain.

Achieving consensus

Charting the course for advancing the profession requires commitment, vision, passion, big-picture thinking, engagement and extensive collaboration. Achieving consensus within a team of content expert panelists requires compromise and a willingness to engage in respectful debate. While most HVPE performance elements are supported by literature, some were derived primarily through panelist consensus based on professional experience. Over the course of the meeting, the collective contributions of each attendee resulted in what we believe to be a significant step in our journey toward defining an HVPE.

Call to action

The HVPE initiative was undertaken to serve as a unique and aspirational blueprint to assist pharmacy leaders with advancing practice and establishing optimal pharmacy enterprises through evidence-based and expert, opinion-based consensus statements and performance elements. While a growing body of evidence demonstrates the relationship between high-performing pharmacy services and improved patient outcomes and organizational performance, challenges are plentiful and there is much work to be done to achieve the HVPE vision.

The first step is to achieve a high level of HVPE visibility within the pharmacy community. Pharmacy leaders must be bold and deliberate toward this aim and work to better align our profession to achieve standards as outlined in the HVPE. This will be especially important given the recent pandemic and the anticipated aftermath that will likely result in new approaches to health care delivery, evaluation of workforce needs, and development of new models and sites of care. As a result, pharmacy leaders and staff will need to be nimble, visible and actively engaged in demonstrating quantitative and qualitative value to health system leaders, team members and patients. Choosing not to do so may place the future of health system pharmacy and the care of patients at risk. The next section contains proposed recommendations for what leaders can do over the next few years at the local level, within their organizations, collectively as colleagues within the Vizient University Health System Consortium Pharmacy Network and at a national professional organization level to make the concept of HVPE a reality.

Local level

- Advance the concept of the HVPE and its recommendations:
  - Distribute the HVPE technical paper containing best practice consensus statements and performance elements as required reading for all pharmacy staff, including pharmacists, technicians, pharmacy interns and residents.
  - Share the HVPE paper recommendation with pharmacy students and faculty (e.g., in faculty meetings, student colloquia, etc.).
  - Engage senior health system executives by sharing the key elements of the HVPE paper and discussing its relevance to health system goals and priorities:
    - Discuss "why" an HVPE supports organizational goals.
    - Provide specific examples and data illustrating HVPE performance derived from the blueprint.
    - Leverage positive results to request resources to establish new HVPE programs and services.
  - Establish a consistent, ongoing process for comprehensive assessment and documentation of the department's value, including quality, safety and financial outcomes associated with pharmacy practice.
- Use the HVPE to drive change:
  - Craft a new or revised departmental strategic plan around the HVPE framework, with specific attention given to establishing HVPE-recommended programs and services.
  - Perform an honest, detailed self-assessment (i.e., gap analysis) of departmental performance elements versus HVPE recommendations.
  - Use the gap analysis results to develop annual department goals and intern/resident projects:
    - Resident projects should focus on implementing an element of HVPE.
    - Establish new programs and services, then collect, analyze and disseminate results and outcomes data that demonstrates the value of HVPE services both internally and through publication.
  - Demonstrate ownership and accountability for advancing all aspects of the HVPE within pharmacy departments.

Vizient Consortium Pharmacy Network level

- Advance the concept of the HVPE and its recommendations:
  - Establish a webpage to host the HVPE technical paper and supporting content.
  - Develop webinar series and continuing education programming to highlight specific aspects of HVPE and the imminent need to transform the profession around this framework.
  - Develop an HVPE executive summary for senior health system executives.
  - Develop an infographic and interactive online educational tool to increase awareness of HVPE.
  - Utilize RxSolutions to spotlight the importance of HVPE.
  - Partner with national pharmacy associations to produce podcasts on the importance of HVPE, as well as to promote each domain with key themes.
- Use the HVPE to drive change:
  - Develop an electronic self-assessment tool to assist departments with completing a gap analysis of their current performance versus HVPE recommendations.
  - Develop toolkits to assist members with implementing HVPE recommendations.
  - Produce and disseminate business case templates with financial pro formas to assist members with advocating for resources to implement aspects of HVPE in their organizations.
  - Host joint in-person meetings (including Vizient national meetings) with pharmacy network executives and leaders from other networks (chief operating officers, chief medical officers, etc.) to discuss HVPE.
  - Engage Vizient consulting services to assist members with evaluating current performance and implementing HVPE recommendations.
  - Partner with national pharmacy associations to advance the national-level strategies outlined in the next section.
- Share positive results and outcomes:
  - Develop webinars, vignettes and continuing education (CE) programming to highlight HVPE success stories.
  - Assign committee members to help publish HVPE success stories.
  - Be deliberate in broadcasting the importance of HVPE and success stories to health system executives via the Vizient and SG2® consulting and network infrastructures.

National organization level

- Pharmacy should leverage HVPE to achieve consensus with external health care stakeholders about the characteristics of high performance in health system pharmacy.
- Pharmacy organizations should provide research grants to better define staffing and performance metrics associated with HVPE recommendations that improve patient outcomes analogous to nursing-sensitive indicators.[5,6]
- Pharmacy should partner with electronic health record (EHR) vendors to develop improved documentation systems that discretely capture and enable analysis of the impact of high-value pharmacy services.
- Pharmacy should lead interprofessional efforts to create influential, pharmacy-sensitive indicators, leveraging evidence to highlight pharmacy programs, services, and/or staffing metrics that are directly associated with improved patient care, safety, and/or outcomes.
- Pharmacy should partner with external stakeholders to establish an HVPE designation analogous to what the American Nurses Association has achieved with its Magnet Recognition Program as a means of improving recruitment and retention of talented staff and raising the organization's brand strength.

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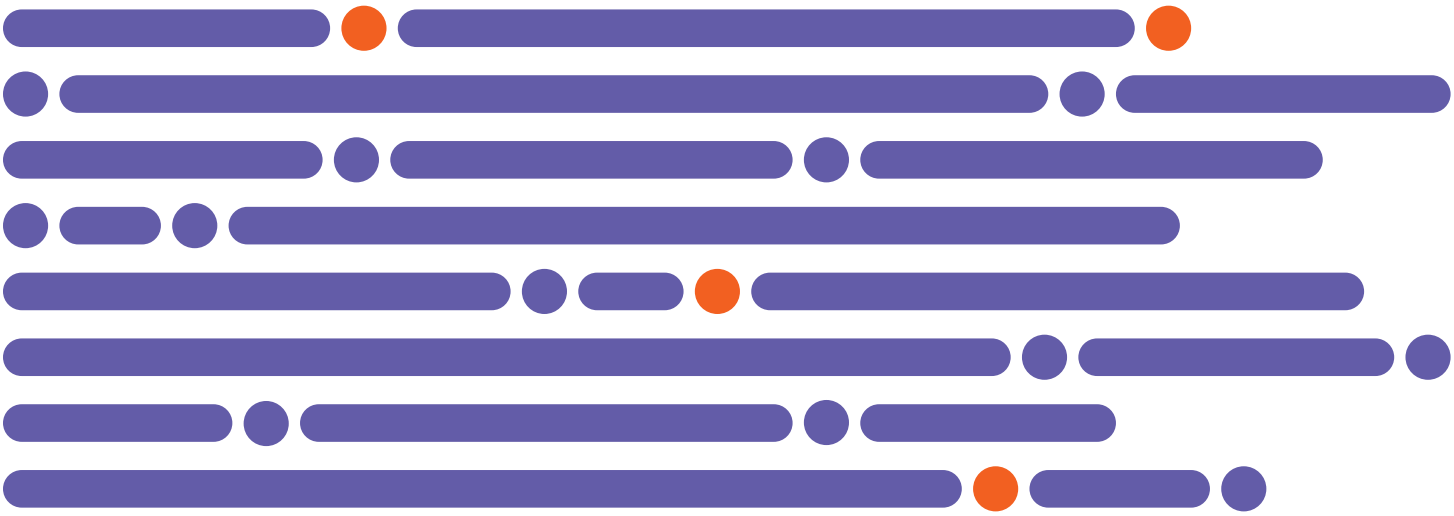

Domain 1: Patient care services

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Introduction

An HVPE provides robust pharmacy patient care services in which pharmacists are accountable members of the interdisciplinary patient care team. These services are optimized to achieve desired patient care outcomes, and they evolve over time as the profession advances. This domain highlights essential aspects of pharmacy patient care services considered to be standard expectations of a modern pharmacy enterprise, with an emphasis on inpatient and care transitions. Ambulatory pharmacy patient care services are addressed in Domain 3.

This domain includes two detailed appendices. **Appendix A** provides a proposed set of pharmacy-sensitive indicators (PSIs) highlighting evidence-based pharmacist patient care services and interventions that are associated with improved patient care, safety, and/or financial outcomes. **Appendix B** provides a proposed list of comprehensive inpatient and transitional care pharmacy services that should be provided in a contemporary pharmacy enterprise.

- Topic 1: Pharmacy services
- Topic 2: Continuity of health care
- Topic 3: Stewardship of resources and programs
- Topic 4: Clinical data analytics

Topic 1: Pharmacy services

Statement 1a

Pharmacists provide comprehensive pharmacy patient care services as providers on the interdisciplinary care team in all settings of care.

Performance elements 1a

- Pharmacists provide collaborative and interdisciplinary care in an evidence-based, cost-effective manner.
- The pharmacy department is accountable for drug therapy services and outcomes, independent of time, day of week, holiday or individual providing the service.
- Specialized services reflect the patient mix of the institution and are provided by pharmacists with postgraduate year 2 (PGY2) residency training (or equivalent experience) and board certification.
- Pharmacists are responsible for identifying and prioritizing which patients require their care, and services are not limited to a consult model.
- Pharmacists participate as essential interdisciplinary care team members on patient care units.
- Pharmacists are aligned with patient care needs in collaboration with the health care team for acute and ambulatory care patients, including, but not limited to:
  - Oncology
  - Emergency medicine
  - Pain management
  - Pediatrics
  - Critical care
  - Transplant
  - Internal medicine
  - Psychiatry
  - Cardiology
  - Geriatrics
  - Neurology
  - Surgery
  - Investigational drug services

Statement 1b

Pharmacists are accountable for all patient medication use needs to support safe and effective drug therapy management.

See **Appendix B** for a comprehensive list of contemporary inpatient and transitional care pharmacy services.

Performance elements 1b

- Pharmacists are accountable for clinically evaluating patients and managing their medication orders.
- Pharmacists directly manage specific medications through interpretation of a patient's clinical conditions and relevant laboratory values.
- Pharmacist documentation pertaining to patient care is available to all members of the health care team.

Statement 1c

Pharmacists ensure appropriate use of pharmacogenomic information and biomarkers to optimize drug therapy selection, prevent adverse events, and reduce the total cost of care.

Performance elements 1c

- Pharmacists collaborate with the health care team to ensure appropriateness of genetic testing and align pharmacotherapy with results.
- Pharmacy provides resources for clinical interpretation of pharmacogenomic data.
- Pharmacy provides pharmacogenomics education to patients and other caregivers.
- Pharmacy is responsible for managing pharmacogenomics in the EHR.

According to national surveys of pharmacy practice in hospital settings conducted annually by the ASHP, pharmacists are being used more than ever to monitor patients, conduct medication management, and provide direct clinical services to avoid and resolve medication-related problems.[1,2,3] One of the most telling statistics from these surveys is the dramatic increase in daily monitoring by a pharmacist occurring in 75% or more of patients in a majority of hospitals. This increase is up from 20.3% in 2000 to 57.8% in 2015.[3]

Pharmacy services continue to expand as pharmacists demonstrate their value in new and novel settings. Multiple specialty services have been documented in the literature as having positive outcomes, as demonstrated in **Appendix A**. A prospective, observational review of the addition of a clinical pharmacist to a hematology/oncology

service demonstrated the impact that pharmacists can have on highly complex patients.[4] Interventions addressed inappropriate medications, untreated indications, inappropriate route, underdosing and overdosing, drug-drug interactions, drug monitoring, and optimizing medical therapy. The pharmacist intervened on 12.6% of prescriptions for hospitalized adult patients with cancer. Interventions had a 96% acceptance rate.

The benefits of adding a pharmacist to a service can be applied to a broad range of clinical specialties that require complex medication management. For example, adding pharmacists to interdisciplinary clinical rounding teams in intensive care units is associated with the avoidance of 54.7 ± 47.2 deaths per hospital annually.[5] As another example, a retrospective review spanning 1,000 hours of emergency medicine pharmacists' time identified 364 medication errors intercepted by the pharmacists, with 88% being considered significant or serious by independent reviewers.[6] Pharmacist interventions included prospective medication review of orders, participation in drug therapy consultation, medication reconciliation, medication obtainment and participation in resuscitations. Therapeutic drug management by pharmacists for medications such as vancomycin, which requires routing monitoring and dose adjustments, has been associated with favorable outcomes. A pilot program at Brigham and Women's Hospital reviewed the pre- and post-implementation of a pharmacy dosing service.[7] Of the 319 patients analyzed, 96.8% in the post-implementation group received optimal vancomycin dosing versus 40.4% pre-implementation. The program also showed a statistically significant reduction in length of stay (8.4 days versus 10.0 days) and incidence of nephrotoxicity (3.2% versus 8.7%).

Many studies have also reviewed the financial impact clinical pharmacists have on interdisciplinary teams for their institutions. The fourth iteration of a review of economic evaluations of clinical pharmacy services covering studies published from 2006 to 2010 describes a benefit-cost ratio from 1.05:1 to 25.95:1.[8] The review stated that recent publications on economic analysis have dwindled significantly, down from 93 studies from 2001 to 2005 to a mere 25 studies from 2006 to 2010. While fewer studies reviewed the economic impact of clinical pharmacist services, a higher proportion involved full economic evaluations and had controlled designs.

The HVPE project literature review focused on published articles from the last 10 years. Because earlier studies clearly demonstrated the significant clinical and economic value of adding pharmacists in direct patient care roles, it is not surprising that new literature in this area has declined. Future research is needed to evaluate new areas of pharmacy expansion, such as proving the value of health system-owned specialty pharmacies.

Pharmacogenomics is a relatively new specialty that offers additional opportunities for medication optimization by pharmacists. With their knowledge and training, pharmacists are well positioned to develop and oversee these services. ASHP advocates the inclusion of pharmacogenomics and its application in therapeutic decision-making, stating that all pharmacists should have knowledge and understanding of pharmacogenomics.[9] Pharmacist involvement in an interdisciplinary pharmacogenomics clinic has been described.[10]

To develop a systemwide pharmacogenomics program, the health system should insource genetic testing, integrate pharmacogenomics-specific clinical decision support (CDS) tools into the EHR and train staff on the complexities of this specialty area. Through the use of resources provided by organizations such as the Clinical Pharmacogenetics Implementation Consortium (CPIC) and Pharmacogenomics Knowledge Base (PharmGKB), pharmacists are able to identify relevant genetic testing for their organizations and lead the development of processes for ordering, reporting and interpreting test results. Pharmacogenomic-specific CDS tools aid in the reporting and interpretation of results and ensure appropriate referral. In a review of primary research articles on genetically guided personalized medicine, automatic CDS and EHR integration into routine clinical workflow were consistently present with success of pharmacogenomics programs.[11]

Topic 2: Continuity of health care

Statement 2a

Pharmacy is accountable for comprehensive medication management across the continuum of care to optimize drug therapy and patient safety.

Performance elements 2a

- Pharmacy is accountable for medication reconciliation services during care transitions, including hospital admission, transfer and discharge, as well as in ambulatory and post-acute settings.
- Pharmacy is accountable for ensuring the accuracy of patient medication lists.
- Pharmacists are accountable for avoidance of polypharmacy and deprescribing as appropriate.

Statement 2b

Pharmacists are responsible for ensuring that patients understand and are proficient in using their high-risk medications.

Performance elements 2b

- Pharmacy creates and maintains patient education information.
- Pharmacists provide patient medication education in areas including, but not limited to:
  - Anticoagulation
  - Chronic heart failure
  - Chronic obstructive pulmonary disease
  - Other high-risk patients as appropriate
- Pharmacy uses remote technology to reach patients.
- Pharmacists educate patients on technologies to help manage their drug therapy.

Statement 2c

Pharmacy staff coordinates transitional and post-discharge drug therapy management for patients at high risk of readmission.

Performance elements 2c

- Pharmacy identifies high-risk patients and prioritizes their care.
- Pharmacy provides post-discharge drug therapy management for high-risk patients.

Appropriate medication management is a critical component in ensuring continuity of health care. To provide high-quality, cost-effective, patient-centered care across the continuum, pharmacists must manage all levels of care. Pharmacy-led transitions of care services, such as performing medication histories, reconciliation and patient education, have shown a reduction in readmissions, improved outcomes and realization of financial savings.[12]

Discharge medication teaching and reconciliation can significantly decrease hospital readmission.[13] A multidisciplinary group with pharmacists providing discharge planning two to four days after hospital admission showed a statistically significant difference in readmission within 30 days compared with standard of care (incidence rate ratio, 0.695). Discharge medication teaching also allows pharmacists to identify barriers in care and help address those barriers with the interdisciplinary team before discharge. A review of pharmacist-provided education and discharge instructions to patients with heart failure showed a reduction in 30-day all-cause readmission, increased patient satisfaction and increased compliance with The Joint Commission (TJC) core measures.[14] Providing discharge teaching is also an ideal opportunity to ensure that patients are receiving the necessary information to help manage their own care. Chronic conditions that have complex therapy and are associated with frequent hospital readmissions can be targeted to reinforce patient adherence with prescribed therapy.

Patient education and teaching are considered minimum pharmacy practice standards by the ASHP.[15] Pharmacy staff must participate in and assure that medication-related teaching and education for patients is accurate, at the appropriate literary level and comprehensive. Disease state-specific medication education in the areas of anticoagulation management, chronic heart failure and chronic obstructive pulmonary disease has demonstrated a reduction in hospital readmissions and improved patient safety outcomes.[16,17,18]

Clinical pharmacy services can also be provided remotely for patients who are geographically restricted.[19] Studies have demonstrated that pharmacists can identify and solve medication problems in home health and telehealth settings.[20] Pharmacists must ensure that patients are aware of the resources and technologies available to assist in the management of their own care.

Specific patient populations and care transitions are more prone to safety and outcomes concerns. Pharmacy should prioritize resources to ensure appropriate medication reconciliation for all high-risk admissions and discharges. By using available technology, predictive modeling can be leveraged to identify patients at the highest risk and those most likely to benefit from pharmacist intervention. One study used such a tool to demonstrate that patients could be stratified into low, medium or high risk for hospital readmission based on medication count, comorbidity count and health insurance status at hospital discharge.[21] In another study, patients identified as high risk for readmission who received post-discharge medication therapy assessment and reconciliation from a pharmacist compared to no pharmacist intervention had significantly reduced readmission at seven days (0.8% versus 4%) and 14 days (5% versus 9%), and an estimated cost savings of $35,000 per 100 patients.[22] Telephonic hospital discharge programs or other remote services should be used to reduce readmissions and improve medication adherence of these patients.[23] Identifying patients as "high alert" and using a step-by-step pathway supports a comprehensive approach to safe medication transition.[24]

Topic 3: Stewardship of resources and programs

Statement 3a

Pharmacy is accountable for clinical and financial stewardship of high-cost and high-risk medications to ensure their appropriate use in all patient care settings, including inpatient, outpatient and procedure settings, preventing the consequences of overuse and underuse.

Performance elements 3a

- Pharmacists evaluate and limit medication use to necessary therapy, frequency and duration and deprescribe as appropriate.
- Stewardship of high-risk drugs include, but are not limited to:
  - Antimicrobials
  - Opioids
  - Anti-thrombotics, including anticoagulants, antiplatelets and procoagulants
  - Antihyperglycemics
- Pharmacists review and manage high-cost medication orders and regimens.
- Pharmacy is accountable for drug-use policy, assuring appropriate medication use across the continuum of care.

Statement 3b

Pharmacists serve on organizationwide patient care committees to promote patient-centered, value-based care.

Performance elements 3b

- Pharmacy has appropriate representation and leadership on the pharmacy and therapeutics (P&T) committee and other committees and teams focusing on medication stewardship.
- Pharmacy participates in clinical, performance improvement and operational committees.

Drug costs have far outpaced inflation over the last decade.[25] As drug budgets become a larger percentage of total supply costs for health systems, it is increasingly important for pharmacists to be effective stewards of their institution's resources. Pharmacists must also protect the organization from inappropriate use of medications from both safety and quality perspectives.

Medications with routine monitoring, significant drug interactions and variable pharmacodynamics are ideal targets for direct management by pharmacists. Federal agencies have identified common medication classes that can lead to substantial patient harm without diligent surveillance.[26] Pharmacy oversight and monitoring of anticoagulants,

diabetes agents and opioids as outlined in these recommendations helps to ensure safer and higher-quality services. With these additional responsibilities and expectations, we need to ensure that pharmacists are appropriately trained, board certified (when available) and credentialed for the specialty service they provide.[27]

Pharmacists act at all levels within the organization to ensure that cost-effective, patient-centered care is provided. Stewardship programs provide targeted efforts to impact how care is given throughout the health system. Many of these programs are interdisciplinary, and pharmacists are a critical part of any successful medication stewardship initiative. Pharmacists must have a prominent role in all health system stewardship programs targeting specific disease states or medication classes. Examples include infectious diseases, anticoagulation, diabetes and pain. These programs aim to decrease costs and overuse or underuse of medications.

TJC standards for antimicrobial stewardship can be used as a model for committee design.[28] These guidelines can be broadly applied to various stewardship groups, as they recommend identifying stewardship leaders, establishing goals, implementing evidence-based practice guidelines, educating clinical staff, and analyzing and reporting data associated with the program. The objectives established by these stewardship programs should coincide with nationally identified targets, such as the Adverse Drug Event Prevention initiative.[26] The Centers for Disease Control and Prevention's Core Elements of Hospital Antibiotic Stewardship Programs define pharmacists as drug experts who are required to be part of the interdisciplinary team, an element that should be consistent for all stewardship programs.[29] Many successful antimicrobial stewardship programs have been implemented across the country through these methods and optimized by incorporating recommendations from organizations specializing in infectious disease.[30]

Stewardship programs focused on opioids, antithrombotics and antihyperglycemics have also shown meaningful improvements due to pharmacist inclusion.[17,31,32] A three-year retrospective review of the implementation of a pharmacy pain management service shows this impact.[33] The pharmacists were responsible for consultations and stewardship activities, such as proactively screening patients with a high risk of opioid-induced adverse effects, use of designated high-risk opioid products or inadequate pain control. Overall, the results showed a reduction in total opioid use, a decrease in the number of opioid-associated code blue events, an increase in provider and patient satisfaction, and significant cost savings. The interventions are multifaceted, and through creation of clinical guidance support, order sets, restrictions, education and direct deprescribing under consult orders, these pharmacists were able to be successful stewards for their health system.

Pharmacists are an essential element of the health system formulary management process through P&T committees. Pharmacists provide crucial clinical and operational drug review, expert opinions, and guidance to these committees so that well-informed decisions are made to manage the organization's specific formulary needs appropriately.[34] High-cost drugs can be targeted to prevent unnecessary expenses in a health system. A P&T subcommittee consisting of pharmacists, clinicians and an ethics representative developed an approval pathway for 35 medications costing more than $5,000 per dose or $10,000 for an expected course of therapy, demonstrating an annual savings of $491,000 by reducing unnecessary utilization.[35]

Stewardship committees play a significant role in formulary management by vetting drug approvals and creating drug restrictions. When doripenem replaced imipenem at The Ohio State University Wexner Medical Center, the antimicrobial committee added restrictions not present for imipenem.[36] These restrictions led to a decrease in the use of doripenem compared with imipenem from a mean of 27 antimicrobial days per 1,000 patient days to 11 antimicrobial days per 1,000 patient days with no increase in the use of other antipseudomonal agents.

Topic 4: Clinical data analytics

Statement 4a

Pharmacy establishes a consistent, ongoing process and key performance indicators for comprehensive assessment and documentation of the impact of pharmacy patient care services on quality, safety, and financial outcomes and other organizational goals.

Performance elements 4a

- Pharmacy performance indicators include the impact of pharmacy services on patient outcomes and cost of care.
- Unnecessary variation in care is reduced.
- Pharmacy evaluates the clinical and economic impact of service through practice research or other means.
- Pharmacists are integrated into quality improvement projects.

Identifying and communicating the value of pharmacy is fundamental to ensuring that all caregivers understand the impact that pharmacy has on patient care. Health systems can differ drastically in terms of pharmacy services offered and patient case mix. Therefore, internal measures should be tailored to the organization. These performance measures should be clearly relatable to the value pharmacy adds to the organization and should directly correlate with actions that pharmacists or other pharmacy staff perform. Examples of such performance indicators are the number of drug-related problems identified per medication history, number of renal dose adjustments per patient day, prescribing errors intercepted per admission and potential adverse drug events (ADEs) avoided per 100 admissions. Performance measures can also be identified by professional provider organizations per their recommendations for optimal care paths and opportunities for deprescribing.[37]

The perils of using external benchmarking data to determine appropriate pharmacy staffing levels and the overall effectiveness of pharmacy services has been well described.[38] Pharmacy departments must establish internal markers that clearly and measurably demonstrate the impact of pharmacy patient care services on patient outcomes. These metrics or key indicators should align with organizational goals and be relevant to decision makers at the health system and health policy levels. In her 2012 Harvey A.K. Whitney Lecture, Rita Shane suggested the following acute care, transition

of care, and post-discharge process and outcome indicators as a starting point for the development of pharmacy-sensitive indicators associated with improved patient outcomes:

- Number and severity of prescribing errors prevented per 100 admissions.
- Number of medication-related quality problems (underuse and overuse) resolved per 100 admissions.
- Number of ADEs in high-risk patients per number of pharmacist hours per 100 beds.
- Number and potential severity of drug-related problems resolved during transitions of care and after discharge per 100 patients.
- Number of successful teach-back encounters after patient education and after discharge.
- Adherence rates (defined as medications taken as prescribed) and readmission rates 30, 90 and 180 days after discharge in high-risk patients with pharmacist follow-up, compared with adherence rates without pharmacist follow-up after discharge.[39]

While multicenter studies should be conducted to identify and validate these and other proposed pharmacy-sensitive indicators, these proposed metrics serve as a suggested starting point for health system pharmacy leaders wishing to routinely measure and demonstrate the value of pharmacist patient care services within their organizations.

Conclusion

An appropriately resourced, well-run pharmacy enterprise leverages its employees to provide high-quality, cost-effective care that has been demonstrably documented in the literature. Implementing proven services and rapidly adopting novel programs will improve the safety and quality of patient care and decrease total health care costs. Health systems providing the pharmacy services described in this domain meet the patient care services component of an HVPE.

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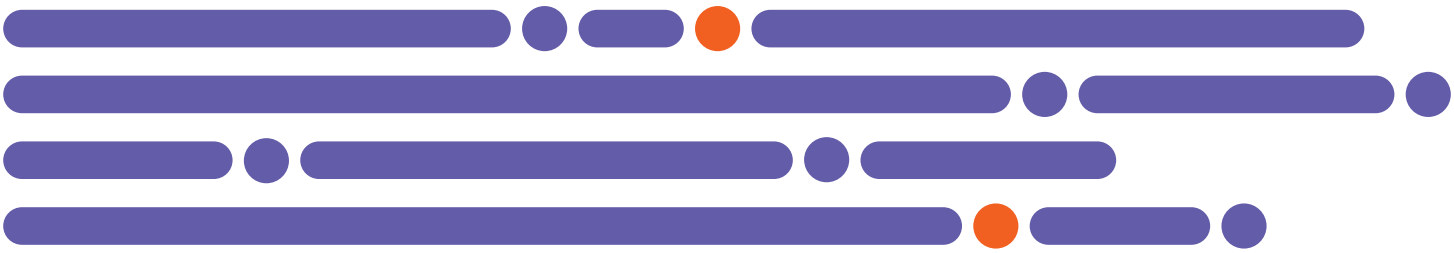

Domain 2: Business services

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Introduction

In an ever-changing climate of diminishing health care reimbursement and increasing expenditures, pharmacy plays a critical role in developing innovative business solutions for delivering patient care and creating value for the health system. Health systems must leverage their pharmacy enterprise to improve medication revenue cycle performance, capture pharmacy-related business and establish expertise in payer contracting processes. Pharmacy is uniquely situated to optimize the complete management of medications across the health system and must routinely seek out opportunities to create business services that decrease costs and expand patient access to care. Maintaining responsibility for all phases of medication acquisition, billing and reimbursement across all sites of care is essential to the HVPE. Additionally, developing revenue-generating business services that can be scaled across a health system brings substantial value to patients and the financial well-being of the organization. This domain highlights essential business services and systems that are deployed in an HVPE.

- Topic 1: Medication cost management
- Topic 2: Medication access
- Topic 3: Revenue integrity
- Topic 4: Business growth

Topic 1: Medication cost management

Statement 1a

A systemwide formulary management system is implemented.

Performance elements 1a

- Formulary management system is organizationwide and includes medication selection, criteria for use of high-risk and high-cost medications, guidelines to direct cost-effective therapy, and protocols to streamline care.
- Systemwide subcommittees are used for specific medication classes (e.g., oncology, infectious diseases, high-cost medications) to perform risk versus benefit assessments and support appropriate use.
- High-cost medications are managed and monitored on an ongoing basis for effectiveness, adherence to established criteria for use, financial impact, optimal site of care, and new clinical and cost information.
- Medication policies to support effective drug management are developed and monitored for compliance (e.g., non-formulary use, medication restrictions, dose rounding, therapeutic interchange, renal dosing, intravenous [IV] to oral [PO] conversion).
- Pharmacists are accountable for ensuring compliance with medication policies.

Functionality is incorporated into the EHR to drive formulary and medication policy compliance.

Statement 1b

Strategies for cost-effective, coordinated medication management are implemented that take into consideration patient care, patient satisfaction and evolving payer requirements.

Performance elements 1b

- Patient-centric options for infusion therapy administration are available (e.g., home infusion, off-site infusion centers).
- Telehealth services are provided, when appropriate, based on clinical and patient-specific criteria.
- Health system-owned retail and specialty pharmacy services are provided and include patient-centered services (e.g., free home delivery, financial assistance).
- Policies related to the most appropriate site of care for infusion therapies are implemented to ensure patient access to cost-effective care.

Statement 1c

Systems are established to reduce medication waste in all phases of the medication use process.

Performance elements 1c

- Monitoring processes are used to anticipate discontinuation of short-stability medications (e.g., pharmacy-prepared intravenous doses, refrigerated minibags).
- Pharmacy-prepared sterile medications are batched to balance timely availability and preparation efficiency with waste minimization.
- Data on medication expiration and waste are tracked and monitored for trends to identify opportunities for improvement (e.g., adjustment to par levels, process changes).
- Automated functionality for expiration date tracking is used and procedures are implemented to prevent waste.

Statement 1d

Medication inventory management systems are documented and implemented across the health system.

Performance elements 1d

- Systemwide, centralized oversight of medication inventory management is established.
- Perpetual inventory software is used to monitor high-cost medication inventory in real time.
- Medication par levels in all storage areas are routinely reviewed and optimized based on current use data.
- Strategic sourcing is used to bring the highest value to the pharmacy supply chain (e.g., long buy, use of secondary wholesalers).
- Inventory that is at risk of expiring is redistributed to the highest area of use to minimize waste.
- High-cost drugs are purchased, stored centrally, monitored and distributed as needed in low units of measure throughout the organization.

Statement 1e

Medication contracting, procurement and distribution are managed by the pharmacy for all sites of care.

Performance elements 1e

- Systemwide, centralized oversight of medication contracting, procurement and distribution is established.
- Contract enhancement opportunities available through group purchasing organization (GPO) portfolios and direct manufacturer offers are reviewed and evaluated on an ongoing basis.
- Major contracts for medication, equipment and services (e.g., wholesaler, automation, software) are periodically evaluated through a request for proposal (RFP) process.
- Medication purchases are monitored for alignment with anticipated contract and tiered pricing, with systems in place to recover savings when appropriate.
- Purchasing coalitions are leveraged to enhance contracting opportunities.
- Contracts are negotiated in accordance with appropriate class of trade.

Statement 1f

For qualifying 340B-covered entities, the 340B program is effectively managed to assure compliance, with savings optimized across the health system.

Performance elements 1f

- Pharmacy implements best practices to provide oversight for the 340B program (e.g., systemwide steering committee, continuous internal compliance assessments, annual external auditing).
- Purchases by account (e.g., 340B, GPO, wholesale acquisition cost [WAC]) are monitored for compliance and optimization opportunities.
- Contract pharmacy arrangements are optimized for savings in a compliant manner.

An optimally developed formulary management process promotes rational, safe and cost-effective drug product use throughout the system and is built into the EHR when possible. This should occur through an integrated approach that enables pharmacists, physicians and other health care professionals to collaborate for improved patient outcomes. Standardization and formulary management should include urgent care, physician offices, and retail and specialty pharmacies.

In the landscape of continually increasing health care expenditures and breakthrough innovation, costly specialty medications represent a key driver of rising expenses, and a robust clinical financial interface is essential. Developing an oversight body for high-cost drugs as one of the system P&T subcommittees is imperative for formulary management. Leveraging the clinical expertise of the subcommittee's interdisciplinary team and fully evaluating outcomes data provide well-informed risk versus benefit assessments to ensure the most cost-effective care.

During the review period, the subcommittee should assess clinical effectiveness, alternative therapies, safety, timing and duration of treatment, and site of care for drug administration, while also addressing ethical and reimbursement considerations.[1] Criteria for use, site of care and drug-specific requirements should be hardwired into the EHR.

Monitoring the appropriate use of high-cost medications, once approved to the formulary, is also critical in minimizing unnecessary medication costs that do not add value to patient care. A medication use team, which includes representatives from pharmacy, revenue cycle, finance, informatics and medical staff, should be implemented to continually assess effectiveness, outcomes, alternatives and risks.[2] Determining payer policies, conducting robust prior authorization and monitoring reimbursement enables organizations to support high-cost therapies and informed decision-making about supporting patients who require these therapies.

Health systems are being challenged to expand the continuum of care, offer individualized outpatient services and provide higher-quality service, all while trying to grow revenue among an ever-changing health care landscape.[3] As part of the health system pharmacy's plan to handle the increase in specialty pharmaceuticals, it should consider providing home- and non-hospital-based ambulatory infusions, which opens a new source of revenue and allows the treatment of patients in more cost-effective locations. Health systems that can serve patients at home are well positioned to capitalize on the market shift. Furthermore, implementing these specialty services enables health systems to develop elevated models for the coordination of patient care.[3] This strategy would also include offering specialty pharmacy and retail pharmacy services.

The health system pharmacy should routinely seek out opportunities to minimize waste of pharmaceuticals as a fundamental core element to inventory management. An area of significant waste reduction opportunity lies in the assessment and management of intravenous product waste.[4] Not only do pharmacies often waste significant amounts of infusion medications, but they generally do not have a clear evaluation on the amount of waste due to inconsistent monitoring processes.

While managing inventory, the health system pharmacy must balance patient care and customer service needs with the goal of minimizing expensive on-hand inventory.[4] This oversight should include a multifaceted, data-driven approach that continuously assesses current inventory, especially for high-cost medications and noncontrolled substances that have been associated with diversion, established pars, medication availability, current use and future anticipated use. Automation in the pharmacy has helped provide several opportunities for streamlining processes; however, the ability to address broader opportunities to improve efficiencies in medication inventory management across the system lies in the partnership of medical supply chain executives and pharmacy supply chain leaders.[5]

Pharmacy should have direct oversight and accountability of the medication supply chain process across the entire health system and all classes of trade. Pharmaceutical purchasing at discounted rates can be contracted through one of three ways: GPO contracts, facility contracts and wholesaler own-use contracts. Understanding the advantages of each of these contract types is critical to the success of contract management.[4] Effective management and control of contracts should use a contract management system to maximize contractual performance and improve audit preparation and contract compliance. Pharmacy must have oversight of the contracting services for all classes of trade: retail, non-hospital-based physician offices, hospital inpatient and outpatient, home infusion, and specialty.

For health systems with covered entities under the 340B program, minimizing purchases at WAC while maintaining 340B program compliance is a critical strategy to navigate a health care landscape of increasing drug costs and shrinking reimbursements.[6] Pharmacy leaders participating in the 340B program must have a robust and properly resourced 340B compliance and monitoring program, which includes close monitoring of GPO, 340B and WAC purchases for unanticipated variances and drug savings opportunities.

Ensuring drug integrity is required by the Drug Supply Chain Security Act to protect patients, and the Centers for Medicare & Medicaid Services (CMS) conditions of participation require that pharmacy is responsible for procurement of all drugs. Health system policies that delineate pharmacy's requirement for drug integrity and purchasing should be approved by the P&T committee and communicated to managed care and contracting leadership to ensure patient safety.

As biosimilars become commercially available, the medical center must determine which medication will be used based on the evaluation by the P&T committee. Both CMS and TJC require that the P&T committee is responsible for formulary decision-making. Reimbursement by the payer should be equivalent to the reimbursement rate for the product regardless of which product is used (e.g., the innovator product or a biosimilar).

With the continuing availability of biologics and therapeutic advances that are administered as infusion therapies, health system pharmacists are able to leverage their clinical and financial expertise to support decision-making about optimal sites of care to support safe, effective therapy, which can avoid unnecessary admissions and/or reduce length of stay. This strategic role supports patients, payers and health systems.

Topic 2: Medication access

Statement 2a

Pharmacy is accountable for ensuring effective and efficient patient access to medications, including benefits review, prior authorization and prescription refill services, to support patients and providers and optimize revenue.

Performance elements 2a

- Pharmacy provides medication benefits review and prior authorization services for clinic-administered medications and outpatient take-home prescriptions (retail and specialty).
- Centralized, pharmacy-run prescription renewal and refill authorization services are available for providers.
- Services are provided for all care settings throughout the health system, including clinics, physician offices and inpatient discharges.
- Centralized medication benefits review and prior authorization services are implemented for the health system to maximize efficiencies and support cost-effective expansion.
- Pharmacists and/or pharmacy technicians are integrated in specialty clinics that require direct patient or provider communications.
- Electronic systems for benefits review and prior authorization are used to streamline processing.
- Pharmacist-driven protocols are used to expedite treatment modifications to align with payer insurance coverage (e.g., alternate designated medication within a therapeutic class).
- Prior authorization turnaround time and success rates are tracked and monitored for timeliness, effectiveness and opportunities for improvement.
- Medication benefit review, prior authorization and prescription renewal services are documented in the EHR and transparent to all members of the health care team.
- Policies are implemented to ensure medications maintain safe storage and secure chain of custody before administration.
- Payer contracts and agreements authorize the health system to determine designated biosimilars and other medications through its formulary management process.
- Payer and pharmacy benefits management contracts and agreements authorize the health system's providers to determine appropriate outpatient site of care settings based on patient needs.

Statement 2b

Pharmacy is accountable for ensuring effective and efficient patient access to medications, including provision of comprehensive medication assistance program services to help uninsured and underinsured patients access free medications.

Performance elements 2b

- Pharmacy provides a medication assistance program to access free take-home and clinic-administered medications.
- Medication assistance program services include coordination of access to drug manufacturer assistance programs, patient enrollment in grants and identification of manufacturer replacement drug programs.
- Medication assistance, access and affordability services are documented in the EHR and are transparent to all members of the health care team.
- Patient savings and medication write-off avoidance outcomes are routinely documented.

The number and complexity of medication prior authorizations that providers and patients must manage has steadily increased over time and will likely continue. The prior authorization process was designed to improve the overall use of evidence-based treatment approaches, as well as to reduce prescription costs; however, many barriers have become overwhelming for health care professionals and, most importantly, patients.[7] Excessive wait times for approval, unfilled prescriptions, possible abandonment of therapy and ultimately increased likelihood of medication non-adherence have led to many negative impacts on patients and their respective health outcomes. Similar outcomes may occur with other barriers to access, including affordability and refill authorization.

Pharmacy personnel are ideally situated to coordinate care of patients through the prior authorization process by interfacing directly with patients and ensuring that medications are obtained and adherence to medication regimens is maintained.[8] Pharmacists and pharmacy

technicians are able to perform many of the prior authorization tasks on behalf of the provider, optimizing care model efficiency, maximizing reimbursement and minimizing patient out-of-pocket expense.

Integrating pharmacists and pharmacy technicians into specialized clinics and using a centralized pharmacy hub model has several benefits, including significantly reduced time to initiate therapy and improved revenue capture. In addition, by taking ownership over the entire prior authorization process for specialty medications, infusions, prescriptions and other high-cost, clinic-administered medications, the pharmacy team streamlines decision-making and reduces the burden on providers and nursing staff. Creating such programs that focus on patients with complex social determinants enhances the services provided by pharmacy and takes a holistic approach to patient care. Documentation of these activities into the EHR creates transparency for all members of the health care team and ensures continuity of patient care.

Multiple studies have demonstrated the value of centralizing prescription management services. A centralized, pharmacy-led prior authorization process displayed a higher prior authorization approval rate, faster time to fill, shorter time to process and reduced staff time versus a clinic-led process.[9] In addition, medication assistance programs can provide cost savings opportunities for patients and the health system. One study documented a decrease of over $6.2 million in Medicare write-offs in a six-month time frame, equating to a 20:1 return on investment (ROI), while another study reported total patient cost savings of more than $2.7 million over a two-year period.[10,11] Centralizing the medication refill process through collaborative practice medication refill agreements can increase provider time, which can then be reallocated to seeing more patients in clinic.[12] In addition, pharmacists are able to ensure appropriate use of health care resources and provide cost savings to the health system through pharmacy-led formulary management services. One study by a Department of Veterans Affairs medical center reported an 81% reduction in cost of therapy and over $420,000 in total cost savings over a three-month period through pharmacist-led adjudication of restricted drugs, which was guided by the National Formulary of the Veterans Affairs Pharmacy Benefits Management.[13]

As the availability of electronic prior authorization becomes available in EHRs, significant operational efficiency and patient safety benefits will be realized. Specifically, resource-intense prior authorization processes that disrupt pharmacy and physician workflows and create a delay for patients to obtain essential medications will be substantially reduced. Furthermore, duplicate therapies that result from patients being discharged on a health system formulary medication in addition to having the health plan's preferred formulary medication for the same indication will be reduced.

Topic 3: Revenue integrity

Statement 3a

Pharmacy is accountable for ensuring optimal medication revenue integrity, limiting medication-related financial liability and ensuring appropriate site of care selection for high-cost medications.

Performance elements 3a

- Pharmacy, in collaboration with finance, payer contracting and applicable patient care areas, coordinates a systemwide medication revenue integrity team.
- Revenue cycle monitoring tools are employed to ensure timely and accurate receipt of payments, track denials and audit for billing accuracy.
- A process for review and escalation of denials and uncollected claims is established, including pursuing options for recovery through payer clinical justification, patient assistance programs and safety net insurance coverage.
- Trends in denials and billing errors are reviewed and action plans for prevention or improvement are implemented.
- Payer policy and contract changes related to medications are routinely reviewed and assessed for potential impact on the organization.

The medication revenue cycle is unique and highly complex. Revenue cycle integrity for medications is essential in ensuring billing compliance and reducing uncompensated care from payer denials, uninsured and underinsured patients, and billing inaccuracies. However, there are many challenges inherent to maintaining revenue integrity related to medication billing, including the vast number of medications and dosage forms, complexities of billing units and variances from dispensing units, payer-specific billing and clinical requirements, ongoing changes in commercial payer drug policies, and federal program restrictions (e.g., CMS and Medicaid billing requirements related to the federal 340B program).[14] Because of these challenges, the specialized expertise of pharmacists and pharmacy technicians is a required element of a successful revenue integrity program to ensure optimal results.

Steps that the health system pharmacy enterprise can take to improve processes around billing include implementing a pharmacy revenue integrity team, developing a collaborative workflow between the pharmacy revenue integrity team and other revenue cycle specialists, establishing data governance workflows and maintenance, and integrating pharmacy data using technology available to best bridge gaps between validated data.[15]

By having a fully cohesive and integrated revenue integrity team, the pharmacy enterprise will most certainly reduce revenue leakage by correcting inaccurate pricing, coding, charging and documentation in the billing process.[16] The team should also improve fluctuations in medication charges, align charges across facilities and enhance overall revenue integrity alongside patient satisfaction.[15]

The health system pharmacy enterprise must also incorporate built-in oversight measures of pharmaceutical data into their billing systems to ensure correct and complete information. This is particularly important for high drug cost areas, such as outpatient infusion centers, where there are frequent changes to drug costs (e.g., 340B quarterly updates) and reimbursement is typically based on medication-specific billing units and dosage form codes.

Also important in revenue cycle oversight is the incorporation of manager guidance with frontline input to ensure an effective revenue integrity strategy. Being proactive in this regard optimizes revenue cycle management efficiency and integrity.[14]

Topic 4: Business growth

Statement 4a

Pharmacy identifies, evaluates and implements new business ventures.

Performance elements 4a

- Pharmacy leadership identifies, assesses, designs, implements and monitors entrepreneurial opportunities for the pharmacy enterprise.
- Organizational business planning processes integrate pharmacy as a core element to ensure decision-making reflects current and future therapy, facility, technology, and staffing requirements.
- The pharmacy strategic planning process includes environmental scanning, opportunity assessment and goal alignment related to new business ventures within the pharmacy enterprise.
- Resources and expertise exist within the pharmacy enterprise to support new business ventures (e.g., business planning, project management, data analysts, scientists).
- Business planning includes pro formas, ROI analysis, buy/lease versus build assessment, estimation of resources (e.g., labor, operational budget, capital), project management and monitoring to determine if business plan goals are achieved.
- Contemporary and progressive business ventures are implemented (e.g., pharmacy benefits management to support health system insurance product, specialty pharmacy, home infusion pharmacy, 503a/503b compounding, central fill).
- Pharmacy-related ambulatory business growth opportunities are routinely evaluated and maximized (see Domain 3 for detailed discussion on areas of pharmacy business growth opportunity).

Pharmacy leadership should continuously monitor the health care environment and evaluate growth opportunities that align with organizational goals, and then communicate with executive leadership on strategies for the future. An effective pharmacy leader must ensure that there are systems in place within their organization that foster strategic thinking and planning. Furthermore, the results of these efforts must be shared with executive leadership and members of the department. Strategic planning ensures that there are opportunities to create the vision that the department will strive to achieve.[17]

The pharmacy enterprise will maximize success and growth through a multidisciplinary approach to strategic planning. Ensuring that the pharmacy enterprise includes staff with competencies in finance, project management and data sciences will provide much-needed support for successful new business ventures. Including these members in pursuit of new business ventures will allow for the most comprehensive business planning process, which must include an ROI analysis, considerations on buying and leasing versus build assessments, estimation of labor resources, and implementation monitoring.

The pharmacy enterprise will also continue to experience the same shifts that U.S. health care experiences, which is the transition from delivering acute care management to the management of patients across their entire continuum of care. In this new landscape, pharmacy leaders must ensure there are continued efforts to leverage a retail and ambulatory presence.[18] Utilizing various technologies that enable the ambulatory pharmacy team to successfully engage patients through virtual or physical interactions helps to bring care to the patient in ways that traditional methods would not permit through convenience and efficiency.[18]

Conclusion

An HVPE ensures that core business services are always intact, while remaining agile in a market that is rapidly changing toward value and comprehensive care. Placing resources and structure around affordability and access to medications ensures that the financial well-being of the enterprise is accounted for, and that the organization is best positioned to provide the most comprehensive care in the most appropriate setting. Beyond the core businesses, the HVPE must focus on consumerism to maximize value and continue to deliver services in creative and meaningful ways across the continuum of care. Being bold in strategic planning, embracing technology and thinking outside the box to continue actively seeking out new opportunities will empower the HVPE to provide the most valuable care to patients while ensuring the organization remains financially solvent.

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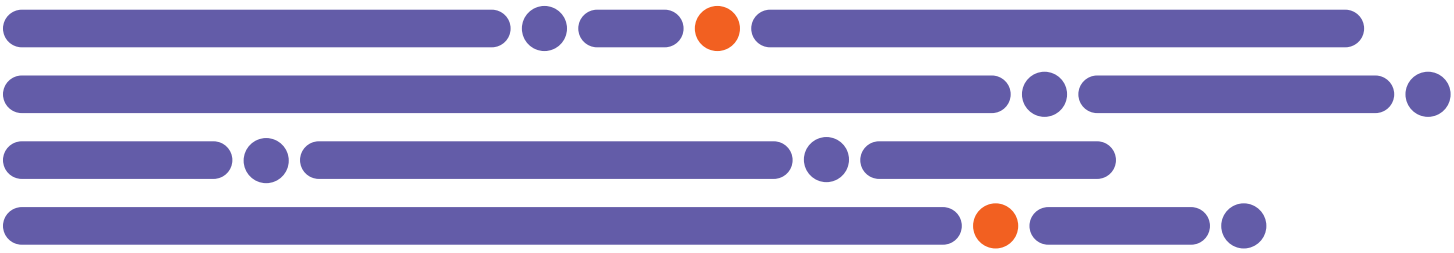

Domain 3: Ambulatory and specialty pharmacy services

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Introduction

Ambulatory care practice is continuously evolving; therefore, it is vital that health systems are able to support these ever-changing needs by expanding existing services and initiating new services. By maintaining a strong infrastructure, the HVPE will have the resources to align with organizational needs, maintain diverse roles, identify clinical trends and opportunities for continued growth, and utilize technology to extend services to a larger population. As ambulatory pharmacy programs expand, it is important to continually focus on improving adherence; ensuring affordability of medications; and enhancing access to clinical resources to achieve optimal financial, quality and satisfaction outcomes. Key aspects of ambulatory and specialty pharmacy practice are discussed in topics one through four and will be covered in more detail in this literature review. This domain also includes a detailed appendix (**Appendix C**), providing examples where evidence demonstrates the positive impact of pharmacist collaborative practice on disease state management. Areas that are not covered are considered to be standard expectations of any modern pharmacy enterprise, out of the scope of this domain (e.g., billing for ambulatory care services) or covered in other domains.

- Topic 1: Pharmacy services that benefit population health and improve access to care
- Topic 2: Retail pharmacy services
- Topic 3: Specialty pharmacy and infusion care services
- Topic 4: Employer-funded health plans

Topic 1: Pharmacy services that benefit population health and improve access to care

Statement 1a

Pharmacists collaborate with care providers across the health system continuum to optimize patient health and well-being.

Performance elements 1a

- Pharmacists provide drug therapy management services in health system-owned primary care and select specialty clinics, in retail pharmacy settings, and across the care continuum.
- Pharmacists leverage remote technologies to improve efficiency and extend drug therapy management services to a larger patient population.

Statement 1b

Pharmacists have an active role in managing pharmacotherapy in all care settings and share responsibility and accountability for medication-related outcomes.

Performance elements 1b

- To the extent possible, protocols or collaborative practice agreements are used to enable pharmacist-led disease state management:
  - Pharmacists initiate, modify and discontinue therapy as appropriate.
  - Pharmacists provide ongoing therapeutic monitoring and follow-up (e.g., ordering laboratory tests).
- Pharmacists perform disease screenings and assessments (e.g., measure risk factor markers, risk assessment questionnaires).

Statement 1c

Pharmacists provide comprehensive medication management services for patients with complex medical regimens and patients on high-risk therapies across the continuum.

Performance elements 1c

- A process is implemented to identify and target patients with the greatest need for pharmacist services.
- Patients have 24/7 access to clinical pharmacy resources in person or through remote technologies (e.g., telephone, patient portal chat feature), including after hospitalization.
- Pharmacists leverage the EHR to monitor prescribing trends and use data to implement quality improvement and patient safety initiatives.
- Pharmacy services use the EHR to identify patients at risk for opioid overdose and dispense naloxone per standing order in accordance with state law, where applicable.
- Pharmacists collaboratively manage patients with substance use disorders in medication-assisted treatment programs.
- Pharmacists identify patient need, make appropriate vaccine recommendations, and administer immunizations in retail and clinic settings.
- Pharmacist-led programs are implemented to optimize and promote outpatient antimicrobial, anticoagulant, antihyperglycemic and opioid stewardship.
- Pharmacists manage chronic conditions and provide patient education on disease states, drug therapy and lifestyle modifications:
  - Appropriate resources are provided to ensure safe medication use (e.g., educational videos and handouts tailored to patient needs based on preferred language and health literacy).
  - Pharmacists provide medication device and injection technique training, when applicable.
  - Pharmacists manage smoking cessation by assessing readiness to quit, implementing a therapeutic plan based on shared decision-making with the patient and providing appropriate follow-up.
  - Pharmacists are involved in health system-sponsored community outreach events (e.g., classroom education provided to school-aged children).
- Pharmacists perform pediatric, weight-based dose checking.

Statement 1d

Pharmacists are actively involved in deprescribing efforts for patients with polypharmacy or who are taking inappropriate, high-risk medications.

Performance elements 1d

- Screening tools are used to guide deprescribing efforts (e.g., Beers Criteria, Screening Tool of Older Persons' Potentially Inappropriate Prescriptions [STOPP] criteria).

- Pharmacists utilize the health system's EHR to identify patients with polypharmacy or who are taking high-risk medications
- Protocols are implemented to allow pharmacist-led discontinuation of inappropriate, unnecessary and financially burdensome therapy in collaboration with the interdisciplinary team.
- Pharmacists follow up with patients to monitor the effect of deprescribing efforts.

Health system pharmacists influence patient care in a variety of ambulatory care settings, including primary care and specialty clinics, accountable care organizations (ACOs), patient-centered medical homes, and retail pharmacy settings. Pharmacist intervention through drug therapy management services has demonstrated value from both clinical and economic standpoints, including a 12:1 ROI in the latter study.[1,2] In addition to improving patient outcomes, pharmacist-provided, comprehensive, medication management may improve the well-being of other health care providers by decreasing workload and mental exhaustion, increasing patient access to a health care provider, enhancing professional learning, and providing reassurance that patients are receiving better care.[3]

The expansion of pharmacists' roles through collaborative practice has allowed for increased access to pharmacist clinical services in primary care and displayed positive outcomes for multiple disease states.[4,5] The Department of Veterans Affairs is the largest integrated health care provider in the U.S. and has served as a role model for other institutions by using pharmacists' clinical expertise outside of traditional dispensing roles, including prescriptive authority.[6] One example includes clinical pharmacy specialist disease management services provided via telehealth modalities, which demonstrated significantly improved patient outcomes.[7] Leveraging telehealth technology can increase efficacy in providing patient care, allowing pharmacy services to be extended to a larger population. Remote technology is particularly beneficial in small clinic, rural or underserved locations where access to clinical pharmacy services may be limited. Pharmacists can also incorporate point-of-care testing (e.g., influenza, human immunodeficiency virus, streptococcal pharyngitis, blood glucose, cholesterol, international normalized ratio) into collaborative practice to further expand patient access to clinical services and expedite the initiation or modification of pharmacotherapy. A community, pharmacy-based group A *Streptococcus* (GAS) management program successfully treated patients testing positive according to a collaborative practice protocol and provided care to many patients with no primary provider or who visited the pharmacy after traditional clinic office hours.[8]

Ambulatory care pharmacists can positively impact population health through multiple mechanisms. As such, pharmacist patient care services should target patients with high-risk disease states and complex social determinants of health. Due to finite resources, pharmacy services should have a process in place to identify patients with the greatest need for pharmacist intervention. Patients most likely to benefit from these pharmacy services should be identified through development and implementation of risk prediction tools, including diagnoses that are highly dependent upon optimal drug therapy to achieve positive outcomes and cost-effective care, and social determinants that may impact medication adherence and access to appropriate medication therapy. These conditions may include high-risk acute conditions (e.g., infectious diseases), uncontrolled chronic disease states (e.g., hypertension, diabetes mellitus, chronic obstructive pulmonary disease, heart failure) despite usual care, and diseases requiring specialized care and management (e.g., cancer, transplant, inflammatory conditions). Additionally, patients should have 24/7 access to clinical pharmacy resources provided through the health system, either in person or remotely (e.g., telephone, patient portal chat feature, video).

Pharmacy services should use the electronic medical record (EMR) extensively to care for patients at a population level. By analyzing trends in prescribing data, opportunities for improvement can be highlighted and programs to optimize patient care delivery and patient education can be created. In collaboration with data scientists, the pharmacy department would be able to drill down on specific metrics to identify trends in particular ambulatory practices, either at the provider level or across the entire health system.

Pharmacists play an active role in curbing the opioid epidemic in the U.S. A method that has proven effective is the distribution of naloxone to patients at high risk of opioid overdose. One study demonstrated states with naloxone access laws (NALs) granting pharmacists direct prescriptive authority of naloxone had decreased opioid deaths relative to the mean number of opioid deaths in states without direct-authority NALs in Medicaid patients.[9] In collaboration with a supervising physician, pharmacists can also manage patients with opioid use disorders through medication-assisted treatment. A collaborative care management program with buprenorphine reported 55% of participants remained in treatment at six months, and aberrant urine toxicology results and craving scores decreased significantly.[10] Although some states allow pharmacists to prescribe controlled substances under collaborative practice agreements, pharmacists are not eligible to prescribe medications for opioid use disorder because they cannot obtain a waiver under the Drug Addiction Treatment Act of 2000. Additional research and continued advocacy may lead to the future expansion of pharmacist-led medication assisted treatment.

Pharmacists can also have a positive impact on preventing and managing infectious diseases through vaccination programs and outpatient antimicrobial stewardship. A systematic review and meta-analysis showed pharmacist immunization programs increased influenza immunization more than twofold and herpes zoster by more than fourfold versus usual care.[11] A separate study demonstrated that a pharmacist-led antimicrobial stewardship program (ASP) in an urgent care setting significantly improved prescribing practices in accordance with guideline recommendations for all diagnoses examined.[12]

Self-management is an essential part of health care for those with chronic conditions. Ambulatory care pharmacists are in an excellent position to educate patients and ensure they can manage the symptoms, treatment and lifestyle associated with their condition effectively. Critical parts of patient education include medication counseling with device teaching, if applicable, and provision of resources that meet the patient's needs (e.g., appropriate language

and health literacy level). A systematic literature review and meta-analysis showed self-management interventions performed by an ambulatory care pharmacist led to a decrease in mean A1C, systolic and diastolic blood pressure, and body mass index (BMI) in patients with diabetes.[13] Pharmacists can also leverage available technology to enhance patient education by assigning videos through the electronic health portal to supplement material discussed during office visits or other patient encounters. Chat boxes through the patient health portal also increase accessibility to clinical resources.

Deprescribing may improve overall medication adherence, avoid medication errors and expenditures, and improve patient outcomes. Pharmacists should be actively involved in deprescribing efforts in collaboration with the interprofessional team to consider patient goals of care, quality of life and benefits versus burdens of therapy. By using an individualized approach, pharmacists can also provide patient education, specific drug recommendations and close clinical follow-up. A systematic review reported the most successful deprescribing interventions used pharmacist-led educational interventions and patient-specific recommendations.[14] To aid in this process, the EHR should be leveraged to identify patients with polypharmacy or who are on high-risk medications to allow for targeted intervention by a pharmacist. Protocols can also be successfully implemented to include pharmacist-led medication reconciliation, use of screening tools to identify potential medications for deprescribing (e.g., Beers Criteria, STOPP criteria), and modification of therapy following discussion with prescribers.[15]

Pharmacists should perform weight-based dose checks in pediatric patients before dispensing to decrease dosing errors and potential harm. An outpatient pharmacy using pediatric dose-checking procedures in patients less than 18 years old reported 29% of pediatric prescriptions were sent to a problem queue for pharmacist follow-up and 50% were modified as a result of pharmacist intervention.[16]

Topic 2: Retail pharmacy services

Statement 2a

Retail pharmacy services are established to ensure patient access to medications and improve medication regimen adherence and affordability.

Performance elements 2a

- Health system-owned retail pharmacy services are established.
- The following services are provided by the health system's retail pharmacy:
  - Compliance packaging (e.g., blister packing, pill boxes)
  - Telehealth-based medication compliance management services (e.g., reminder call, text, email to alert patients when prescriptions are ready or late for pickup)
  - Medication synchronization program
  - Interactive voice recognition (IVR) and interactive web response (IWR) software integrated into the patient electronic health portal
  - Free prescription mail and home delivery services
- Retail pharmacy infrastructure enables medication delivery to patients at hospital and clinic discharge (e.g., medication delivery to patient's bedside).
- Compounding formulas are aligned with inpatient formulary to avoid concentration mismatches when patients are transitioning care.
- Benefits investigations are performed and followed up on to limit barriers to medication compliance.
- Financial assistance programs are established to improve medication access and affordability.
- Pretreatment and posttreatment supportive care medications, including nonprescription drug products, meet the needs of patients.

Developing a health system-owned retail pharmacy can improve patient experience, health outcomes and the health system's financial performance. By expanding the patient care team to include health system retail pharmacists, fragmentation of care is decreased and communication with patients and providers is improved.[17] Pharmacy services throughout the health system should continuously strive to increase patient access to medications and improve medication adherence. Some evidence suggests the effectiveness of adherence strategies differs by disease state; therefore, methods should be individualized to meet the patient's needs.[18] Strategies such as compliance packaging (e.g., blister packs, pill boxes), prescription refill reminders and appointment-based medication synchronization have been associated with improved medication adherence.[19,20,21] IVR and IWR software can provide patients with a convenient channel to request prescription refills and manage questions, especially if it is integrated within the patient electronic health portal.

The channel through which patients receive their medications can influence both adherence and clinical outcomes. Discharge medication delivery to a patient's bedside (commonly referred to as meds-to-beds) provides a convenient service, improves patient experience, ensures first-fill adherence and may play a role in decreasing 30-day readmissions.[22] In addition, by insourcing such services through the health system's retail pharmacy, patient care is coordinated more easily with increased ability for communication, reduction in last-minute discharge issues and easier access to patient affordability information before discharge.[17,23] With access to the EHR, retail pharmacists can review documentation and determine provider rationale if unusual doses are prescribed, which may prevent the need to reach out to the provider for clarification and also expedite the dispensing process. Compounded medications can also be coordinated prior to discharge. Aligning retail pharmacy compounding formulas with the inpatient formulary prevents concentration mismatches and medication errors during care transitions. Outside of hospital discharge, home delivery services may also increase medication adherence for patients with chronic diseases.[24] Enrolling patients into home delivery programs can also capture refills after hospital discharge.

Pharmacy technicians, working under the supervision of a pharmacist, should provide benefits investigations to all patients filling prescriptions at the health system-owned retail pharmacy. These investigations should be followed up on in a timely manner

by initiating prior authorizations or contacting the prescriber (see Domain 2 for additional details). By maintaining transparency to the patient and prescriber, barriers to medication compliance will diminish. Connecting patients to options for assistance, such as manufacturer-sponsored bulk replenishment programs, internal and external prescription assistance programs, philanthropic foundations, and the federal 340B Drug Pricing Program, improves access to medications that patients may not otherwise be able to afford. One study examining prescriptions for novel oral anticancer drugs found that over one-third of patients studied, with nearly half of those ages 65 years or older, received charity funds to help offset out-of-pocket costs.[25] Pharmacy staff are well positioned to coordinate these financial assistance services to improve medication access for patients with conditions where financial toxicity may occur (e.g., cancer, hospice, end of life). The health system's retail pharmacy can also streamline the process of purchasing supportive care medications available without a prescription. By ensuring these medications are adequately stocked, patients would have the ability to easily pick up all medications associated with treatment regimens or scheduled procedures (e.g., emollients for patients receiving epidermal growth factor receptor [EGFR] inhibitor therapy, stool softeners or laxatives after surgery).

Topic 3: Specialty pharmacy and infusion care services

Statement 3a

Health system offers a comprehensive, dual-accredited specialty pharmacy program to support optimal patient care and strong organizational financial performance.

Performance elements 3a

- Health system-owned, fully integrated, comprehensive, specialty pharmacy program is established (sole ownership preferred).
- Specialty pharmacy model includes clinic-based pharmacists who support medication management activities in the health system's specialty clinics.
- Pharmacy technicians (e.g., specialty pharmacy liaisons) work under the purview of a pharmacist to provide medication prior authorization (PA), benefits investigation and medication assistance program support services for all health system patients who are prescribed new specialty medications.
- Specialty pharmacy model includes a drug therapy management call center with 24/7 access to specialty pharmacy liaisons and pharmacy clinical services.
- Outcomes metrics are analyzed regularly and used to improve specialty pharmacy services:
  - Patient medication adherence (e.g., medication possession ratio, proportion of days covered)
  - Turnaround time of initial prescription (e.g., time from decision to prescribe to medication dispensing) for clean and non-clean (e.g., requires provider clarification or prior authorization) prescriptions
  - Time from medication refill request to pick-up/delivery of prescription
  - Customer and provider satisfaction of specialty pharmacy services
  - Percentage of patients receiving financial assistance

Statement 3b

Pharmacy participates in comprehensive medication management services for patients receiving infusions and other high-cost, clinic-administered medications throughout the health system and affiliate locations.

Performance elements 3b

- Pharmacists prospectively review infusion orders in home infusion and clinic-based infusion center settings (e.g., provider-based, stand-alone facilities).
- Pharmacists anticipate and resolve potential drug therapy problems before treatment starts.
- Clinical pharmacists review and approve medication/infusion orders for off-label use before starting therapy for regimens that do not align with national protocols or standards of care.
- Pharmacists monitor drug therapy and compliance and ensure continued appropriateness.
- Pharmacists provide supplemental patient education and counseling throughout therapy.

Specialty pharmacies combine medication dispensing with clinical disease management to improve outcomes in patients with complex, chronic or rare diseases. Although specialty pharmacy services have been rapidly expanding, the decision to open a specialty pharmacy or select an alternative approach is dependent upon multiple institution-specific factors. The average cost of chronic therapy for a specialty prescription drug was over $52,000 per drug, per year at the retail level in 2015 and has nearly tripled since 2006.[26] Establishing specialty pharmacy services provides tremendous opportunity to generate revenue for the health system. Although sole ownership of the specialty pharmacy is preferred, in some cases it may be advantageous to partner with other hospitals to ensure there is adequate prescription volume to remain financially viable.[27]

Payer reimbursement to outpatient pharmacies is increasingly dependent on quality metrics. CMS and commercial payers are choosing pharmacies to participate in their drug plans based on ability to help patients achieve desired clinical outcomes and control overall costs of care.[17] To ensure specialty pharmacy success in meeting these metrics, it is important to first establish a strong retail pharmacy infrastructure. Retail pharmacies focus on customer service, managing high prescription volume and maintaining inventory. Specialty pharmacies build from this foundation, as they require enhanced customer services through close care coordination, maintaining strong patient relationships, managing adverse effects and ensuring treatment compliance. In addition, specialty pharmacy accreditation is increasingly required to access certain payer networks or medications. Dual accreditation provides a competitive advantage when contracting with payers.

Insourcing a specialty pharmacy within a health care system can reduce fragmentation of care, particularly through closer monitoring and intervention regarding medication adherence and adverse effects. Centralizing specialty pharmacy operations and leveraging advanced pharmacy technician roles (e.g., PA management, copay assistance and billing support, refill phone calls) are also methods to increase patient enrollment and specialty pharmacy revenue.[28] Revenue from the specialty pharmacy and, when available, savings from the federal 340B program, should be used to expand pharmacy services, including the addition of clinic-based pharmacists and technicians to specialty clinics. This integrated model may increase specialty pharmacy prescription volume, decrease time to medication approval and provide significant financial aid for patients who require assistance.[29] Integration of pharmacists and technicians into clinic settings supports prospective drug utilization review and concurrent benefits investigations; provides face-to-face patient education, including administration training for injectable devices; and allows ongoing follow-up for tolerability and efficacy (through return visits or telephone calls). Through collaborative practice, pharmacists can also ensure laboratory monitoring is up to date. With the growth of population health and risk-based payment models, a specialty pharmacy program will support quality and appropriate utilization management of high-cost therapies.

The pharmacy department also plays a critical role in the oversight of infusion care throughout the health system and affiliates, both in clinic-based infusion centers and through home infusion. Pharmacists should assess appropriateness before treatment starts and anticipate potential drug therapy problems, which may be due to clinical, financial (e.g., patient affordability) or access (e.g., non-formulary medication) reasons, to ensure medication safety and streamline the time to treatment initiation. Medications ordered for off-label use may involve complex safety, efficacy, legal and financial implications; therefore, clinical pharmacists should oversee all orders for outpatient infusions intended for off-label use. One institution detailed its effective process in which clinical pharmacists prospectively reviewed and approved off-label requests for parenteral cancer treatment before administration of the first dose.[30]

Patients who require parenteral medications for long treatment courses may benefit from home infusion, as these services show comparable patient outcomes with significantly lower costs versus the medical setting.[31] By insourcing such services within the health system, pharmacists can play a major role in coordinating care and monitoring therapy in collaboration with other health care providers. Continuity of care would likely improve as pharmacists would have access to the patient's medical record and communication with other providers would be streamlined. Multiple roles for home infusion pharmacists, including monitoring drug therapy and compliance, as well as providing supplemental patient education and counseling throughout therapy, have been previously described.[32]

Topic 4: Employer-funded health plans

Statement 4a

Pharmacy helps lead and oversee employer-funded health plan medication management practices to ensure formulary alignment, coordination with pharmacy benefit managers (PBMs), plan design, and use of health system-owned specialty and retail pharmacies.

Performance elements 4a

- PBM services for direct-to-employer plans are separately carved out from the health plan third-party administrator contract.
- Pharmacy leadership participates in PBM selection and PBM agreement oversight.
- Health plan has at least one dedicated pharmacist from the health system with a reporting relationship to the pharmacy executive.
- Health plan design includes strategies to maximize employee use of employer-owned retail and specialty pharmacy services.
- Pharmacy data scientists work with pharmacists to identify opportunities for enhancing the clinical management of health plan members.

Statement 4b

The health plan uses pharmacists to provide preventive services through employer-sponsored wellness and disease state management programs.

Performance elements 4b

- Services provided meet the needs of health system employees (e.g., drug therapy management, smoking cessation, immunizations).
- Financial incentives are available through the health system's retail pharmacy to encourage employee health (e.g., waiving copays for diabetes medications or nicotine replacement products).

Statement 4c

The health plan supports employees with complex diseases and conditions through comprehensive medication management services.

Performance element 4c

- High-risk employees are managed by an internal pharmacotherapy clinic.

PBMs administer prescription drug programs. Over the past decade, the roles of PBMs have expanded.[33] As a result, various concerns have been raised, including a lack of transparency in revenue streams through spread pricing. In addition, there are potential conflicts of interest if the PBM owns mail order and specialty pharmacies. An audit of the Ohio Medicaid prescription drug program reported a dramatic $224.8 million spread in 2017.[34] Employers have the option to carve in or carve out their pharmacy benefit program from their medical benefit. A carve-in approach contracts directly with the health plan for medical and pharmacy benefits, where the medical plan will either administer the program in-house or contract with a PBM to process claims and administer pharmacy programs. The carve-out approach allows the employer to contract directly with a PBM vendor to administer pharmacy benefits programs. For employer-funded health systems, a carve-out approach allows greater flexibility to align the PBM's formulary with its own. This may result in greater opportunity for full disclosure and transparency, as well as provide greater control and access to customized plan design for network, formulary and

clinical programs. In addition, a carve-out plan would give the health system greater ability to manage pharmacy benefits costs separate from the rest of the medical plan. These efforts present opportunities to decrease employee copays, use appropriate medications at the lowest cost to the patient and health system not based on PBM-negotiated rebates, and ensure self-administered medications fall on the pharmacy benefit side while provider-administered medications remain on the medical benefit side. Having a dedicated pharmacist working directly with the health plan would ensure the health plan is meeting the needs of the health system and its employees. For example, contracting with the health plan to require covered lives to fill specialty and maintenance prescriptions at a health system-owned pharmacy would generate dramatic savings for the health system and assure employee medication appropriateness and adherence.[35]

Health systems should leverage data available from the health plan and PBM to identify opportunities for improvement. Pharmacy data scientists are an invaluable resource in this effort, as their data analysis expertise and close collaboration with pharmacists and technicians can streamline the data reporting and analyzing process. With access to PBM data analytics, pharmacy can drill down on prescribing trends and work closely with providers to address areas of clinical and financial improvement. Having access to near real-time medication dispensing elements supports formulary management, analysis of variations in prescribing practices, identification of opportunities for improvement and creation of expanded pharmacist patient care services.[36]

For self-funded health plans, pharmacists can play a role in population health for employees and covered lives. Pharmacist-provided comprehensive medication management services can improve health outcomes for beneficiaries with chronic diseases and have a positive ROI for the organization.[37,38] Financial incentives provided to employees through the health plan may also increase participation in workplace wellness programs and use of health care services.[39]

Conclusion

As health systems adapt to changing times, pharmacy services must strive to improve health outcomes and care delivery and lower costs for patients and the health system. Pharmacists play an important role in optimizing patient health in ambulatory care settings through medication reconciliation, collaborative management of pharmacotherapy and ongoing monitoring. The beneficial impact of pharmacists on health care outcomes is especially apparent for patients with high-risk or difficult-to-manage disease states. By leveraging technology, clinical pharmacy services can be provided to a larger population. Advanced pharmacy technician roles enhance medication access and affordability through benefits investigations, financial assistance and care coordination across sites. Health system-owned retail and specialty pharmacies should be established, and initiatives should be implemented to capture pharmacy-related business, improve patient experience, expand medication access and decrease fragmentation of care across settings. Through payer contracting processes, the health system should ensure steerage of employee prescriptions to health system-owned pharmacies and use pharmacists to provide employer-sponsored wellness programs.

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Domain 4: Inpatient operations

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Introduction

Inpatient pharmacy operations are evolving in terms of scope and complexity. They are increasingly regulated (TJC, CMS, the Food and Drug Administration, United States Pharmacopeia, the Drug Enforcement Administration, the National Institute for Occupational Safety and Health, the Centers for Disease Control and Prevention, the Environmental Protection Agency, Departments of Natural Resources, Boards of Pharmacy) and vitally important to the delivery of safe patient care in all hospitals. Inpatient operations pharmacists must be adequately trained and competent to oversee all aspects of a highly technical pharmacy operation, including safe and efficient drug storage, preparation, and distribution systems throughout the organization. Effective drug shortage management and controlled substance diversion prevention systems must also be maintained to optimize patient safety and organizational compliance. Technical operational practice standards are maintained in contemporary pharmacy professional organization guidance documents and in law to assure safe patient care, and it is expected that pharmacy operations and workflows comply with these standards. As hospitals become multihospital systems, a centralized approach to maximizing pharmacy operational efficiency should be aggressively explored. While maintaining a highly trained and competent pharmacy technical workforce is vital to inpatient pharmacy operations, the discussion of pharmacy technicians has been centralized in the Pharmacy Workforce Chapter (Domain 6).

- Topic 1: Medication use systems and operations pharmacists
- Topic 2: Drug shortage management
- Topic 3: Drug diversion prevention
- Topic 4: Safety of medication storage, preparation, distribution, administration and disposal
- Topic 5: Efficiency within a multihospital system

Topic 1: Medication use systems and operations pharmacists

Statement 1a

Inpatient operations employ pharmacists who are specialty trained and credentialled in medication use systems and operations.

Performance elements 1a

- Pharmacists practicing in inpatient operations have advanced training and knowledge related to safe and effective medication use systems and procedures in the following areas:
  - Sterile compounding
  - Non-sterile compounding and repackaging
  - Medication-related technology and automated systems
  - Supply chain management, including inventory management
  - Drug distribution in all areas of a health system (acute care, procedural care, perioperative care, clinics)
  - Controlled substance medication management systems
  - Hazardous drug handling
  - Drug waste stream management
  - Pharmacy and cleanroom facility design
  - Contemporary quality improvement methodology
  - Recordkeeping and required documentation
  - Handling of novel and high-cost breakthrough therapies (e.g., gene therapies, biologics)
  - Overseeing the work of pharmacy technicians
- The health system requires certification of all inpatient operations pharmacists in sterile compounding and/or other areas pertaining to pharmacy operations as certifications become available.

Inpatient pharmacy operations are increasingly complex, high risk and error prone. Effectiveness as an inpatient operations pharmacist requires more than just being able to check finished products. Inpatient operations pharmacists must be able to design, improve and troubleshoot the medication use process to make it reliable and sustainably safer. They should have advanced training in medication use systems and operations, and those practicing in sterile compounding should be board certified in sterile compounding. These pharmacists are accountable for assuring the safety and effectiveness of the medication use process. Many schools of pharmacy do not prepare pharmacy students for these roles, nor do most postgraduate year 1 (PGY1) residency training programs. A white paper and commentary on the need for pharmacy specialists in medication use systems and operation provides a comprehensive description of the rationale, dimensions and competencies for these positions.[1,2] Health system pharmacy leaders must advocate with professional organizations to establish residency training and credentialing programs, as well as certification programs, in this highly specialized area of practice.

Topic 2: Drug shortage management

Statement 2a

A system to prevent, manage and mitigate medication shortages is implemented to reduce patient harm.

Performance elements 2a

- There is a well-defined drug shortages management program with elements related to:
  - An interprofessional team with pharmacy leadership
  - Inventory management
  - Medication safety considerations
  - Pharmacy operational needs
  - Obtaining stakeholder input on clinical matters
  - Pathways for rapid therapeutic care decisions
  - Procurement of alternative therapies
  - Coordinated processes for making changes in all associated pharmacy information technology (IT) systems
  - CDS and alternative therapy suggestion alerts in the EHR
  - Drug costs associated with alternative medications
  - Systems for caregiver education and communication

  - Access to the organization's ethics committee
  - Coordination with materials management for shortages of drug products they distribute (e.g., IV fluids, continuous renal replacement therapy [CRRT] fluids, etc.)
- Dedicated pharmacy staff is accountable for oversight of medication shortage management systems.
- All medication suppliers and vendors are fully vetted and verified for quality of products procured.

Drug supply chain integrity is increasingly a challenge with the impact of drug product quality, recalls and shortages requiring pharmacy departments to demonstrate assurances that supply chain integrity is maintained at the safest standards.[3,4] There is much concern about the tremendous resources required to effectively manage drug shortages. The annual cost to purchase more expensive substitute products in the U.S. was estimated at $209 million in 2013,[4] while the labor cost required to manage drug shortages was estimated at $216 million in 2011.[5] Drug shortages also have the potential to negatively impact patient care and safety by delaying medical procedures and causing medication errors that can lead to patient harm. They create patient safety risks from unfamiliarity of products obtained to replace normal formulary items, diversion of manpower to react to emergent shortages, and changes necessary to support technology drug libraries and CDS.

The management of drug shortages has become a significant challenge, with each shortage requiring a thorough evaluation of communication, the impact on the system, and development and implementation of sound mitigation strategies with stakeholders. Processes must be continuously evaluated for integrity and ability to provide medications to support patient care needs.[6] As the complex nature of managing drug shortages can have a significant impact on patient care, it is critical to have a comprehensive management process with detailed procedures for preventing and managing drug shortages, and to minimize effects on quality patient care. A team should be responsible for making clinical decisions on how to manage the shortages. In addition, there should be a resource allocation committee dedicated to the ethical decision-making related to medications with limited inventory and alternatives. Health systems should consider utilizing a shared database with other health systems to communicate current drug shortages, share plans they have implemented to manage the shortages and discuss their predicted impact on the health system.[4]

It is important that pharmacy departments lead organizational efforts to maintain a drug shortages management plan that includes a dedicated drug shortages team, a resource allocation committee, a process for approving alternative therapies and a process for addressing ethical considerations.[4] The management plan should not circumvent a rigorous supplier assessment process. Additional pharmacy responsibilities pertaining to drug shortage management include gathering information regarding shortages; expedited reviews to find suitable alternatives quickly to avoid interruption of care; assessing on-hand inventory and reviewing utilization across the organization; and educating caregivers about anticipated shortage duration, severity, alternative therapies and operational implications.[7]

Topic 3: Drug diversion prevention

Statement 3a

Maintain an effective drug diversion prevention plan for controlled substances and high-cost medications.

Performance elements 3a

- Pharmacy implements a rigorous program to ensure compliance with organizational policies, laws and contemporary practice standards pertaining to controlled substances.
- Pharmacy maintains an effective drug diversion surveillance program, with documented gap analysis of organizational performance versus best practices with an accompanied action plan.
- A multidisciplinary program exists to focus on diversion prevention, detection and response.
- At least one dedicated controlled substance diversion auditor position exists in the organization as part of an overall effort to detect and prevent drug diversion.
- A system exists to routinely reconcile controlled substances and high-cost drugs at high risk of diversion from the point of purchasing through administration and waste documentation.
- The pharmacy department integrates data and establishes teams to conduct audits of inventory and billing systems between the medications purchased and dispensed, and between amounts charged and/or payments received for controlled substances and high-cost medications.

Drug diversion presents a unique challenge for pharmacy leaders, in that diversion can result in impaired workers and/or liability for the organization. Drug diversion can also impact availability of medications for patients, as well as have detrimental effects on patient outcomes, coworkers of the diverter and the individual.

Best practices for preventing diversion of controlled substances in health systems are well established.[3] Health system pharmacy should lead efforts to establish and implement an interprofessional drug diversion plan, with special emphasis on diversion of controlled substances and high-cost medications.[3,8] This plan should comply with statutory and regulatory requirements and with systems that discourage diversion and enhance accountability.[3] An interdisciplinary committee and processes should exist to proactively review and implement contemporary best practice diversion prevention tactics and develop employee education on diversion prevention. It is important to have buy-in and participation in this process from the organization's nursing, anesthesia, human resources, security, compliance, risk management, legal and employee health departments.

Technology solutions integrated with data analytics is a key combination and part of an effective approach to identifying controlled substance diversion and misuse patterns. Controlled substances should be secured at all points in the chain of custody, including procurement, preparation and dispensing, prescribing, administration, waste, and removal. This system should interface with the EHR and automated dispensing cabinets (ADCs) and have

the capability to capture medication dispenses, administrations, and waste or return verification.[3] This information should be used to show trends and create assessments for similar areas and peers. An electronic diversion prevention software should be implemented to address all points of access and trend usage, as well as ensure adequate surveillance and auditing for controlled substances and high-cost medications in real time.[9] Maintaining an effective auditing system, with rigorous checks and balances for accurate documentation throughout all phases of the medication use process, will identify theft, erroneous charting and lost revenue — all of which can significantly influence patient care.

Topic 4: Safety of medication storage, preparation, distribution, administration and disposal

Statement 4a

Pharmacy ensures drugs are procured, stored, prepared, dispensed, distributed and disposed in the safest possible manner.

Performance elements 4a

- The pharmacy department assures organizational compliance with U.S. Pharmacopeia (USP) Chapters <795>, <797>, <800> and <825> standards and related accreditation, regulatory and legal requirements.
- The pharmacy department utilizes technology at each step in the medication use process to document receipt, storage, preparation, distribution and administration of medications.
- The pharmacy department leverages automation and technology that interfaces with or is embedded within the EHR to ensure accurate, efficient and timely distribution of medications:
  - Fully or semi-automated dispensing systems (e.g., robotics, carousels, etc.) are utilized to support routine medication dispensing to patient care areas, maximize medication storage, optimize inventory management and facilitate accurate medication selection.
  - ADCs are available in all patient care areas where medications are routinely administered. ADCs store emergency medications, drugs that require high-security storage (such as controlled substances) and the most commonly used medications in the most ready-to-administer form without manipulation outside the pharmacy.
  - ADC inventory should be optimally configured for each institution to minimize the number of steps for nursing and pharmacy departments to distribute and administer medication to the patient.
  - The organization follows best practices for ADC optimization and utilization that includes, but is not limited to:
    - Tightly controlled and monitored authorized user access to medications stocked in the ADC.
    - The ADC interfaces with the EHR, bar code medication administration and inventory management systems.
    - Recordkeeping is maintained for all user transactions, including stocking and dispensing of medications.
    - The organization has dedicated pharmacy personnel responsible for the monitoring and surveillance of ADCs to ensure safe use.
- Automated systems are maintained to ensure safe and accurate documentation and disposal of narcotic waste throughout the organization.
- Appropriate pharmaceutical waste streams, specifically related to hazardous and controlled substance waste, are maintained throughout the organization and overseen by pharmacy.

Statement 4b

Systems are in place to monitor and evaluate the storage and distribution of medications across the organization to minimize waste, and to ensure they are delivered as close to due time.

Performance elements 4b

- Radio-frequency identification (RFID) tagging is utilized for emergency kit medication tracking, and to track inventory amounts and locations, as well as medication distribution, when possible.
- Pharmacy operations uses technology to improve visibility of the drug distribution process that indicates the disposition of medications for care providers and reduces calls for missing medications.
- Workflows are optimized in the pharmacy to incorporate a triage system for phone calls and electronic communication from other health care providers.
- Remote/automated temperature monitoring is used for temperature monitoring of refrigerated or frozen medications in collaboration with facilities management.
- Workflows are established to ensure expiring/expired medications are removed from inventory before they are administered to patients.
- Batch and delivery times are evaluated to decrease lead times and provide medications just in time for patients.

Statement 4c

Bar code scanning is used throughout the medication stocking, preparation, distribution, dispensing, delivery and administration processes.

Performance elements 4c

- Each step in the medication use process integrates bar code scanning with each input into and output from a storage location/pocket (e.g., receiving into pharmacy inventory, receiving into a carousel, dispensing from a carousel, refill into an ADC, dispensing, storing in a nursing unit, administering to a patient).
- A system exists to assure that a bar code assessment step occurs as far upstream in the process as possible to make sure the bar code will scan in all downstream dispensing systems.
- Systems are in place to ensure staff compliance with bar code scanning expectations.
- Near-miss reporting data is analyzed for the purposes of performance improvement, including troubleshooting reports of bar codes that do not scan.

Statement 4d

Technologies such as IV workflow management systems, picture-taking, gravimetric technology and robotics, in conjunction with bar code scanning, are used to support safe, efficient medication sterile compounding.

Performance element 4d

- Medication errors related to compounding workflows are evaluated and workflows are reassessed to prevent future errors on a regular basis.

Statement 4e

Contemporary quality improvement principles are leveraged to ensure the ongoing safe, timely, efficient and effective provision of pharmacy services.

Performance elements 4e

- A dashboard of key quality indicators is maintained to evaluate the ongoing effectiveness of inpatient pharmacy operations. Suggested indicators include, but are not limited to the following:
  - First-dose medication turnaround time
  - STAT dose medication turnaround time
  - ADC stockout rate
  - Missing medication and redispense request rates
  - Percentage of doses dispensed from ADCs
  - ADC stockout refill timeliness
  - ADC override rate
  - Controlled substance discrepancy rate
  - High-cost drug discrepancy rate
  - Medication wastage dollar amount
  - Medication dispensing accuracy rate
  - Percentage compliance with bar code scanning at medication administration (or percentage override rate)
  - Percentage of doses prepared with bar code scanning or other technology support
- Quality indicator performance is routinely shared with pharmacy and nursing staff and leadership.
- Performance improvement initiatives are ongoing to continuously improve key quality indicator performance.

Statement 4f

When self-administered medication processes are implemented, robust systems are in place to ensure patient safety.

Performance element 4f

- Self-administered medication workflows are assessed on an individual basis for each unit in the institution and not implemented as blanket workflows.

To increase productivity in a health system pharmacy, the deployment of automation and technology should be maximized in a fashion that maintains pharmacist accountability and oversight of the process while reducing pharmacist time spent on drug preparation and distribution activities.

Medication carousels are utilized in health systems to promote overall efficiency and effectiveness of medication storage and dispensing. Utilization of such technology optimizes the organization of medication inventory and streamlines the medication ordering process when interfaced with the EHR, leading to reduced stockouts.[10] Technician labor can be redistributed from manually reviewing paper refill reports and medication distribution-related tasks to other areas of need.

To optimize workflow, a hybrid model incorporating robotics or central fill for unit dose carts and ADCs is a cost-effective strategy for medication distribution. A 2014 analysis of several medication distribution models showed that if the University of Wisconsin Hospital and Clinics (UWHC) transitioned from its hybrid model (64% cart fill, 36% ADC) to a more decentralized model (11% cart fill, 89% ADC), it would increase annual human capital cost by $229,600 and annual on-hand medication inventory by more than $1 million.[11] Assessments of the optimal percentage of medications located in an ADC should be individualized to each institution, considering the institution's ordering workflow, medication distribution and workload statistics.[12] Optimal configuration should be assessed by reviewing par levels and reviewing low-use medications at 30, 60 and 90 days to assess the need for removal.[13] Par levels should be maintained so that every medication need not be restocked daily.[14] System reporting capabilities, such as stockout rate, expired volume and number of doses restocked per technician can be used to assess inventory, utilization rates and full-time equivalent (FTE) requirements.

In addition to serving as a cost-effective medication distribution strategy, the use of ADCs frees pharmacy personnel from distributive activities and enables them to dedicate increased time to direct patient care activities. ADCs also improve patient care provided by nursing staff by facilitating immediate access to urgent and frequently used medications. Improved accountability and medication-to-patient accuracy and safety are other benefits of ADCs, particularly when interfaced with the EHR.[15]

Core safety processes for the use of ADCs outlined by the ISMP should be followed. One of the major safety risks related to the use of ADCs is the use of cabinet overrides, which involves the removal of a medication from an ADC prior to pharmacist review when clinical assessment of the patient indicates that a delay in medication therapy would cause harm.[16] Risks associated with cabinet overrides include the selection and removal of the wrong medication, strength or dose. Overrides should only be used in justifiable situations, and processes should be in place to limit the unnecessary use of overrides. The establishment of a policy that outlines the appropriate situations for cabinet overrides should be developed, and strategies to mitigate errors when an override is used should be implemented. It is recommended that an interdisciplinary group be established to regularly assess override reports.

For medications distributed outside of ADCs, such as from central pharmacy and in emergency and anesthesia trays, the pharmacy department has a system in place to track medications up to the point of administration. Ideally, each medication should be trackable using RFID tagging or bar code scanning to identify the location of the medication at each step in the delivery process.[17] RFID tagging utilizes wireless technology and radio waves to automatically identify a medication and its location virtually. In addition to tracking, RFID tagging integrated into inventory management and validation can increase productivity, reduce medical errors and expedite collection of data required for audits.

Bar code scanning should be used in inventory management and dispensing. The ISMP and the ASHP both strongly recommend bar code scanning for an increase in patient safety, easier inventory management, and better allocation of pharmacists' knowledge and skills.[18] Using bar code scanning for inventory management can prospectively reduce medication errors that may occur before the medication reaches the patient, such as stocking the incorrect medication or stocking expired medications for distribution. It can also ensure that products are placed in the correct location and the correct ingredients are used for sterile and non-sterile compounded products. Cabinet replenishment should also require bar code validation before restocking medications. Once medications are prepared, they should have a unique medication identifier for the pharmacy staff and nursing staff to scan when the medication leaves the pharmacy and before the medication is administered to the patient.

Missing medications in the inpatient setting delay patient care, disrupt pharmacy and nursing workflows, increase waste, increase labor, and negatively impact employee satisfaction. To create transparency among the pharmacy and nursing staffs and optimize the distribution of medications, inpatient pharmacies should implement a dose tracking system. Medication dose tracking technology (MDTT) identifies where medications are located once they have been dispensed from the pharmacy. The impact of MDTT was evaluated at Duke University Hospital after an MDTT system was implemented in the cardiothoracic intensive care unit (ICU).[19] The number of medication requests per medication dispensed in the three-month period before and after MDTT implementation was 0.0579 and 0.0513, respectively, representing a significant decrease of 11.4%. Nurse satisfaction significantly increased post-MDTT implementation as the ease of accessing information regarding a medication's location increased substantially. Further, a study at Prince Sultan Military Medical City (PSMMC) in Saudi Arabia demonstrated a significant reduction in telephone calls between nursing and inpatient pharmacy staff following the implementation of MDTT.[20]

In addition to missing medications, incorrectly routed phone calls to inpatient pharmacies can disrupt workflow and be an additional barrier to effective communication among interdisciplinary health care providers. Workflow should be optimized to incorporate a triage system for phone calls and electronic communication from other health care providers. Interruptions in medication distribution by unnecessary phone calls to nursing staff can lead to an increase in medication errors. A 2007 trial showed that about 62% of pharmacy errors are due to interruption of nursing workflow by a phone call.[21]

Wireless temperature monitoring should be implemented for all refrigerators and freezers that house medications to support product integrity. This method is a relatively inexpensive way to meet TJC requirements for temperature monitoring, and it eliminates the need to perform an otherwise labor-intensive process, freeing up technician and other pharmacy personnel time. Staff members can customize notifications via a paging system, telephone, email or a combination of these modalities when a refrigerator is out of temperature range. The pharmacy department should be responsible for monitoring the temperatures and collaborating with facilities management should an out-of-range refrigerator need repair.

Pharmacies should utilize bar code scanning to verify solutions and ingredients utilized in compounded sterile preparations (CSPs), as verification by pharmacy personnel alone is not as effective at detecting errors as artificial intelligence.[22] To adhere with the recommended ISMP standards, utilizing an IV workflow management software system (WFMS) that includes gravimetric technology can help automate the process. A WFMS requires bar code scanning of each product to electronically validate its identity before it is incorporated in the CSP. These systems also create product labels, calculate diluent and drug doses, identify the correct beyond-use date, photo-capture the CSP ingredients and final product throughout all compounding steps, track doses, and archive each of these informational components electronically. Gravimetric technologies can be added to the system to utilize a pre-verified density or specific gravity to determine the volume accuracy of each component before addition to the final CSP. These systems and technologies have shown to reduce errors that can be unidentifiable by the human eye alone. For example, evaluation of a WFMS at Boston Children's Hospital concluded that 23% of the errors caught by the system were unable to be identified in the pharmacy's previous manual verification practices.[23] In a study in an ambulatory oncology setting at M.D. Anderson in Houston, Texas, 15,843 doses were prepared utilizing a WFMS and 1,126 errors were detected by the workflow software during dose preparation.[24] Each error detected was caught and corrected during the compounding process, and utilization of the software decreased technician production time by 34% and pharmacist checking time by 37%.

In recent years, significant changes in pharmaceutical waste stream disposal regulations and requirements have been handed down by the Environmental Protection Agency (EPA), the Drug Enforcement Agency (DEA) and the Occupational Safety and Health Administration (OSHA). These changes have had a significant impact on health systems, as they generate a significant portion of the pharmaceutical waste that was traditionally "sewered" into wastewater. These changes are particularly important to pharmacy departments, which are responsible for implementing practical (manual and automated) hazardous waste pharmaceutical management and disposal systems in pharmacy and patient care areas across the organization.[25]

In addition to medication production, preparation and delivery, medication administration is also a high-risk point for patient safety in health systems. Self-administered medication (SAM) programs allow patients to self-administer select medications, often using the patient's home supply of medications for medication prescribed prior

to admission. This practice has been implemented in many countries, including the United Kingdom, Canada and Australia. The most commonly observed benefits included increased patient satisfaction and reduced self-reported pain scores in the elderly population or in labor and delivery wards.[26,27,28] When a SAM program is implemented, it should incorporate shared decision-making between the medical team and the patient to ensure competence and safety. This should not be a blanket program for every patient in the hospital, as some patients (e.g., those in intensive care or behavioral health units) may be unable to self-administer their medications, and drug therapy regimens for inpatients with chronic conditions often change on a daily basis. Overall, this is a strategy that may decrease hospital resources spent on medication reconciliation, production and administration and improve patient satisfaction, but these benefits should be carefully weighed versus risk of error and other unintended consequences.

Topic 5: Efficiency within a multihospital system

Statement 5a

Multihospital systems evaluate and implement strategies to improve the operational performance, efficiency and integration of its internal pharmacy programs and services.

Performance elements 2c

- A business case and financial pro forma to support capital budget approval of a centralized consolidated pharmacy services center (CPSC) has been developed and presented to health system senior leadership to meet the needs of the health system.
- Inpatient pharmacy programs and services that should be considered for inclusion in the CPSC design are as follows:
  - Limited batch sterile compounding (503A compounding facility) as allowed by state law and federal guidance documents
  - Non-sterile medication compounding
  - Drug distribution and delivery systems for hospitals and clinics
  - Drug packaging, unit-dose drug repackaging and pharmacy manufacturing services, including bar code packaging
  - Emergency code tray replenishment
  - ADC replenishment
  - Hazardous material storage
  - Narcotic, controlled substance, and high-cost drug storage and distribution
  - High-cost, low-use medication distribution
  - Pharmacy supply chain, warehouse, 340B, purchasing and inventory management
  - Prior authorization and medication assistance program services
  - Pharmacist medication order review and management
  - Pharmacist sterile product accuracy checking (when deployed with an IV WFMS incorporating gravimetric-based technology-assisted workflow)

Systemwide standardization often reveals redundant inpatient pharmacy operations and services that result in limited resources being used inefficiently. Centralizing select aspects of inpatient pharmacy operations can lead to decreased operating costs, more efficient utilization of facilities' resources, and greater investment in pharmacy technologies that can improve patient care and safety.[29] Dramatic cost savings and economies of scale can be achieved by centralizing services, particularly in the pharmacy supply chain area. Remodeling costs are also significantly less in locations outside of the main hospital setting.

After considering their current inventory and the medications that are frequently acquired in large quantities or compounded in large quantities, health systems should strongly consider developing a centralized compounding or service center.[30] Multiple factors must be assessed and accounted for when making the decision to develop such a center. A new space with the ability to comply with compounding standards, good manufacturing practices, and legal and regulatory requirements must be built or acquired, along with personnel to manage the operational, quality and risk aspects of the facility. It is strongly recommended that the health system overseeing the 503A or 503B service centers has a backup supply plan for facility outages and active ingredient shortages. The proposed financial gain should also be compared with the capital and operating expenses to ensure this infrastructure and the center are in line with the health system's goals through an ROI and business plan proposal.

Conclusion

Inpatient pharmacy operations are increasingly complex, regulated and automated, requiring a highly specialized pharmacist and technical workforce to assure safe and efficient delivery of medications for health system patients. The skill set of a successful inpatient operations pharmacist extends far beyond the ability to check finished products. Specialized residency training and credentialing are both necessary to ensure a competent operations pharmacist workforce of the future. The incorporation of bar code scanning and other technologies at every input and output throughout the medication use process is necessary to build accuracy and efficiency into the drug delivery system. Within multihospital systems, there are many opportunities to improve service and efficiency and lower costs through centralization and consolidation of many aspects of inpatient pharmacy operations.

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Domain 5: Safety and quality

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Introduction

Patient safety and quality of care are essential to ensure that patients achieve optimal outcomes. Pharmacists are an integral component of the interprofessional team to achieve safety and quality. Achievement of both requires visionary leadership, operational infrastructure, continuous quality improvement and accountability frameworks. Road maps have been developed by consensus-based, standard-setting organizations, including the ISMP, the ASHP, the National Quality Forum (NQF) and the National Academy of Medicine (NAM). These goals have been translated into requirements by CMS and accreditors, such as TJC and Det Norske Veritas (DNV), and subsequently integrated into payment systems to ensure the value of health care expenditures is realized. The complexity of patient care and the rising costs to provide patient care services mandate that the HVPE integrate best practices for medication use to provide the most value for patients and health systems to ensure the highest level of confidence in medication management.

Pharmacy leadership is critical in optimizing safety and quality and implementing the HVPE statements. Foremost is having a strategic planning process for establishing priorities and positioning pharmacy for success and influence. Additionally, pharmacy leaders should promote alignment with organizational goals and ensure full integration of pharmacy services in acute, ambulatory and post-acute care settings. It is imperative that the outcomes of required measures, as well as pharmacy-centric measures, are routinely communicated to organizational leadership, specifically including how the pharmacy department is supporting the organization's overall safety and quality goals.

The following topics have been identified as critical areas to master in pursuit of safety and quality in an HVPE. These areas are integrated and dependent on the other HVPE domains.

- Topic 1: Cultural and organizational characteristics that define safety and quality
- Topic 2: Role of the P&T committee in ensuring evidence-based care
- Topic 3: Accountability and monitoring for patient safety
- Topic 4: Accountability and monitoring for quality and value
- Topic 5: Special considerations for patient and health care worker safety

Topic 1: Cultural and organizational characteristics that define safety and quality

Statement 1a

A dedicated pharmacist medication safety officer is responsible for maintaining the organization's medication safety strategic plan and continuously evaluating its effectiveness.

Performance elements 1a

- The pharmacy department applies principles of a "just culture," differentiating system risks and behavioral risks that may lead to patient harm.
- The pharmacy demonstrates routine evaluation of the medication use process across the continuum of care, including diagnostic, procedural, and ambulatory care sites, especially with implementation of new drugs, regulations and technology impacting the management of medications.
- Medication safety efforts are adequately resourced, led by a dedicated pharmacist resource (i.e., medication safety officer) and operationalized by a medication safety committee.

Statement 1b

Routine monitoring of national and local evidence-based best practices and gathering of interorganizational shared experiences related to medication safety and quality are routinely performed to maximize organizational engagement and improve safety.

Statement 1c

Organization demonstrates a commitment to routine collection and analysis of medication- related adverse events and near misses utilizing provider reporting, data analytics and reporting from other organizations to continuously and proactively improve patient safety and outcomes.

Statement 1d

Organization cultivates a learning health care system as a framework to provide safe and effective care.

Performance elements 1d

- Pharmacy leadership demonstrates the cultivation of a learning health care system that fosters ongoing learning from the complexity of the health care environment, the development of CDS, and improved patient safety and outcomes.
- Pharmacy applies machine learning to support continuous learning, promote safety and efficiency, and inform clinical decision-making.
- Implementation science is used in the health system to ensure uptake of evidence-based practices, enabling the quality and effectiveness of pharmacy services.
- Dedicated pharmacy staff support data management, analytics, and reporting of selected quality and outcomes information and dashboards.

Pharmacist leadership is critical in the development, implementation and monitoring of medication use systems that promote patient safety and improved outcomes. The development of a safety-focused strategic plan that incorporates industry best practices, risk mitigation strategies, and routine root cause analysis is essential.[1,2] Optimizing the unique training of pharmacists through direct patient care positively impacts medication safety and should be optimized for all patient populations to improve outcomes and provide the data necessary for continuous improvement of medication use systems.[3]

In 2017, the American College of Healthcare Executives, together with the Institute for Healthcare Improvement and the National Patient Safety Foundation, identified the following principles that must be included in an organization's strategic plan to establish a culture of safety:

- Establish a compelling vision for safety and value.
- Model and cultivate trust, respect and inclusion.
- Select, develop and engage your board.
- Prioritize safety in selection and development of leaders.
- Lead and reward a just culture.
- Establish organizational behavior expectations.[4]

These principles are the foundation on which organizations can develop a culture of safety. Pharmacy leaders must instill a just culture in their organizations, for that is an area where leadership and frontline health care staff intersect.[5]

Leadership and a culture focused on patient safety with the dedication of resources to assess the medication use system systematically and routinely are paramount.[6] The use of risk identification and assessment tools helps identify system strengths and vulnerabilities, subsequently guiding prioritization of steps to address the vulnerabilities. Safety-promoting organizations like TJC, the ISMP and the ASHP create self-assessment tools for safe medication use practices. For example, the ISMP maintains the Targeted Medication Safety Best Practices for Hospitals (TMSBP) to promote adoption of evidence-based medication safety practices for common patient safety issues that continue to cause harm. The recommendations are consensus based and informed by voluntary submissions of errors to the ISMP National Medication Errors Reporting Program. Since TMSBP was launched in 2014, a growing number of hospitals have adopted some or all of the best practices and as a result, have demonstrated improvements in levels of compliance.[7]

The Medication Safety Self Assessment for Hospitals developed by ISMP in 2000 has seen increased application over the past two decades.[8] There are 20 core characteristics, such as communication of medication orders, patient education, and quality processes and risk management. Hospitals that reported higher performance in organizational culture and safety education regarding medication error prevention characteristics were associated with higher performance on error detection, reporting and analysis, indicating a need for organizational leadership and commitment to preventing medication errors.

The coordination and oversight of organizational strategic planning and execution of safety initiatives should be done through a multidisciplinary medication safety committee (or equivalent) that is adequately resourced and led by a pharmacist medication safety officer who embodies the skills to set vision and direction, identify opportunities to improve the medication use system and lead implementation of error-prevention strategies. Organizations should actively promote pharmacists to fill these roles, as pharmacists are uniquely qualified to handle the duties meet the responsibilities of the medication safety leader in hospitals and health systems.[9]

A learning health care system culture is committed to improving patient safety and quality through "systematic problem solving, experimentation with new approaches, learning from their own experience and past history, learning from the experiences and best practices of others, and transferring knowledge quickly and efficiently throughout the organization."[10] Establishing a learning health care system within a culture of safety should be a top priority for contemporary pharmacy leaders.

Characteristics of successful learning health care systems as defined by the Agency for Healthcare Research and Quality include:

- Have leaders who are committed to a culture of continuous learning and improvement.
- Systematically gather and apply evidence in real time to guide care.
- Employ IT-empowered methods to share new evidence with clinicians to improve decision-making.
- Promote the inclusion of patients as vital members of the learning team.
- Capture and analyze data and care experiences to improve care.
- Continually assess outcomes and refine processes and training to create a feedback cycle for learning and improvement.

Health system leaders also need to be actively engaged in the development of machine learning and artificial intelligence applications and solutions to enable continuous patient safety and quality improvements.[11] Application of machine learning to analyze, process and adapt big data has the potential to solve clinical and workflow problems.

Topic 2: Role of pharmacy and therapeutics committees in ensuring evidence-based care

Statement 2a

Leverage the P&T committee to promote evidence-based formulary management, drug use policy and stewardship.

Performance elements 2a

- The pharmacy department leads the health system's P&T committee and formulary management system.
- Pharmacists are recognized for medication management expertise and accountable for enforcing evidence-based drug policies approved by the organization's P&T committee.
- The pharmacy department standardizes formulary management decisions across the multihospital pharmacy enterprise.

Statement 2b

The pharmacy department leads stewardship efforts to optimize safety and quality of medications.

Performance elements 2b

- The pharmacy department leads stewardship efforts related to the use of medications, including antimicrobials, antithrombotics with a focus on anticoagulants, antihyperglycemics and opioids.
- The pharmacy department addresses the opioid crisis through initiatives including, but not limited to:
  - Developing specific roles for pharmacists and/or other providers in the care of patients who are opioid naïve, opioid exposed and have opioid use disorder.
  - Supporting safe prescribing by leveraging the capability of EHRs and prescription drug monitoring programs.
  - Supporting disposal programs for prescription medications.

Statement 2c

Pharmacy departments engage with the P&T committee for accountability over the routine evaluation of the safety and quality of the organization's medication use process.

Performance elements 2c

- The pharmacy leads the systematic review of high-risk, high-alert and look-alike/sound-alike medications with demonstrated best practices to mitigate and prevent adverse events from occurring.
- The pharmacy maintains standardized medication concentrations approved and enforced by the P&T committee.
- The pharmacy department is responsible for management of drug infusion pump libraries and routine review of their effectiveness.
- The pharmacy department routinely evaluates performance and safety indicators associated with bar-code medication preparation, dispensing and administration.

The P&T committee has an important organizational patient and medication safety role and accountability for overseeing policies and procedures related to all aspects of medication use within an institution, as well as managing the formulary system.[12] P&T committees have evolved from formulary managers to medication use change agents with broad expertise and a highly matrixed infrastructure. In accordance with ASHP guidelines, the P&T committee and formulary management should be led by the pharmacy department.

Fundamental to a sound medication use system is the use of an evidenced-based, decision-making process for the development of policies and procedures and individualized patient care decisions that include an approach of assessing quality, quantity and consistency of evidence.[13] Through its P&T committee, an organization should balance the important principles of evidenced-based decision-making with practical solutions based on root cause analysis to improve patient safety in its selection of approved medications and the development of medication use policies and procedures.

With increased mergers and acquisitions of hospitals in the U.S., standardization of policies and procedures across health systems is an opportunity to improve patient safety through a well-organized, system-level P&T committee.[14,15] This includes a systematic, systemwide approach to managing high-risk, high-alert and look-alike/sound-alike medications with demonstrated best practices to mitigate and prevent adverse events.[16]

Many of the medications at highest risk of resulting in an error and carry the greatest degree of variability are delivered by intravenous infusion.[17,18,19] While the use of standardized concentrations has been steadily increasing over the past decade and has shown to decrease medication errors, it has yet to reach universal adoption.[18,20] The P&T committee must leverage this safety opportunity and take a leadership role in approving and enforcing standard concentrations throughout the health system. A useful resource is the ASHP Standardize 4 Safety initiative, a national, interprofessional effort to standardize medication concentrations to improve the safety of continuous infusions, oral liquids, IV intermittent medications, and patient-controlled analgesia.[21]

In its oversight role on the optimal use of medications, the P&T committee must embrace a stewardship approach in developing policies and procedures, as well as a cultural shift, to support comprehensive, interprofessional care of high-risk populations and medication use processes. The National Academies of Sciences, Engineering, and Medicine's Quadruple Aim of improving population health, improving the patient experience, lowering per capita cost, and improving provider work life requires organizations to embrace a stewardship approach to providing health care to achieve optimal outcomes.[22] TJC's antimicrobial stewardship requirements provide a framework that can be applied in various targeted initiatives: identify the stewardship leader; establish a stewardship goal; implement evidence-based practice guidelines related to the goal; provide clinical staff with educational resources related to the goal; and collect, analyze and report data related to the goal. [23] The combination of the Quadruple Aim and the stewardship framework provide an organized approach to improving quality and optimizing outcomes.

Stewardship programs in health care have become an important method to organize efforts to improve quality and outcomes for patients and organizations, as the philosophy encompasses the total health and interdependence of the patient, organization and community. Pharmacy should be engaged in all of the organization's stewardship programs and provide a leadership role in those programs involving medication use. The impact of pharmacist engagement in antimicrobial, anticoagulation and opioid management has been demonstrated in numerous studies.[24,25,26,27,28] Pharmacists' roles in managing patients treated with opioids should be expanded as organizations work to improve inappropriate use of opioids.

Topic 3: Accountability and monitoring for patient safety

Statement 3a

Align medication safety strategy and priorities with patient safety goals and objectives of the organization.

Performance elements 3a

- Pharmacy departments engage with clinical quality and risk management departments to identify and assume accountability for medication safety measures selected for internal, regulatory and payer reporting requirements.
- Routine documentation and evaluation of intercepted prescribing errors is performed and shared with appropriate stakeholders to identify opportunities for improvement.

Statement 3b

Leverage real-time reporting and alerting tools to monitor and support medication safety.

Performance elements 3b

- Pharmacy departments have dedicated analytics resource(s) to collect, aggregate, measure, visualize and disseminate data related to safety performance.
- Pharmacy departments lead a culture of routinely monitoring and reporting of near-miss medication errors.
- Pharmacy departments participate in local, state, and national reporting agencies and groups that support the identification of trends and knowledge-sharing of solutions.

Real-time reporting tools are useful to ensure that the organization's resources and patient care services align with and achieve optimal safety goals.[29,30] The pharmacy department needs to demonstrate engagement and accountability for medication management services to ensure medication use safety and outcomes. Critical considerations for achieving this include identifying measures that meet the organization's goals, align with national safety initiatives and address known high-risk patient populations. Accountability for medication use safety requires diligent monitoring of patient critical factors (e.g., laboratory values, comorbidities), identifying high-risk patients, and collecting adverse drug reactions and events. It is also important to include a focused commitment to prevent, address and monitor ADEs from anticoagulants, diabetes agents and opioids as outlined in the National Action Plan for ADE Prevention.[31]

Because specific patient populations (e.g., patients on anticoagulants or who lack access to supportive care services) and types of transitions (e.g., from hospital to long-term care facility) are more prone to safety and outcomes concerns, pharmacy departments should prioritize scenarios that include high-risk admissions, discharges and medications. In addition, mechanisms to identify and monitor patients who are candidates for deprescribing should be incorporated into pharmacists' patient care responsibilities.

Topic 4: Accountability for monitoring for quality and value

Statement 4a

Pharmacy practice leaders engage with hospital and health system safety and quality executives to identify continuous quality improvement priorities and opportunities.

Performance elements 4a

- The pharmacy department aligns with the quality improvement and measurement priorities of the organization.
- The pharmacy department has processes to stratify patient populations based on an assessment of value and pharmacy staffing resources.
- Health system pharmacy leaders demonstrate the value of medication management services to influence decisions related to the strategic direction of their institutions.

Statement 4b

A robust medication safety and quality dashboard is maintained and routinely shared with key stakeholders and staff to improve patient care.

Performance elements 4b

- The pharmacy department integrates core safety and quality measures for pharmacy accountability into its dashboard.
- The health system's formulary decision-making process includes metrics to support the concept of value.
- The pharmacy department demonstrates its role in supporting value-based purchasing measures and requirements.

Pharmacists must accept and demonstrate accountability for patient outcomes related to medication use. Value-based purchasing directs payments to improvements in quality, determined by performance on consensus-based quality measures. Despite current lack of an attribution method to assign patients and quality outcomes to a pharmacist, there are means for pharmacy departments to monitor and report performance on quality measures. To support the selection and benchmarking of relevant measures, the ASHP Pharmacy Accountability Measures (PAM) effort identified and prioritized existing medication-related quality measures that health system pharmacists can use to establish accountability for and demonstrate value in clinical outcomes.[29] The goal of PAM is to increase pharmacists' awareness of existing national quality measures to promote patient safety, improve quality measure performance and demonstrate value within their institutions. Armed with this information, pharmacists should work with quality leaders within their organization to develop dashboards.[30,32]

In addition to the national quality measures as indicators for performance, other metrics should be used to demonstrate the value of pharmacy services. For instance, metrics and dashboards promote adherence to formulary-based medication-use decisions, monitor medication safety priorities and identify trends in pharmacy costs.[32,33] Leveraging data is also important for stratifying populations of patients proactively to prioritize pharmacist services and ensure adequate pharmacy staffing to meet safety and quality goals. At the same time, capturing performance data enables pharmacy leaders to demonstrate the value of medication management services to influence decisions related to the strategic direction of their institutions, including value-based contracts with payers.

Topic 5: Special considerations for patient and health care worker safety

Statement 5a

Implement strategies to support workforce resilience and well-being.

Performance elements 5a

- Pharmacy leaders assess the work environment for fatigue and burnout and implement best practices to mitigate the risks of patient care errors.
- The pharmacy department uses human factors engineering and design and has processes to assess the environment routinely to optimize performance.
- The pharmacy department implements policies and procedures to prevent and respond to the occurrence of workplace violence.

In today's health care environment, top-performing organizations will be successful in establishing the necessary infrastructure to support the highest level of patient and health care worker safety. This will necessitate many strategies that impact the medication use system beyond culture, evidence-based patient care policies and procedures, and pharmacists' patient care. Areas for special consideration include the misuse and diversion of controlled substances (see detailed description in Domain 4), supply chain integrity (see detailed descriptions in Domains 2 and 4), and health care worker burnout.

Health care worker burnout has shown to have negative consequences on patient and health care worker safety.[34,35] Stress, fatigue, distractions and multitasking are associated with medication errors. While due diligence must be taken by the health care worker to

minimize distractions, a number of system factors contribute to the problem that require equal, if not greater, attention.[36] For example, workload demands characterized as interruptions, divided attention and rushing negatively impacted medication safety and employee well-being. The health system pharmacy department should be actively engaged in reducing workforce fatigue, burnout and violence through demonstrated assessment of the work environment for fatigue and burnout and implementation of best practices to reduce patient care errors, including a documented action plan to mitigate risks.[35,36]

Conclusion

HVPEs need to be proficient in key principles guiding the creation of a culture focused on safety and achieving optimal quality outcomes. Pharmacy leadership must integrate organizational commitment to safety and an empowered workforce into the culture and operations of the HVPE, thereby leveraging the expertise of the pharmacy team and evidence that demonstrates the positive impact of pharmacy on safety and achieving quality outcomes. Through effective strategic planning, use of evidenced-based and consensus-developed tools and resources, and management of outcomes measures, the HVPE will be successful in the alignment of safety and quality initiatives as tools to decrease clinical variation, increase clinical services and demonstrate the value of pharmacy.

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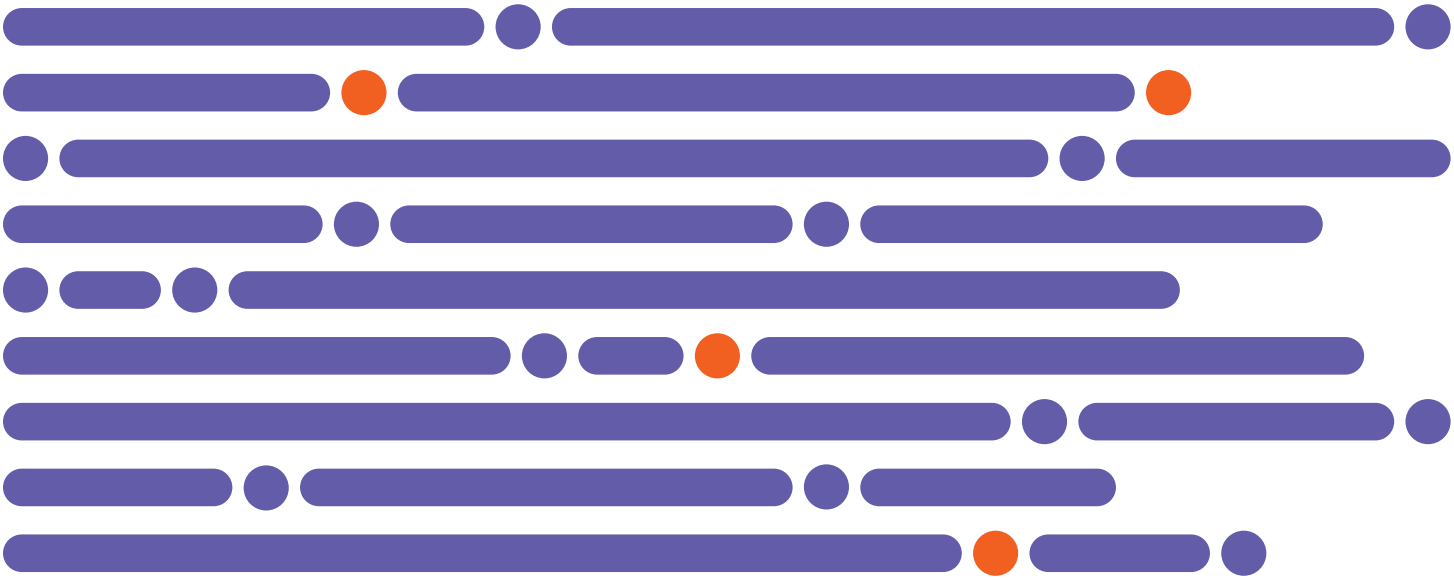

Domain 6: Pharmacy workforce

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Introduction

An HVPE requires a trained, competent and engaged workforce to provide optimal outcomes at the lowest cost. As a result of advancing technology, new interprofessional care models and evolving payment systems, the U.S. health care system is changing at a rapid pace. These forces present new opportunities and challenges to the pharmacy enterprise, as well as new demands on the roles of the pharmacy workforce. Continued advancement in pharmacy technology changes roles for technical staff, requiring them to assume more challenging positions maintaining and operating automation. With the shift toward increased interprofessional, patient-centered and evidence-based practice, pharmacists, student pharmacists and pharmacy technicians require continuous professional development to practice at the top of their license and skill set. A focus on value within evolving payment systems requires a reassessment of what tasks are done by what members of the pharmacy enterprise. Only through role expansion and practice advancement will the pharmacy profession meet the needs of health care organizations into the future. Therefore, efforts must be made to support the advancement of pharmacists, pharmacy technicians, support staff and learners. Modernizing pharmacy education, expanding pharmacist and pharmacy technician scopes of practice, increasing scholarship, and supporting professional development are essential to advancing the pharmacy workforce. This domain explores elements related to the pharmacy workforce that are present in an HVPE.

- Topic 1: Pharmacy education
- Topic 2: Pharmacist scope of practice, staffing and practice model
- Topic 3: Pharmacy technicians
- Topic 4: Scholarship
- Topic 5: Professional development

Topic 1: Pharmacy education

Statement 1a

The health system engages in a collaborative relationship with associated schools of pharmacy.

Performance elements 1a

- Strategic plans between the health system and associated school(s) of pharmacy demonstrate alignment and integration of priorities.
- The health system pharmacy executive and associated school of pharmacy deans have a regular cadence of meetings with a focus on innovating patient care, teaching and research.
- Health system leadership has input on the curriculum and design of associated schools of pharmacy.
- Experiential activities are mutually planned between the health system and associated schools of pharmacy.
- Health system clinical pharmacists engage in regular didactic instruction within associated schools of pharmacy.
- A pathway for health system clinical pharmacists to advance within associated schools of pharmacy is established.
- Joint scholarship activities occur between the health system and associated schools of pharmacy.

Statement 1b

Learners at each level of training (e.g., Introductory Pharmacy Practice Experiences [IPPE], intern, Advanced Pharmacy Practice Experience [APPE], PGY1 resident and PGY2 resident) engage in activities at the highest level of their competence.

Performance elements 1b

- The health system educates all levels of student pharmacists.
- The health system has an established internship program that transitions student pharmacists from dispensing to direct patient care roles.
- The health system has an established longitudinal APPE program that transitions student pharmacists to residency training and/or fellowship.
- Learners are positioned intentionally to instruct the learners below them at all levels (PGY2s teach PGY1s, PGY1s teach APPEs, APPEs teach IPPEs, etc.).
- Learners are utilized to provide direct patient care activities as pharmacist extenders for services such as medication education, admission histories and reconciliation.
- Learners across different levels collaborate on scholarship activities to achieve a high rate of publications and/or presentations.

Statement 1c

Interprofessional education occurs at all levels of student pharmacist education within the health system.

Performance elements 1c

- Learners have defined opportunities to practice with other disciplines through each year of education.
- Health system preceptors are positioned to provide formative feedback on learner participation in interprofessional care.

Statement 1d

Pharmacy residency training programs advance the organization's patient care model.

Performance elements 1d

- Pharmacy residency training programs and the number of residency positions continue to expand as the roles of pharmacists advance.
- Pharmacy resident projects and research are focused on expanding pharmacy services.
- Resident duty hours are focused on direct patient care activities and extending pharmacy services.
- The pharmacy department proactively measures the benefits of pharmacy residents and their impact on achieving organizational goals and shares these results with health system senior leadership.
- Pharmacy residents are positioned to be essential within the overall pharmacy practice model.

Collaboration of the health system with schools of pharmacy is a catalyst for innovation in pharmacy practice. Partnerships generate opportunities for both the health system and the academic institution that neither could create alone.[1] This partnership must begin at a

strategic level and be supported at the highest level of leadership within both organizations.[2] Cohesive relationships between health system pharmacy leaders and school of pharmacy deans must be supported through regular contact.[3] The goal of these meetings must go beyond information sharing and focus on joint efforts to create mutually beneficial advanced practice models, innovative teaching collaboration and joint scholarship activities. The affiliated school(s) must maintain an optimized curriculum that produces student pharmacists with the skills and abilities needed for contemporary practice. This requires health system input on curriculum design as the needs of advanced practices seen within health systems continuously evolve, particularly as health system positions take an increasingly large share of the job market as opposed to the traditional community-based pharmacy model.[4] Collaboration between schools of pharmacy and pharmacy enterprises has for many years revolved around experiential education due to large needs from both organizations.[5] Schools of pharmacy seek high-quality experiential education sites to meet accreditation requirements and health systems seek high-quality students to meet patient care needs. To provide optimal value, organizations must collaborate on standardization of experiential student requirements, preceptor development and rotation design. Multiple models for partnerships between health systems and schools of pharmacy exist. Innate incentives to meet the teaching and patient care needs of both organizations exist if faculty are jointly funded by a health system and a school of pharmacy. These types of relationships should continue to expand. When this is not possible or when specific subspecialties are not available, health system pharmacists should contribute to the direct didactic instruction of student pharmacists, as practical application of clinical knowledge is vital to student development and development of the clinical pharmacist's knowledge base.[6] These types of engagements should be reinforced with a pathway for clinical pharmacist advancement within the school of pharmacy. Financial incentives are not necessary; however, the value that health system pharmacists provide to student pharmacist education should be recognized through tangible rewards.[2] Further, many health systems value scholarship and schools of pharmacy have similar interests in advancing knowledge. Collaboration on joint scholarship activities can enhance the standing of both organizations.[7] Optimal partnerships between health systems and schools of pharmacy have shown to embrace a culture of creativity and communication around innovative pursuits.

The development and education of learners during their pharmacy education and residency training are vital for developing an innovative pharmacy workforce.[8,9,10,11] Positioning learners within a layered learning model where more experienced learners directly instruct learners with less experience improves teaching, develops precepting skills and facilitates top-of-license practice for all levels of pharmacy professionals.[12] Incorporating students and residents in pharmacist activities has resulted in improved clinical outcomes and measures.[12] Implementation of the layered-learning model has also led to reduced medication costs and improved patient satisfaction.[13] To free pharmacists' valuable time for complex clinical tasks, pharmacy technicians and learners should be used to assist with transitions of care activities. Learners and technicians have demonstrated accuracy and efficiency in performing medication histories and can help provide interventional support with medication reconciliation services.[14] Maximizing pharmacy extenders allows pharmacists to focus on more clinically intensive transitions of care activities.[15]

With a complete layered-learning model there is opportunity to grow organizational scholarship. Increased involvement of pharmacists in research provides the concurrent benefits of creating opportunities to enhance both student and resident research training. Currently there is a gap between institutional expectations regarding entry-level pharmacists' research capabilities and the research training provided to learners.[16] Standards have yet to be established in research training opportunities for students and residents.[17] This results in low publication rates by pharmacy learners. Strategies to improve residency research training include formalizing research processes, developing collaborative relationships with pharmacy faculty to serve as mentors and standardizing research training among residency programs.

As pharmacists have become more integrated within the health care team, interprofessional education has proved essential to preparing learners for their roles as pharmacy practitioners of the future.[18] Early implementation and continuation of interprofessional education throughout the pharmacy curriculum prepares students to take on active roles on the health care team as they develop clinical rapport with various health care professionals and establish a foundation for communication with future health care teams.[19,20,21] One essential component to effective interprofessional education is evaluation of individual learner performance in team-based care activities. Established interprofessional assessments should be utilized by health system preceptors to provide formative feedback of the learner's participation on interprofessional teams. Such assessments allow students to objectively develop interprofessional skills and aid in preparing students to serve as effective team players within the health system.[22]

Pharmacy residency training programs are essential components for health systems, as they enhance competencies and promote career development for entry-level pharmacists, while also supporting their expanding roles in pharmacy practice.[23,24] As roles expand in pharmacy practice, the scope of residencies also expands to provide practitioners with skill sets to meet required competencies. Currently, 66% of pharmacy graduates who pursue postdoctoral training obtain residency positions, while 94% of medical graduates who pursue postdoctoral training obtain residency positions.[25] Growth of pharmacy residencies is necessary to meet increasing pharmacy graduate demand and it supports enhancement of the layered-learning practice model to improve overall pharmacy workforce efficiency.[26]

Pharmacy residents play an integral role by serving as patient care providers, developing services, conducting research and engaging learners.[27] Residents also facilitate redeployment of pharmacists, expanding the capacity for new services within the pharmacy department.[28] Resident engagement in quality improvement initiatives and practice service implementation develops resident research abilities while simultaneously benefiting health systems. Involvement in research and participation in direct patient care

services elevates pharmacy residency training. Direct patient care activities enable residents to meet clinical training requirements, while participation in broader pharmacy services such as high-cost drug reviews and stewardship activities supports organizational goals. ASHP recommends pharmacy residents participate in direct patient care for the majority of their duty hours to be optimally prepared upon completion of residency training.[29] ASHP also recommends measuring and communicating the value of pharmacy residency programs with health system leadership, physicians, nursing and pharmacy staff.

Topic 2: Pharmacist scope of practice, staffing and practice model

Statement 2a

The pharmacist's scope of practice is as a provider and is continuously expanding.

Performance elements 2a

- Collaborative practice agreements or the pharmacist scope of practice are structured to allow pharmacists to independently manage patient medication therapy with a degree of judgement commensurate to their education and training.
- Scopes of practice are defined alongside other providers (e.g., nurse practitioner, physician assistant, MD, DO) to minimize overlap.
- Pharmacists in direct patient care roles are privileged through a similar process as other health care providers.

Statement 2b

Performance metrics and productivity measures are developed and maintained to ensure appropriate staffing models.

Performance elements 2b

- Metrics are used to help determine pharmacy staffing to optimize patient outcomes, medication safety and productivity.
- Labor and cost metrics are blended to optimize pharmacy staffing levels.
- Individual key performance indicators are used to reflect productivity and evaluate the performance of pharmacy staff.

Statement 2c

The health system only hires and retains pharmacists competent for top-of-license practice.

Performance elements 2c

- The health system requires all entry-level pharmacists to have completed residency training.
- The health system requires certification of all pharmacists in direct patient care roles as defined by the Board of Pharmacy Specialties (BPS).

Statement 2d

Innovative pharmacy positions are created to meet contemporary health care opportunities.

Performance elements 2d

- Pharmacists are involved in the health system's population health strategy (e.g., access to immunizations, reduction in opioid use disorder and other ACO outcomes).
- A transition of care program inclusive of pharmacy department accountability for admission medication reconciliation, discharge medication reconciliation and discharge medication teaching is in place. If high-risk patients are identified, organizational-specific data for readmission risk is utilized to identify high-risk patients.
- Pharmacists are involved in disaster response planning.
- There is a presence of specialized supportive roles in the pharmacy department, including but not limited to:
  - Informatics
  - Finance
  - Data science
  - Business analytics
  - Industrial engineers
  - Research support

In 2012, CMS expanded its definition of medical staff to include nonphysician providers, which allows pharmacists to be credentialed and privileged like other medical staff.[30] Credentialing is a process that health care organizations perform to ensure those providing services are qualified to do so. Assessment of pharmacists' credentials includes verification of licensure, experience and other qualifications for specialized practice, such as board certification by BPS.[31] Clinical privileging is a process at the institutional level that authorizes a practitioner's specific scope of practice for patient care based on their credential(s) and performance. This process ensures that pharmacists are competent to perform specified activities as nonphysician providers in an interprofessional setting. Credentialing and privileging in pharmacy practice enables pharmacists to specialize and operate at the top of their license to improve the quality of care and patient outcomes.[32]

Collaborative practice agreements (CPAs) between pharmacists and physicians are supported by applicable state pharmacy practice regulations. They delegate pharmacists the authority to assess, execute and monitor patient care activities, such as medication or medication-related lab ordering within a well-defined protocol. These agreements enhance efficiency of patient care and complement care provided on interprofessional care teams that may include educating patients and caregivers about medications.[33] Currently, 49 states and the District of Columbia support collaborative practice, which enables pharmacists to expand their scope of practice. Additionally, more than 20 states passed laws around pharmacist provider status as of 2017 and there were 109 state pharmacist provider status bills in process in 34 states in 2019.[34] However, state laws vary in the description of provider designation, scope of practice and payment for services.[35] Until there is national provider status, health system pharmacy leaders in states with pharmacist provider statutes should research and take advantage of opportunities for pharmacists to advance their roles through these laws.

The scope of pharmacy practice that includes advanced roles should be defined alongside other providers to minimize overlap. For instance, the scope of advanced practice providers (APPs) includes disease screening and diagnosis, prescribing, and other specialized practices.[36] The scope of the pharmacist as a provider offers a focus on medication therapy needs of complex patients, including the ordering and interpretation of relevant laboratory tests along with the initiation and adjustment of medication therapy.[37] By defining their scopes of practice alongside other providers, pharmacists will be better positioned to provide quality patient care and ultimately, add value to the health system.

The use of benchmarking and productivity within health system pharmacy can be used to continually improve departmental performance, while also evaluating departmental resources and success.[38] Staffing-to-demand models have become a popular tool for increasing productivity of pharmacists.[39] Additionally, the use of pharmacist key performance indicators, such as those defined by ASHP's Pharmacy Accountability Measures Work Group, allows the health system to ensure accountability and quality of care provided by pharmacists.[40] Health system pharmacy leaders should develop metrics and methods of productivity monitoring to help establish pharmacy staffing models that optimize medication outcomes, improve medication safety and maximize value.

Current board-certified specialties range from ambulatory care to nutrition support to pediatrics, and these specialties continue to evolve as pharmacists develop expanded competencies in specialty practice areas. The American College of Clinical Pharmacy, in conjunction with the Council on Credentialing in Pharmacy, have agreed that clinical pharmacists providing direct patient care must be board certified and have established collaborative drug therapy management agreements to maximize their role in improving patient outcomes through the delivery of high-quality patient care. With increasing complexity of care, an increase in differentiation in pharmacy practice is essential to ensure competency.[41]

To further ensure pharmacist competency, completion of an ASHP-accredited, postgraduate residency must be a requirement for all pharmacy school graduates seeking roles in health systems. Skills attained in a pharmacy residency program build upon pharmacy school curriculum and prepare pharmacists to provide direct patient care in any practice setting.[26] Optimal patient care by a pharmacist requires development of clinical judgement that can only be accomplished through the experience and reflection of pharmacy residency training.[24] Benefits of pharmacy residency training include development of problem-solving skills, broad exposure to pharmacy practice areas and professional networking. Pharmacists who complete residency training are more likely to be active within pharmacy organizations and publish, ultimately contributing to the advancement of the profession.

With evolving complexity of care, a focus on population health management has emerged in which pharmacists play a crucial role. For years, pharmacists have held specific public health responsibilities related to infection control through antimicrobial stewardship, substance abuse prevention through pain and opioid stewardship strategies, and disease prevention through immunization.[42] As proven key contributors in public health, pharmacists are equipped with the knowledge and skills required to develop population-specific, evidence-based disease management strategies tailored to the patient populations served by the health system.

Health systems must include pharmacy in transitions of care quality measures as part of their efforts to focus on population health. Pharmacist involvement in hospital discharge transitions of care has shown to decrease subsequent inpatient readmissions and emergency department visits.[43] Health systems can capitalize on reduced risk of readmissions and optimal transitions from hospital to community by ensuring pharmacist involvement to include, at a minimum, medication reconciliation and teaching in transitions of care.

Pharmacists play essential roles in disaster response through acquisition and allocation of medications and supplies, patient triage, medication identification and safety assessments, and monitoring chronic disease patients who are vulnerable to pandemics. Pharmacists also play a key role in preventing and mitigating disasters through administration of vaccinations, education on reducing spread of communicable diseases, point-of-care messaging for chronic disease patients and optimization of medication supplies.[44]

In addition to specialized clinical roles, there is a need for pharmacy personnel in specialized roles, such as informatics, finance, data science and research.[45] Informatics is especially important as the use of technology in pharmacy continues to expand and evolve. Formal informatics training in the pharmacy curriculum is needed to meet the demand for these specialized pharmacist roles.[46] The role of data science specialists has grown to provide essential support to pharmacy research. A specialist with the ability to acquire, analyze and apply data to pharmacy practice is a critical component of advancing pharmacist roles in health care.[47] Industrial operations engineers have shown to provide substantial support to pharmacy services, including improving operational efficiencies contributing to cost savings for the health system.[48] As U.S. health care expenditure continues to grow and emerging drug therapies require difficult cost-of-care decisions, pharmacy departments require more dedicated finance expertise.[26] This expertise supplements pharmacy departments' essential roles in clinical operations by meeting broader organizational objectives. Research support pharmacists can elevate pharmacy practice by enabling pharmacists to reach their full scholarly research potential.

Topic 3: Pharmacy technicians

Statement 3a

Pharmacy technicians participate in advanced roles in all practice settings to expand the scope of pharmacist practice, promote efficiency and improve patients' access to care.

Performance elements 3a

- Patient outcomes are evaluated as a result of advanced pharmacy technician roles.
- A scope of practice document for pharmacy technicians is maintained, defining pharmacy technician core competencies.

- Advanced technician roles are present in all the following sites of care (**Appendix D** provides a proposed list of expanded pharmacy technician roles and responsibilities to support advanced pharmacy practice):
  - Community pharmacy (e.g., product verification, remote dispensing)
  - Ambulatory pharmacy practice (e.g., administrative support for medication therapy management services, patient rooming, prior authorization services)
  - Transitions of care (e.g., telephone follow-up following hospital discharge, discharge medication prior authorization, prescription assistance programs, meds-to-beds, home visit services)
  - Inpatient care (e.g., medication history, meds-to-beds)
  - Leadership (e.g., manager, technician supervisor, technician training program coordinator)
  - Pharmacy finance (e.g., pharmacy billing, reimbursement reconciliation)
  - Supply chain (e.g., drug shortages management, purchasing)
  - Compliance (e.g., narcotic diversion auditing, survey readiness)

Statement 3b

Health systems attract new entrants into pharmacy technician careers and only employ competent technicians who are certified.

Performance elements 3b

- All pharmacy technicians have completed an accredited technician training program.
- All pharmacy technicians are certified upon hire or within one year of hire.
- The health system offers an accredited technician training program or has an affiliation with an accredited technician training program.
- Technicians are provided health system-sponsored resources to maintain certification.

Technicians are a critical part of the pharmacy team, performing duties under the supervision of a pharmacist that do not require a pharmacist's clinical judgment. Advanced pharmacy technician roles free up pharmacists' valuable time for direct patient care roles, enabling both technicians and pharmacists to practice at the top of their license.

The consensus of the Pharmacy Practice Model Summit called for standardization in scope of practice, competencies, education, training and licensure of pharmacy technicians.[49] Until there is an established profession-wide common ground defining pharmacy technicians' roles, health systems must continue to be the place for innovation for utilizing technicians in advanced practice settings.[50] Evaluation of patient outcomes due to expanding pharmacy technician roles will allow hospitals and health systems to define pharmacy technician scope of practice for their own institutions. Literature supports technicians performing advanced tasks, as they improve patient outcomes and increase pharmacist engagement in clinical services.[51] Expanding technicians' operational autonomy through tech-check-tech and bar code verification programs,[52] and/or increasing their clinical activities such as medication histories can free pharmacists to provide complex, direct patient care.[53] In a pilot program by Froedtert Hospital, a retrospective review of 12,329 first-time doses found no difference between technician bar code scanning versus pharmacist visual inspection, while significantly decreasing processing time — showing the impact these services can have.[54] Technicians have also shown to outperform pharmacists at certain tasks, which further promotes their increased scope of practice. Specialized Accuracy Checking Pharmacy Assistants for final visual verification in an Australian study showed a 1.59% error miss rate versus a 3.77% error miss rate for pharmacists.[55] Additional examples of expanded roles for pharmacy technicians from the traditional dispensing and data entry roles include administrative support for medication management services, immunizations, and telephone follow-up and home visit services following hospital discharge.[56]

Health systems must uphold standards for training, competence and certification for pharmacy technicians. With appropriate education and by demonstrating their competency through certifications provided by the Pharmacy Technician Certification Board (PTCB), technicians can have more advanced and innovative roles.[51,57] Pharmacy departments need to identify and expand pharmacy technician roles that fit the unique needs of their sites. The goal should be to continuously re-evaluate work and ensure it is necessary to be completed by that level of employee. The Accreditation Council for Pharmacy Education and the PTCB agree that standards for entry-level pharmacy technicians must be established by health systems. These standards must include education through an accredited technician training program to ensure public safety. This can be accomplished either prior to or within the first year of hire to allow some flexibility to meet patient care needs. To accomplish this systematically the health system will need to offer its own technician training program or have access to technician training programs through a partner organization.[58] Beyond initial certification, health systems should support technicians through ongoing provision of resources to assist them in maintaining their certification. This is often accomplished through reimbursement for continuing education, organization-provided membership to professional organizations or internally provided continuing education credits specific to the needs of technicians.

Topic 4: Scholarship

Statement 4a

Pharmacy-led scholarship is a highly valued output of the department.

Performance elements 4a

- A formal educational program related to research methods and publishing is provided for the pharmacy workforce within the health system.
- There is a standard process for approval and feedback on formal research proposals.
- Scholarship activities are tracked and reported to senior leadership.
- Barriers to pharmacist engagement in scholarship are routinely surveyed and addressed.

- Pharmacists are supported financially to attend professional conferences to share scholarly works.

Statement 4b

Pharmacists engage in the design, implementation and evaluation of quality improvement initiatives.

Performances elements 4b

- Health system leadership supports pharmacist involvement in quality improvement teams and the sharing of their results.
- There is an established quality improvement methodology and training program for all pharmacy department employees.

As pharmacy practice evolves, the pharmacy workforce will continue to expand its role in advancing practice through research.[59,60,61,62] In order to successfully meet this objective, the pharmacy workforce will need to evolve to support the pharmacist in the development of critical skills in designing, conducting and communicating research. While many pharmacists are interested in advancing their involvement in research, current pharmacy didactic, experiential and postgraduate pharmacy education curricula have not placed a large focus on developing these skills,[63,64] and practice models pose substantial barriers, including lack of time, training and support.[65] Formal research training programs have demonstrated success in improving clinicians' knowledge, confidence and attitudes toward research,[66,67] as well as potentially increasing scholarly productivity.[68] These research training programs are often offered as resident certificate programs, but could serve to support clinicians at any practice level, offering a formalized program to receive didactic and practice-based research education, mentorship and feedback.

New practice models supported by health system leadership must be created to allow pharmacists to advance their practice through expanded research opportunities. To optimize and justify these new practice models or financial commitments required to support such training programs, leadership should identify and address barriers to pharmacist engagement with research and publication and monitor pharmacists' scholarly activities, which are likely to increase with additional research training support.[68] Scholarship should be routinely reported back to key stakeholders across the organization to highlight this important aspect of pharmacist value to organizations. To incentivize pharmacist engagement, leadership could consider prioritizing financial support of professional development opportunities toward pharmacists who are communicating their scholarly results.

With health care moving toward quality-based metrics, pharmacists are key players in the design, implementation and evaluation of quality improvement initiatives. Adopting and applying standardized models for quality improvement elevates pharmacist engagement in such initiatives.[69] Measurement and feedback on quality improvement initiatives is fundamental. This can guide successful projects and assess project progress toward departmental and organizational goals.[70] The Educating Pharmacy Students and Pharmacists to Improve Quality (EPIQ) program is an established tool to educate pharmacy practitioners on quality improvement.[71] This tool has shown to improve pharmacist understanding of quality measurement and reporting. Health systems must have established education for pharmacy employees to ensure competency in measuring, reporting and improving quality in pharmacy practice.[72] With this expanded training, health systems should leverage the pharmacy workforce to support quality improvement teams throughout the organization and share these results broadly.

Topic 5: Professional development

Statement 5a

Career ladders and other professional advancement programs are used to maximize growth and engagement of pharmacy personnel.

Performance elements 5a

- Professional advancement programs such as career ladders are established and used to reward professional development for pharmacy technicians and pharmacists.
- Pharmacy leaders collaborate with human resources to evaluate and report outcomes of career ladders or advancement programs to the organization.
- The continuing professional development (CPD) process is supported for all employees and the health system supports resources to be available to support employee development plans (e.g., membership within professional organizations, continuing education credits, certification expenses).

Career ladders are becoming more prevalent to advance employee engagement and performance. Career ladders allow pharmacists to expand their contributions to the health system while simultaneously advancing their personal professional trajectory.[73] Pharmacist professional advancement and recognition programs have demonstrated increases in employee engagement, as well as increased quality improvement and professional development activities.[74] In addition to career advancement, career ladders in the pharmacy workforce have led to an increase in documented clinical interventions and medication use reports, as well as improved recruitment.[75] To increase transparency, human resources involvement in review committees, creation of programs and/or their ongoing evaluation is helpful. Human resources is able to evaluate and report outcomes of career ladders to organizational leaders. As pharmacy technician roles expand, career ladders for pharmacy technicians can help the health system meet its needs for a more efficient and specialized workforce, while providing technicians with career opportunities and rewards that recognize their value to the organization and their commitment to high-quality patient care. For all career ladders, it is not only essential to provide a pathway for advancement but also to provide the resources to support advancement within that plan.

CPD is a key component of career advancement. Oftentimes, this is achieved through membership in professional organizations and the networking that is associated with that involvement. Clinical pharmacists work within professional organizations to facilitate career development and assess core practice competencies.[76] Health system support for professional development increases opportunities for postgraduate pharmacists and enhances the quality of training for clinical pharmacists.[77]

Conclusion

The key to success for the pharmacy profession in the changing value-based health care environment is focusing on advancing pharmacy practice through workforce development. This requires a multipronged approach across the entire spectrum of roles within the workforce. Health system partnerships with schools of pharmacy are essential to redesigning education to create the types of pharmacists needed for the new health care environment. Advanced pharmacy technicians with status as professionals need to be trained and developed to achieve the profession's goals. Promoting the pharmacy profession and demonstrating its impact on patient outcomes through scholarship will help foster expanded positions and more consistent roles on a national scale. Health systems must establish pathways for advancement to encourage retention and engagement by the workforce within these new roles. Health system leaders must focus on the pharmacy workforce to advance the profession.

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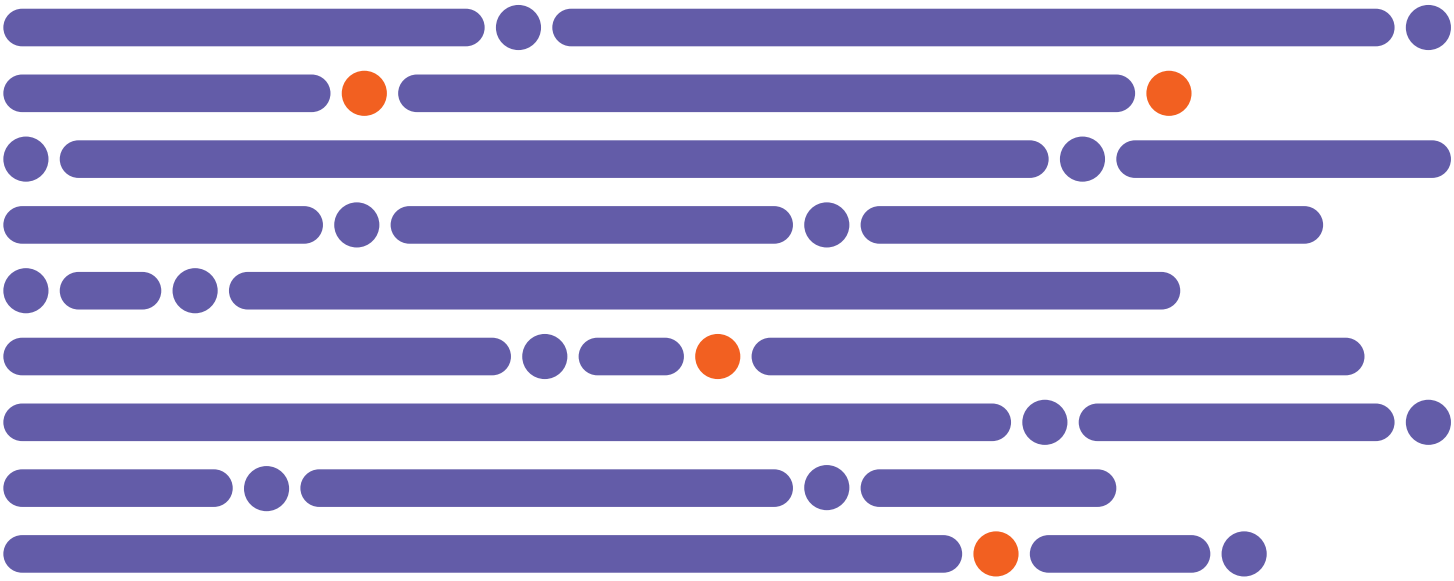

Domain 7: Information technology, data and information management

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Introduction

The use of IT in the medication use process has transformed medication safety, quality, clinical and operational activities. The focus of this domain is core technology expectations, including data management and technological requirements important to future success. Existing technologies have demonstrated many important benefits to patient care outcomes, safety and operational efficiency, despite the additional risks they can potentially introduce. To prepare for the forecasted advancements in technology, the following elements of a strong IT program are essential for health system pharmacy.

- Topic 1: Deploy fundamental medication management supporting technologies
- Topic 2: Maintain a competent pharmacy workforce by planning for current and emerging technology needs
- Topic 3: Manage data, information and analytic platforms to evaluate end-user acceptance and efficiency while improving patient safety and outcomes

Topic 1: Deploy fundamental medication management supporting technologies

Statement 1a

Proven medication management technologies are leveraged to maximize patient safety and clinical practice effectiveness.

Performance elements 1a

- An integrated longitudinal EHR is used.
- Computerized provider order entry (CPOE) and e-prescribing order management systems are in place.
- Pharmacy information management systems (PIMS) allow pharmacists to evaluate, prepare and dispense medications effectively in real time and in the context of the broader EHR.
- Medication administration technologies are used, such as bar code-enabled bedside verification of medications at administration and smart pump technology.

Statement 1b

Proven medication system technologies are leveraged to support safe and efficient pharmacy operations.

Performance elements 1b

- Machine-readable bar coding is used by inventory management, distribution and dispensing systems, such as:
  - ADCs
  - Compounding, repackaging and labeling
  - Carousels
  - Sterile compounding workflow management
  - Automated robotic compounding technology (ARCT)
- Community and specialty pharmacy technologies are in place, such as:
  - Interactive voice recognition for community settings
  - Automated prescription filling (e.g., prescription dispensing robots)
- Virtual services are deployed to optimize pharmacy operations and patient care services.

Statement 1c

Employ available technologies to engage patients beyond the walls of health care facilities to allow them to be active owners in their care.

Performance elements 1c

- Engage with patients through technology that provides secure, two-way patient messaging and electronic refill capabilities.
- Collect patient information and monitor medication use using portals designed with patient questionnaires and patient-reported outcomes.
- Exchange patient data and outcomes between patients' health care providers, payers, and community and specialty pharmacies.
- Use telehealth technologies to engage with patients and optimize clinical services in real time.

Statement 1d

Deploy real-time, point-of-care technologies to assist clinicians in evaluating and managing patient care, such as CDS, artificial intelligence, machine learning and other algorithms.

Performance elements 1d

- An interdisciplinary process is established for acquiring knowledge to create, verify and validate CDS, artificial intelligence and machine learning technologies.
- An interdisciplinary governance structure oversees CDS, artificial intelligence, and machine learning technology planning use and usability.
- Comprehensive quality controls and processes are in place to monitor, measure, evaluate, modify and maintain effectiveness and performance of technology for CDS, artificial intelligence and machine learning.

Statement 1e

Prepare and participate in business continuity best practices for data integrity, security and availability during technology downtimes.

Performance elements 1e

- Establish high-reliability processes for systems to avoid downtimes, in partnership with clinical operations and IT.
- Ensure system downtime policies and procedures are documented and readily available to all to ensure safe and efficient medication use system processes across all areas of the organization.
- Perform system downtime drills and refine processes based on lessons learned.
- Establish effective quality controls, best practices and processes to ensure data integrity and security.

Despite a number of early challenges, organizations have been able to effectively leverage evolving health care technologies and the discipline of clinical informatics to improve value.[1] This has allowed

pharmacy departments to identify best practices while implementing a core suite of medication management support systems proven to transform patient safety and practice efficiency.[2] Researchers have found hospitals and pharmacists increasing their use of EHR functionality to manage drug formularies, access medication histories and improve medication therapy management services across the care continuum.[3]

Integrated and interoperable ambulatory and acute care electronic prescribing systems are cornerstones to a high-value pharmacy and a health system's plan for improved safety and quality. The deployment of medication-related technologies for CDS to assist clinicians across the medication use processes are essential for optimizing drug therapies, preventing adverse events and improving patient outcomes. A number of systematic reviews examining the effectiveness of CPOE combined with CDS on medication errors, ADEs, patient length of stay and mortality rates have shown significant improvements.[4,5] Successful implementation of CDS requires attention to both technical and sociotechnical factors, as well as a number of best practices outlined in the research community.[6] Measuring the impact of CDS technologies to know if and how they are being used, if clinical goals and objectives are being met, and whether processes are unnecessarily disruptive can help the high-value pharmacy fine-tune and assess their overall benefits.[7] Ambulatory e-prescribing systems have produced similar results, indicating a reduction in prescribing errors and health care costs and improved efficiencies.[8] The combination of e-prescribing, the exchange of pharmacy health information, and interoperable ambulatory PIMS allows the high-value pharmacy to manage medicines across the ambulatory and acute care settings effectively. The PIMS should reside within the context of a longitudinal EHR to allow for effective communication and management of medications across all supporting technologies, disciplines and episodes of care. Interoperable community and ambulatory PIMS allow for the seamless exchange of health information.[2]

The bar code-enabled electronic medication administration record integrated within the context of an electronic health record and derived from upstream CPOE and PIMS is an important technology for improving medication safety. A reduction in medication error rates, decreased wrong-dose errors and increased nurse time spent on clinical care have been attributed to these systems.[9] Adopting implementation best practices further improves the overall quality and safety of bar code-enabled medication administration (BCMA), including implementation across the health system's continuum of care and a target of scanning both patient and medication bar codes in at least 95% of medication administrations in BCMA-equipped units. The features expected to be in place have been outlined in ASHP's statement on BCMA.[10] Evidence is also strong that smart infusion pumps play a significant role in preventing medication errors. Although smart pumps do not eliminate programming errors, they play a key role in intercepting medication errors such as wrong rate, wrong dose and pump-setting errors.[11] Interoperable smart pumps can add additional safety measures, including documentation and programming accuracy.[12]

High-value pharmacies must select and deploy additional technologies that effectively support pharmacy operations, augment core systems, and create an end-to-end, closed-loop medication management system. Deployment of standard technology at an enterprise level across multiple sites within the same health system further strengthens the benefits achieved at a local level, while maximizing efficiencies and fostering standardization.[13] The value, safety and efficiencies rendered when implementing these systems are highly dependent on use of acknowledged best practices, including the degree of integration and use of a readable bar code, which should be deployed wherever possible.[10]

Bar code-enabled inventory management, distribution and dispensing systems, such as carousels, have also shown to improve dispensing accuracy and reduce refill turnaround times of ADCs and resource requirements, while improving inventory turn rates by 15%.[14] Machine-readable bar coding should be used in a number of identified areas, including stocking inventory in the pharmacy and ADCs; manual packaging of oral solid and liquid medications; sterile and non-sterile compounding, repackaging and labeling processes (scanning source ingredients); retrieving medications from ADCs; and dispensing from the pharmacy to any location.[15] Research involving ADC implementation has identified reductions in dispensing, wrong-time administration and missing dose errors.[16]

The use of emerging technologies, such as sterile compounding workflow management systems and ARCT, has grown significantly in the last several years, even though there is currently little evidence supporting the advantage of these technologies. The complexity, variation and number of human steps involved in sterile compounding create opportunities for error and are amenable to using advanced technologies to improve quality and safety and reduce risk to both patients and health care workers. Advanced techniques, such as photo validation, gravimetric dose validation and bar code scanning, are available to improve safety and accuracy during sterile compounding; however, most of these techniques are not widely used. Two recently published studies show that the technology-assisted workflow in sterile compounding has detected more errors, resulted in faster preparation and has a lower cost for preparation in multisized hospitals.[17,18] Further studies are also needed on ARCT. While it has been suggested that robotic automation devices have safety benefits, including consistency of preparation, ultraviolet light sterilization and the ability to handle products that present hazards to personnel during preparation, this technology has had mixed results on operational efficiency and pharmacy costs.[19]

In community and specialty pharmacies, evidence exists to support interactive voice recognition to screen patients who are started on target drugs and then transfer them to a pharmacist if a positive symptom response is detected.[20] Pharmacies should also have prescription dispensing robots, which are demonstrated to reduce dispensing error rates, stockout ratios and staff time for stock management.[21]

To engage with patients directly, pharmacists should capitalize on secure communication technologies and services. Platforms for these communications are facilitated by the pervasiveness of home computing devices, mobile phones and tablets. Leveraging technologies with demonstrable impact, such as questionnaires, patient portals and telehealth, is a minimum expectation of high-value pharmacies. Patient portals with electronic refill capabilities

have shown to improve adherence rates for patients with statin medications.[22] Patient questionnaires provide rich data on the patient's medical and social history to inform pharmacists and other clinicians regarding their health and medication needs. Pharmacists in the community and ambulatory practice settings should have access to pertinent patient information and outcomes to effectively evaluate medication therapy management decisions.[23] This includes access to patient-reported outcomes available through patient portals.[24] Additionally, the ability to engage with patients through telehealth technologies should be leveraged for providing pharmacist clinical and dispensing services to remote hospital and community locations.[25] These technologies are affordable and proven to improve care while reducing costs in remote locations.[26]

Finally, all areas that rely on technology for the medication use process must invest in the rigor of establishing high-reliability processes for maintaining the systems for the care of patients. This includes system stability, security and data integrity. These areas must be evaluated as a factor when reviewing vendors and technologies, and best practices must be deployed in collaboration with the operational and IT leadership of the organization. Effective quality controls must be in place to avoid data or system integrity issues. Technology systems can be unavailable due to a variety of complex factors, and this unavailability has proven to result in medication errors.[27] There is growing importance on the need for downtime policies and procedures, accessibility of resources, practiced responses via drills and simulations, and individual accountability to manage the medication use process in situations where a technology system is not available.

Topic 2: Maintain a competent pharmacy workforce by planning for current and emerging technology needs

Statement 2a

Maintain a medication management informatics team with accountability to pharmacy to support safe and effective use of medications.

Performance elements 2a

- Medication management informatics teams led by pharmacists must oversee the medication use systems in all areas of the organization, including those used outside the pharmacy department.
- Medication management informatics resources must support the highest clinical and operational practice needs, with accountability to ensure alignment to both pharmacy and IT leadership.
- Pharmacists and pharmacy technicians are expected members of the medication management informatics team and must receive benefits, such as CPD opportunities, in alignment with or through the pharmacy department.
- Data analysts and/or scientists must reside in the pharmacy department to collect, visualize and disseminate data pertaining to pharmacy's financial and clinical performance.
- The medication management informatics leader must be located at the highest possible level of the leadership structure in the department in which they reside, with accountability to the pharmacy executive.
- Transparency in resource management should occur between pharmacy and IT leadership on expertise and resources available for all initiatives within and outside of pharmacy.
- The pharmacy executive or designee should be a member of the IT governance process to ensure alignment of organizational priorities with medication use process needs.

Statement 2b

Engage in active workforce planning to ensure readiness for adoption of emerging medication-related technologies and ongoing workforce development needs.

Performance elements 2b

- Medication management informatics resources must be involved in emerging technologies and translational opportunities.
- Pharmacy department leaders should ensure adequate baseline knowledge of all pharmacy staff, including the informatics team, to ensure readiness for adoption of emerging technologies.

Central to the success of all technology-driven performance elements is a highly skilled pharmacy team. This includes the medication management informatics team responsible for systems and the staff members within and outside the pharmacy department who use the systems.

Organizations must devote ample resources to recruiting, developing and maintaining a medication management informatics team with the required set of skills to provide comprehensive design, build, support, maintenance and optimization of medication management supporting technologies, reporting and analytics across the enterprise. The skill set needed within this team is multifactorial, necessitating the integration of pharmacists trained and specialized in the discipline of clinical informatics, pharmacy technicians with an operational background and IT analysts. Each specialty is integral to the team, as optimal technology deployment is dependent on a breadth of knowledge related to clinical practices, medication workflows and technical design. Pharmacist informaticists play a crucial role in managing the effective management and delivery of medication-related data, information and knowledge across systems that support the medication use processes.[28] Pharmacy technicians are also important members of the medication management informatics team, and their role should also be recognized and compensated for the expertise they provide across the spectrum of technology support.[29] The organization of pharmacy informatics resources must be closely linked with both pharmacy and IT leadership.[13] In addition to managing the current technologies, pharmacy informaticists are accountable for leading and managing change within the pharmacy and organization.[28] Major initiatives for integration of pharmacy technologies require skills in managing interoperability, improved workflows and usability, quality improvement, and documentation standards.

Medication management informatics leaders must be available at the highest level of their department to lead technology-associated health care redesign and support initiatives and integration activities proactively.[30] If medication management team members are embedded within the pharmacy department, they should directly report to the chief pharmacy officer or other highest individual

who has accountability for all medication use processes. Because some pharmacy leaders are focused solely on the processes within the pharmacy or a portion of the organization, the medication management informatics team may reside outside pharmacy to ensure its full scope of services are supported. If so, the medication management informatics leader should reside at or report to the highest level of oversight for clinical application services. Strong relationships within and outside pharmacy are the key to success for the informatics team.

Given their unique qualifications and expertise, system support provided by the medication management informatics team members must go beyond the pharmacy department and include medication ordering, documentation and monitoring tools such as those used in stewardship programs.[28] The medication management informatics resources must be positioned to manage the systems effectively and collaboratively across all areas and levels of an organization.[13] The workforce needed to support IT is expected to continue to grow significantly over the next 10 years.[31] Pharmacy leaders support innovation by devoting human and financial resources to investigating, testing and developing emerging technologies, including translational programs that support the implementation of technologies into clinical practice. Both clinicians and informaticians should be involved in the development and deployment of machine learning technologies to facilitate long-term clinical and technical viability.

In the current health care landscape, artificial intelligence and other automated and digital technologies are emerging, and it is anticipated that the technologies used by pharmacies will naturally shift over the coming years in response to new developments, impacting traditional workflows. Pharmacy leaders and staff will need education and training to determine how evolving technologies will support the medication use process and pharmacy staff members' roles, responsibilities and functions. A road map for staff development is an important investment for pharmacy leaders.[32] The intent of this review is not to forecast how pharmacy may change in response to these technologies, but rather to emphasize the importance of taking a leadership role in developing strategies that will permit pharmacy departments to thrive throughout future changes. Pharmacists must be at the forefront of evaluating these technologies to ensure accuracy, efficacy and safety of these systems during their development.

The introduction of technology and adjustment of workflows have inherent risks for health systems. The introduction of innovative technologies in a health system increases the demand for resources with a deep understanding of core operations, clinical practice and the discipline of clinical informatics. Organizations need to understand what technologies can provide and prepare the workforce for their introduction.[33] As disruptive technologies gain momentum, the analytical and technical skill exposure of the pharmacy department workforce will increase. There is a continuous need to advance the educational offerings and workflow skills to support the new technologies.

Topic 3: Manage data, information and analytic platforms to evaluate end-user acceptance and efficiency while improving patient safety and outcomes

Statement 3a

Integrate and capitalize on existing big data and predictive analytics tools to measure and improve outcomes and efficiency.

Performance elements 3a

- Data generated through the EHR at the institution is readily accessible electronically to appropriately trained individuals, permitting evidence-based research, quality initiatives and clinical operations.
- Evidence-based predictive analytics models are regularly sought out from the literature and are implemented at the institution.
- Predictive analytics models are developed internally and are made available for clinician use following appropriate validation.

Statement 3b

Pharmacists should have access to real-time, aggregated inpatient and outpatient data to assist with care management.

Performance elements 3b

- Pharmacists have access to intervene with hospitalized patients who are at high risk based on using predictive analytics to identify, prioritize and manage populations of patients, such as those at risk for hospital readmissions, specific disease conditions or both.
- Patient registries should be used by pharmacists to identify outpatients eligible for interventions and to target high-risk populations.
- A review process exists for additions or updates to CDS, predictive analytics tools and other patient care tools that rely on aggregated data.

Statement 3c

Dashboards are used to support patient care services, operations and organizational initiatives.

Performance elements 3c

- Real-time and interactive dashboards exist and are used to monitor operational productivity, efficiency, performance and other areas directly related to the patient care activities and setting of the pharmacy.
- Dashboard metrics are curated for both internal monitoring and external benchmarking and are reviewed on an ongoing basis to ensure alignment with business objectives and accuracy.
- A medication-related data mart exists through a data warehouse and is available to perform ongoing and ad hoc data aggregation and report generation.

The adoption of EHRs has been instrumental in the generation and storage of large amounts of health care data. As data are generated through these systems, there is great potential to use these data for clinical practice, quality improvement, research initiatives and business oversight. To facilitate effective use of data, pharmacies must engage in initiatives that support the acquisition and meaningful interpretation of data.

Predictive analytics is a branch of advanced analytics that aims to make predictions of future events, such as disease development or medication response, using preexisting data sets.[34] As predictive analytics initiatives have occurred, clinicians have developed the ability to access information quickly at the point of care, allowing them to optimize patient care and better predict patient outcomes to provide preemptive interventions.

To develop evidence-based advancements in clinical tools, pharmacists require adequate technical support to acquire data from the EHR. Second, to facilitate the uptake of evidence-based recommendations that are generated, pharmacists should be part of an interdisciplinary team charged with the implementation of models and care prediction tools into the EHR. Fragmentation of informatics resources frequently leads to hindrance of translational efforts.[35] The provision of these data permits successful innovation adoption and optimal clinical care. In addition to clinical use of predictive models for patient assessment, pharmacists are in a powerful position to influence the development of quality improvement initiatives.

In each pharmacy setting within an enterprise, including inpatient, ambulatory, community and specialty pharmacies, metrics are integral for assessing performance and ensuring that goals are met. Metrics such as those that monitor drug distribution, supply chain management, compliance, workload measurements, productivity and resource management should be molded to fit the goals and initiatives of individual pharmacies. Additional examples include, but are not limited to, adherence rates, clinical outcomes, compliance with medication therapy guidelines, prescription capture rates, patient or employee satisfaction, reductions in ADEs, and financial improvements.[36]

Predictive analytics models are currently in place at many institutions and are being used to predict hospital readmissions and disease risk, as well as many other patient outcomes.[37] The value of a predictive model can conceptually be derived from its resulting actions that arise from both the characteristics of the model and the number needed to screen, understanding that predictive tools do not result in action on all patients screened.[38] Organizations derive substantial benefit from using these tools, as they generate in-depth insight for high-risk patients while simultaneously reducing clinician time required to acquire and assess data to make patient care decisions.[39]

Patient registries should be used by pharmacists to identify patients eligible for interventions and to target high-risk populations.[40] Whether internally or externally created, a system needs to exist for the request and generation of reports. This may include self-access to a report portal for aggregate patient data or a data-requesting service that permits the manual acquisition of data from a designated group of technology personnel.

Conclusion

The HVPE must implement and support a core suite of medication management technologies that are proven to transform patient safety, quality and efficiency across the continuum of care. Improved value and safety are attained when core systems are augmented with tightly integrated and interoperable solutions that create an end-to-end, closed loop, medication management system. Deployment at an enterprise level further strengthens any benefits achieved at a local level and maximizes efficiencies, fosters convergence and creates a single point of accountability. Existing technologies that allow medication information to be reviewed and entered on demand must be leveraged to serve patients across all care settings. These systems must be highly reliable, secure and overseen by a medication management informatics team. To further position itself to use emerging technologies and big data, the HVPE must build a workforce with the needed skill set. Pharmacy leaders should provide a road map for the existing pharmacy workforce within their organization, including the informatics staff, as well as support opportunities for further education and skills needed to address existing and emerging technologies.

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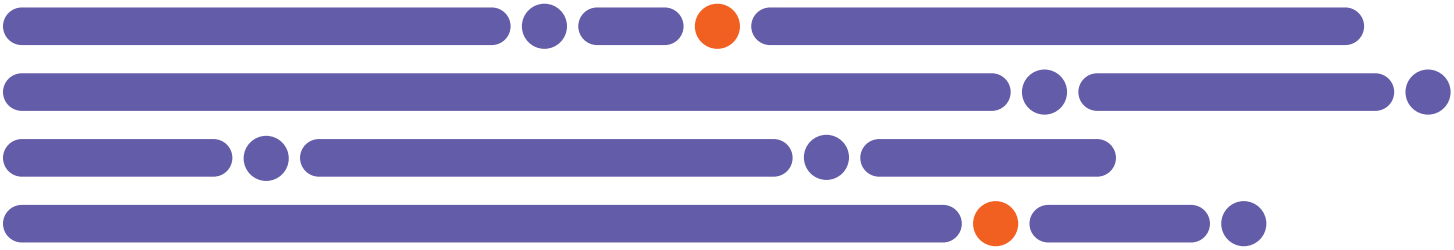

Domain 8: Leadership

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Introduction

An HVPE needs bold leaders to create a vision, maintain and execute a strategic plan, and lead the pharmacy workforce in advancing pharmacy services to optimize patient outcomes and meet organizational goals. The pharmacy enterprise should be directed by an effective pharmacist executive leader who capitalizes on the strengths of a collaborative and well-rounded team to advance exceptional pharmacy services. This domain outlines the essential attributes of effective pharmacy leaders. Only through extremely effective pharmacy leadership will the elements of the other seven domains be achieved.

- Topic 1: Attributes of the pharmacy leadership team
- Topic 2: Organizing for maximum effectiveness
- Topic 3: Strategy and innovation
- Topic 4: Leading for results
- Topic 5: Developing future leaders

Topic 1: Attributes of the pharmacy leadership team

Statement 1a

A pharmacy leadership team is accountable for all aspects of the pharmacy enterprise.

Performance elements 1a

- The pharmacy leadership team is responsible for all aspects of medication management performance throughout the organization.
- The pharmacy leadership team motivates all pharmacy staff to improve patient outcomes by medication management throughout the organization.
- The pharmacy leadership team creates an environment that functions effectively as a learning organization.

Statement 1b

Members of the leadership team exhibit executive presence as an essential characteristic necessary to succeed in advancing pharmacy practice.

Performance elements 1b

- Members of the pharmacy leadership team have the temperament, competencies and skills to influence others and drive results.
- Members of the pharmacy leadership team are driven by a mission and vision designed to optimize organizational value from pharmacy services and programs across the continuum of care that will result in positive patient outcomes.
- Executive presence is effectively demonstrated by personal dimensions of passion, poise and self-confidence; communication occurs with candor, clarity and openness; and relationships are built with thoughtfulness, sincerity and warmth.

Statement 1c

Pharmacy leaders demonstrate a high level of emotional intelligence.

Performance elements 1c

- Pharmacy leaders are perpetual optimists, exhibiting a positive attitude to motivate and encourage others.
- Pharmacy leaders have good self-awareness with respect to their strengths and weaknesses.
- Pharmacy leaders are self-assured with a candid sense of purpose.
- Pharmacy leaders have vibrant interpersonal skills, are authentic, demonstrate caring and empathy, and cultivate strong relationships with others.
- Pharmacy leaders demonstrate servant leadership and altruism in their actions.
- Pharmacy leaders demonstrate sound stress management skills and impulse control, are proactive, and demonstrate stress tolerance to specific events and ongoing stressors.
- Pharmacy leaders seek compromise that results in win-win results.
- Pharmacy leaders embrace change as a positive and enriching process.
- Pharmacy leaders act with integrity in all personal, professional, financial and operational aspects of their leadership and practice.
- Pharmacy leaders demonstrate effective work-life integration and are enriched, successful and gratified in both their personal and professional endeavors.

Statement 1d

Pharmacy leaders actively pursue productive and vibrant individual CPD plans.

Performance element 1d

- Pharmacy leaders maintain CPD plans that document specific goals.
- Pharmacy leaders create an environment in which CPD is encouraged across the entire pharmacy workforce.

Leaders of a high-performance pharmacy are able to create an idea or vision and motivate others to share or act on it — individuals who continually make a constructive difference.[1] While no one style or set of traits and skills defines an effective leader, these leaders uniformly "make things better" by having a clear vision of what they want to achieve, confidence in that vision and the ability to execute it. As identified in the ASHP Pharmacy Practice Model Summit, the development of leadership at all levels is essential for success in ensuring the provision of safe, effective, efficient and accountable medication-related care for patients in health systems.[2] A 2017 article by Forbes Coaches Council outlines 16 leadership skills, most of which can be developed and honed, that are imperative to the future of work. These are fearless agility, earning respect, empathy, selflessness, flexibility, committing to a clear vision, listening, humility, communication and "soft skills," steadiness while remaining adaptable, learning quickly, cultural intelligence, understanding the individual, authenticity, leading through change, and versatility.[3]

Having pharmacy leaders accountable for all aspects of the pharmacy enterprise is important to assure coordination resulting in alignment with organizational objectives and effective deployment of resources. A single governing structure, responsible for both clinical and business

objectives, is essential to ensure optimal patient care and financial viability and to support the broader health care delivery system.[4] The role of the pharmacy leadership team includes strategic planning, advancing pharmacy practice, advancing IT, medication management, quality and drug use management, supply chain and financial management, regulatory and accreditation standards, research and education, institutional representation, new business development, and leadership.[5] With medications representing approximately 10% of health care and health system costs, the pharmacy executive must prioritize the financial and economic impact of the pharmacy enterprise across the entire health system in concert with driving optimal medication use stewardship.[4] Health systems are advancing physicians into the most senior executive roles, leveraging their clinical expertise to foresee and exploit various opportunities that can improve patient care.[6] The same rationale holds that the most senior pharmacy leader in an HVPE must be a pharmacist.

Executive presence — the gravitas, verbal acumen and physical appearance of a leader — is required for pharmacy leaders to succeed. It can be argued that one's executive presence and emotional intelligence are rooted in what Billy W. Woodward described as a core of principles, which are an individual's fundamental personal and professional values and beliefs.[7] This core serves as the basis for developing professional priorities and leading with integrity, as well as the basis of what W.A. Zellmer characterized as the "soul" of pharmacy, enabling leaders to lead staffs toward creative improvements in the delivery of care and to practice with "uncommon assurance, joy and peace of mind."[8]

A strong synergy exists between leadership and high-performance pharmacy practice. As noted by Zilz et al., critical components of a leader in high-performance pharmacy practice are the core self, vision, relationships, learning and mentoring.[1] A similar theme is evident in Linda S. Tyler's identification of four behaviors that explain the variance among strong and weak organizations and leadership effectiveness. Important behaviors include the ability of leaders to solve problems effectively, operate with a strong results orientation, seek different perspectives and support others.[9] In doing this, the pharmacy executive can be the stimulus for the creation of innovative, bold advancements in practice, such as making the commitment that pharmacists proactively provide clinical services for all patients within the organization, communicating and relating with the interdisciplinary team to integrate all tasks related to medication management.[10]

CPD is an approach to lifelong learning that is self-directed, ongoing, systematic, outcomes-focused and applied in practice.[11] It involves the process of active participation in formal and informal learning activities that assist individuals in developing and maintaining continuing competence, enhancing their professional practice and supporting the achievement of their career goals. As a working document, a CPD plan should include documentation of the competencies developed and applied in practice, as well as reflections on a pharmacist's current state of development and plans for future development. Pharmacy leaders should also foster an environment in which the discipline of CPD is encouraged and implemented for all members of the pharmacy workforce.[12]

Topic 2: Organizing for maximum effectiveness

Statement 2a

The most senior pharmacy leader reports to the highest level of organizational leadership (e.g., chief executive officer, chief operating officer).

Performance elements 2a

- The most senior pharmacy leader is part of the highest governing, decision-making and policy-making bodies of the organization.
- The preferred title to represent the most senior pharmacy leader role is the designation of chief pharmacy officer, with the responsibility for all pharmacy services throughout the organization.

Statement 2b

Pharmacy maintains an organizational structure that supports its leaders' focus on strategy, priorities, tactics, and timely and effective decision-making.

Performance elements 2b

- Each member of the pharmacy leadership team is responsible for a manageable number of direct reports to enable their ability to delegate and oversee the success of the department.
- Business units within the organization are structured to include leadership by individuals with direct day-to-day responsibilities for those areas.

Statement 2c

All pharmacists and pharmacy technicians in pharmacy practice roles report to leaders that report into the pharmacy leadership team.

Performance element 2c

- Pharmacists and pharmacy technicians throughout the organization in pharmacy practice roles (e.g., inpatient, ambulatory, information systems, clinics, etc.) report up to a member of the pharmacy leadership team.

Statement 2d

Members of the pharmacy leadership team maintain effective working and personal relationships with leaders from other areas throughout the organization.

Members of the pharmacy leadership team should be regular participants in strategic decisions of the organization.[13] Pharmacy services extend across interdisciplinary boundaries, and pharmacy leaders need to be involved in discussions and decisions related to medication-related changes in medical and surgical practice, as well as other significant operational changes in the organization leading to improved clinical outcomes, compliance and financial performance.

Strong pharmacy leaders play a critical role in practice change, owning and championing the change by being visible, public and active in communicating the change throughout the change process.[14] They should invest their personal time and attention to follow through on actions and be recognized as change advocates, taking personal initiative and challenging the status quo to propel toward achieving the vision for the pharmacy enterprise.

Leading across spheres of influence within the health care organization and the profession is an essential component of a high-performing pharmacy department.[1] With senior health system leadership, the pharmacy executive should promote the pharmacy vision and strategic plan in alignment with the health system's goals for improving outcomes, quality and patient satisfaction, as well as meeting financial objectives. To do this, the pharmacy executive should be visible and effectively sell pharmacy's value to administration. In addition, pharmacy leaders should actively participate in the health system's committees, including medical staff committees, to provide direction and recommendations that are consistent with organizational goals. Similarly, because nursing is an important partner in medication administration and monitoring of medication therapy, pharmacy leaders need to cultivate strong relationships with nursing leaders to achieve optimal drug therapy for patients.

Pharmacy leaders need to cultivate and maintain relationships with the pharmacy workforce to ensure that they are enthused, encouraged, motivated, and aligned with day-to-day operations and strategic direction for pharmacy practice advancement.[1] A key to that, beyond sharing the vision for pharmacy enterprise with staff, is following through on issues that are important to staff. This is in addition to developing strong collaborative relationships with peers in professional service departments, given the interdisciplinary nature of health care delivery and opportunities to create synergistic practices.[1] Pharmacy leaders are often valued by peers because of their education, decision-making skills, personal effectiveness and professional competency. The relationships built with staff and peers contributes to a positive impact on patient relationships.

To have influence outside of the health system, pharmacy leaders need to develop and maintain relationships with leaders in other organizations, such as professional organizations, regulatory and accreditation organizations, colleges of pharmacy, pharmacy benefit management, health plans and health insurance companies, and the supply chain industry. A leader's influence on these relationships can impact recruiting, training, contracting, formulary management, communication and career advancement. Influences outside of and within the organization and an effective organizational structure create an environment for success in strategizing, creating a vision, aligning the enterprise and executing.

Topic 3: Strategy and innovation

Statement 3a

The pharmacy leadership team creates and maintains a contemporary strategic plan for pharmacy practice, aligned with organizational goals and strategic priorities.

Performance elements 3a

- The pharmacy leadership team assures the development and maintenance of a clear strategic plan, defining the department's vision, mission and strategic priorities.
- The pharmacy leadership team engages team members at all levels in development and routine review and revision of the strategic plan.
- The pharmacy leadership team facilitates others to adopt and act on the plan as it becomes a shared and common vision for the pharmacy workforce and organization by:
  - Providing structured messages and rationale that allow others to connect, prepare and perceive their roles as part of the vision.
  - Allowing dialog that permits the exchange of perspectives and refinement of the vision.
  - Planning for feedback, addressing and overcoming any problems or setbacks.
- The pharmacy plan is appropriately designed, funded and executed.
- The pharmacy leadership team provides structure in the plan, such as by incorporating the Specific, Measurable, Achievable, Relevant and Time-bound (SMART) goals format, to make the plan understandable and attainable.

Statement 3b

Pharmacy leaders monitor the health care environment for new opportunities, take calculated risks and encourage innovation that advances practice.

Performance elements 3b

- The leader's proactive, futuristic outlook incorporates the changing needs of the patients served, the organizational mission, new technologies, regulatory requirements, available resources, and opportunities for new partnerships and collaborations.
- Leaders quickly react to new ideas and opportunities, taking calculated risks and challenging the norm to identify areas in which pharmacy can improve patient outcomes.
- Leaders are comfortable bringing bold new ideas to senior leadership.
- Leaders are persistent in bringing ideas to fruition, yet also exercise patience by waiting for a more opportune time if the ideas lack initial support.

Pharmacy leaders need to use big-picture thinking to develop and execute a vision for the role of pharmacy, and what actions are needed to achieve that vision.[15] Key elements of this thinking are understanding the business of health care, studying the environment, exploiting change and taking risks. The vision should be bold, futuristic and adventurous — while still mission-driven — without being egocentric, inspiring the entire pharmacy workforce to see themselves as part of the vision.

Strategic planning is an organized, thoughtful and reflective process by which strategic advances in pharmacy practice are explored, contemplated, analyzed and vetted.[16] Starting with the organization's mission, the pharmacy executive should lead the pharmacy enterprise in strategic planning. Core elements of strategic planning include creating a clear vision and mission for pharmacy as previously described, incorporating and stating values, exploring possibilities, aligning goals, defining strategies and tactics to meet the goals, developing priorities, identifying roadblocks, and establishing milestones. Phases of strategic planning should include research, authoring and development, presentation and review, approval, communication, and implementation.[17]

According to Steve Rough, an effective pharmacy leader constantly strives to transform practice through innovation, exhibiting an unselfish commitment and refusal to make excuses.[18] Keeping up with the literature and recognizing and translating trends is an essential part of doing this. In the current health care environment that is experiencing rampant consolidation, greater impact of retail medicine, rapid expansion in telehealth, unsustainable rising drug costs, and growth in regulatory requirements and precision medicine, there is a need for pharmacy leaders who can provide innovative responses and ensure that pharmacy is involved in addressing these challenges.

Topic 4: Leading for results

Statement 4a

Pharmacy leaders demonstrate business acumen to ensure the effective use of organizational and pharmacy resources to optimize patient outcomes.

Performance elements 4a

- The pharmacy leadership team is comprised of individuals with business-related skills, including budgeting, variance reporting, business plan development, revenue cycle management and project management.
- Strategic goals for the organization and the department are shared routinely with staff and displayed prominently, as is evidence of progress toward these goals.

Statement 4b

Pharmacy leaders advocate for pharmacy services on an ongoing basis by influencing and demonstrating the positive impact of the pharmacy enterprise on achieving organizational goals and strategic priorities, including patient care outcomes and financial performance.

Performance elements 4b

- Pharmacy leaders represent the enterprise on multidisciplinary organizational committees.
- Pharmacy services and their impact are routinely shared with senior health system executives.

Statement 4c

Pharmacy leaders are actively engaged in contributing to the profession by sharing successful practices with colleagues.

Performance element 4c

- Leaders routinely share successful pharmacy practice advancements and achievements with state and national colleagues through platform presentations and publications.

Statement 4d

Pharmacy leaders share pharmacy department and team member successes within the department to engage and motivate pharmacy staff.

Performance elements 4d

- Pharmacy milestones and successes are routinely shared with pharmacy staff and displayed in a common area of the pharmacy department.
- Department meetings include a standing agenda item to discuss pharmacy advances, including the positive impact of pharmacy services on patient care, medication safety and achievement of organizational goals.

Statement 4e

Pharmacy leaders actively participate; serve in leadership roles; and support staff involvement in local, state and/or national pharmacy organizations.

Performance elements 4e

- Pharmacy leaders take an active role in professional organizations.
- Leaders encourage and support staff involvement and leadership in professional organizations at all levels.
- Leaders include active professional organization participation in their CPD plans and document progress.
- The enterprise encourages staff member involvement in specialty and professional organizations related to the practice areas of the organization.

Business acumen is essential to ensuring effective medication management, financial stewardship and success of the pharmacy enterprise. This includes effective communication of the value of pharmacy services that are integrated into planning, preparing and presenting business proposals and the budget.[4] Leaders must be prepared to monitor, interpret and take action based upon the pharmacy's financial performance, all while being transparent in sharing the budget, fiscal goals and financial forecasts of the organization with staff. The pharmacy budget should be used as an instrument of change within the enterprise to support the organization's financial viability and mission.

Pharmacy leaders use internal and external benchmarks to compare their department's operational, clinical and financial performance with themselves over time and with peers to identify potential areas for improvement. For instance, medication safety reporting should be encouraged, monitored and acted upon to identify gaps in patient care. Similarly, clinical quality outcomes measures, such as CMS core measures, should be collected and shared to demonstrate the impact of pharmacy services on patient outcomes. An internal operational productivity monitoring system should be established to evaluate and demonstrate improved staffing efficiency over time.[19]

The success of the pharmacy enterprise should be routinely shared with colleagues through presentations and publications that advocate the importance and impact of pharmacy services. By actively participating and leading in local, state, national and international pharmacy associations, pharmacy leaders stay at the forefront of contemporary practice issues, which in turn greatly benefits the organization and serves to advance the profession. Similar benefits accrue from serving in leadership roles with GPOs and various other professional organization committees.

The pharmacy leader's active involvement in pharmacy associations serves as a model for the pharmacy workforce. That modeling should be paired with departmental policies that promote staff involvement and leadership at all levels of professional society activity. Sharing successful practices with pharmacy staff on a regular basis cultivates

a culture of pride and encourages continued high performance. Noteworthy accomplishments to share include the positive impact of pharmacy services on patient care and outcomes, medication safety, and achievement of departmental and organizational goals, as well as administrative, clinical and technological advancements.

Topic 5: Developing future leaders

Statement 5a

Pharmacy leaders inspire the development and success of future pharmacy leaders by teaching, modeling, coaching, facilitating and mentoring in college of pharmacy curricula.

Performance elements 5a

- Pharmacy leaders offer opportunities for both IPPE and APPE student rotational experiences.
- Pharmacy leaders offer IPPE and APPE students the opportunity to be coached in creating and sharing vision, strategic planning, and leading change.
- Pharmacy departments offer a wide array of APPE rotational experiences with pharmacy leaders.

Statement 5b

Pharmacy leaders engage in developing the leadership skills of future pharmacy leaders.

Performance elements 5b

- Pharmacy leaders offer administrative learning experiences for all PGY1 and PGY2 pharmacy residents.
- Pharmacy residents within the enterprise meet routinely with pharmacy leaders, including the pharmacy executive, during their training for discussions on professional and personal leadership development.
- A PGY2 Health System Pharmacy Administration and Leadership (HSPAL) residency training program is offered if the organizational structure can support a wide selection of experiences demonstrating excellence.

Statement 5c

Pharmacy team members serve as leaders within the organization by effectively contributing to interdisciplinary teams and committees.

Performance elements 5c

- Pharmacy team members are integrated into organizational committees that maintain oversight of the medication use system.
- Pharmacy team members contribute on specific service line committees and teams that rely on medication therapy for optimal patient outcomes.

Statement 5d

Leaders maintain a pipeline of future employees by connecting with local colleges of pharmacy to establish contemporary education and rotational sites for pharmacy students.

Performance elements 5d

- Pharmacy students are incorporated into the workforce to the extent possible to provide opportunities to develop clinical, operational and patient interaction skills.
- Pharmacy leaders connect and present didactic classroom lectures in school of pharmacy curricula, including the classroom and experiential settings.
- Pharmacy leaders participate in leadership groups and organizations as educators, preceptors, advisers and mentors for school of pharmacy students.

Statement 5e

Pharmacy leaders have a dynamic succession plan that evolves to meet the needs of the organization and pharmacy enterprise.

Performance elements 5e

- The pharmacy enterprise has a system to track and assist in identifying and developing potential successors for leadership positions at all levels.
- Pharmacy department succession planning efforts are present and in alignment with succession planning strategies of the organization.

Pharmacy leaders need to take an active role in developing staff, students and residents to be future leaders.[20] Exposure to pharmacy leadership should begin early in the school of pharmacy curriculum, including introductions to the concepts of clinicians as leaders, personal and professional development, and change leadership.[21,22,23] Experiential training, such as IPPE and APPE rotations, should expose pharmacy students to real-life pharmacy leadership career opportunities. Pharmacy leaders and staff should embrace opportunities to cultivate future practitioners through engagement with students.[24]

Pharmacy leaders should contribute to the development of the next generation of leaders by incorporating leadership development activities and participation in planning efforts for residents and student pharmacists.[25] Exposure to both staff and leadership perspectives and involvement in departmental planning is a valuable component to leadership development. Additional activities can also include discussions of key leadership articles, annual resident retreats, self-assessments (e.g., CliftonStrengths) and reviews of professional achievement award lectures.

In addition to pharmacy learners, pharmacy staff should also be encouraged and supported in leadership development. This should be intentional to ensure development of core competencies, such as demonstrating personal qualities, working with others, managing services, improving services and setting direction.[26] Leadership development is attained through a variety of opportunities, and leaders can foster it informally and when reviewing staff members' CPD goals during midpoint and annual evaluations. Pharmacy leaders should individualize recommended activities to provide the individual with knowledge, skills and experience that will enhance their portfolios and leadership acumen, such as academic or professional studies, scholarly activity, teaching and precepting

experience, specialty certification and certificate programs, expanded involvement in workplace activities, and professional or community service.

Pharmacy leaders should be intentional in the succession planning of the enterprise. While the need for succession planning is evident, the lack of succession planning is prevalent in most health systems — a problem not unique to pharmacy.[27] Just as the organization's priorities and vision evolve, the succession plan should evolve to meet the needs of the organization and pharmacy enterprise. Succession planning should result in a synergistic and seamless transition, having started well before the departure of the current leader.[28] To maintain a healthy pool of future employees and potential leaders of the enterprise, pharmacy students should be incorporated into the workforce and leaders should keep open communication with past high-performing students. Continued lifelong mentoring of residents by preceptors and leaders often creates career opportunities as jobs arise. Professional organization meetings and conferences are the ideal setting to engage with past residents to keep high-quality candidates within reach for future openings.

Effective succession planning includes succession management.[29] According to the 2012 University Health System Consortium Succession Planning survey, mentoring and coaching, leadership and skill development, and internal commitment and support are the key themes of successful succession planning.[30] Succession planning should be integrated into the pharmacy strategic plan and coordinated by a succession planning team. The team can be responsible for needs forecasting, turnover analysis and identification of candidates, as well as identifying and assessing employee competencies and skills objectively. Employee profiles, including preferred assignments, departmental committee preferences and clinical specialty areas of interest, should be collected, in addition to talent inventories. A succession planning implementation guide can be useful for pinpointing future leadership gaps, identifying top talent, customizing high potential development and personalizing onboarding for new hires.[31]

Conclusion

Strong leadership is the cornerstone of an HVPE. This demands a dynamic and engaged presence and organizational structure. Pharmacy leaders in an HVPE strive to optimize patient outcomes through interdisciplinary medication management. This domain defines core expectations for pharmacy leaders, who provide the foundation for organizational success and advancement of pharmacy practice.

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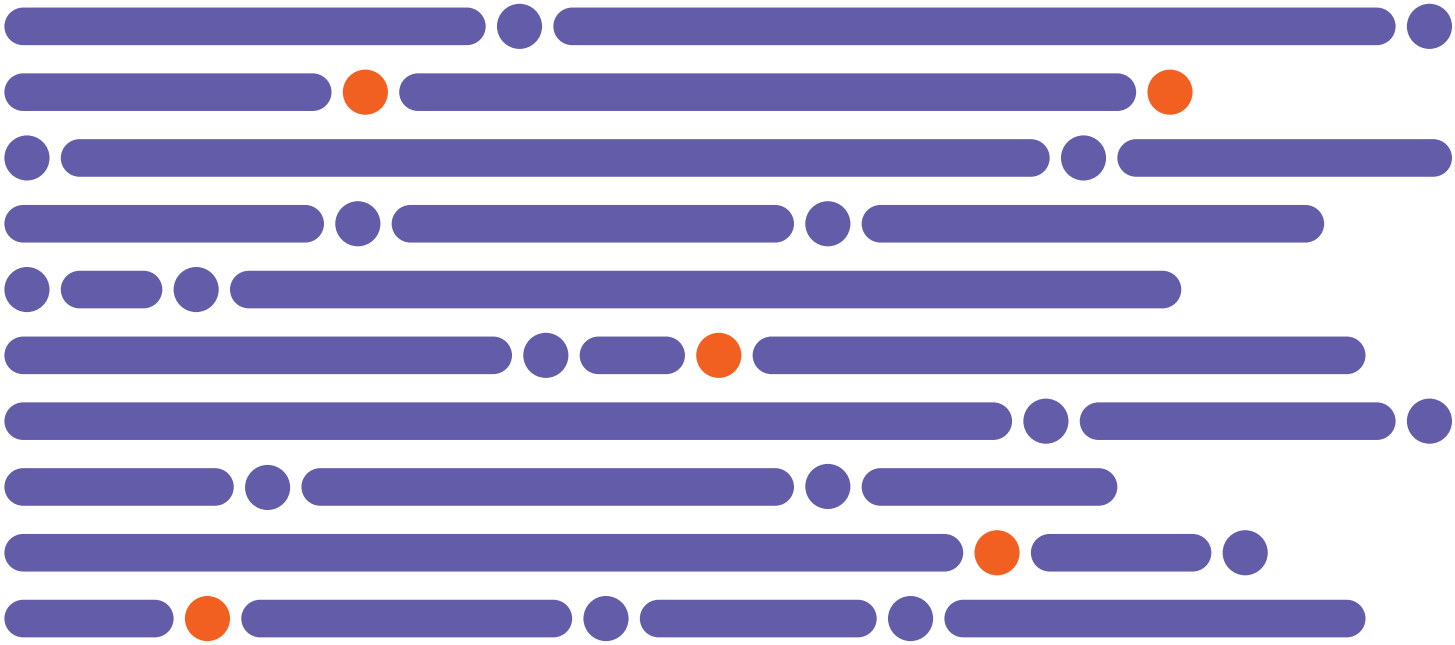

Appendix A

Proposed pharmacy-sensitive indicators

Pharmacy-sensitive indicators (PSIs) reflect evidence-based pharmacist patient care services and interventions associated with improved patient care, safety and/or financial outcomes.

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Inpatient pharmacy services			
Anticoagulation service Dager WE, Branch JM, King JH, et al.[1]	Comprehensive warfarin pharmacy consultation service with prescribing and drug monitoring	Reduction in length of hospitalization by 2.6 days Reduction in number of patients/patient days with supratherapeutic INR: • Patients with INR > 3.5 (27% vs. 62%) • Days with INR > 3.5 (7% vs. 25%) • Patients with INR > 6.0 (3% vs. 33%) • Days with INR > 6.0 (1.5% vs. 8.8%) Fewer patients receiving drugs with major interactions with warfarin (6 patients vs. 13 patients)	p = 0.009 p < 0.001 p < 0.002 p < 0.001 p < 0.001 p = 0.02
Anticoagulation service Mamdani MM, Racine E, McCreadie S, et al.[2]	A 24-hour, 7-day/week pharmacist-managed anticoagulation service for unfractionated heparin and warfarin with dose adjustments and lab monitoring	Greater proportion of therapeutic aPTT values (47.7% vs. 41.5%) Greater proportion of patients who received warfarin within 2 days of UFH initiation (82% vs. 63%) Shorter hospital stay (7 days vs. 5 days)	p = 0.05 p = 0.05 p = 0.05
Vancomycin and aminoglycosides Bond CAC, Raehl CL.[3]	Lab monitoring and dose adjustment of vancomycin and aminoglycosides from various practice sites	Lower (vs. hospitals without pharmacy management): • Death rates by 6.71% • Length of stay by 6.30% • Total Medicare charges by 6.30% • Drug charges by 8.15% • Lab costs by 7.80% • Ototoxicity complications by 46.42% • Renal impairment by 33.95% • Death rate in patients who developed complications by 10.15%	All endpoints: p < 0.0001

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Vancomycin Marquis KA, DeGrado JR, Labonville S, Kubiak DW, Szumita PM.[4]	Pharmacist-directed vancomycin dosing and lab monitoring service	Optimal dosing post-pharmacist-directed vancomycin dosing (96.8% vs 40.4%) Shorter length of therapy (10.0 vs. 8.4 DOT) Lower incidence of nephrotoxicity (8.7% vs. 3.2%)	p < 0.001 p < 0.003 p < 0.006
Aminoglycosides Greenwood BC, Szumita PM, Lowry CM.[5]	Pharmacist-driven aminoglycoside dosing and lab monitoring service	Increased number of patients with optimal therapy (80% vs. 44%) Reduced incidence of acute changes in renal function (6.2% vs. 14.9%)	p < 0.001 p < 0.05
Aminoglycosides Streetman DS, Nafziger AN, Destache CJ, Bertino JS Jr.[6]	Individualized pharmacokinetic monitoring and dosing of aminoglycosides by clinical pharmacy specialists	Reduction in aminoglycoside-associated nephrotoxicity (7.9% vs. 13.2%)	p = 0.02
Aminoglycosides Destache CJ, Meyer SK, Bittner MJ, Hermann KG.[7]	Clinical pharmacokinetic service for patients with culture-proven, gram-negative infections treated with aminoglycosides	Shorter febrile periods (50.05 +/- 79.38 hrs. vs. 92.23 +/- 122.50 hrs.) Lower pharmacokinetic service direct costs ($7,102.56 +/- $9,898.19 vs. $13,758.64 +/- $22,874.31)	p < 0.05 p < 0.05
Direct thrombin inhibitors Cooper T, White CL, Taber D, Uber WE, Kokko H, Mazur J.[8]	Credentialed pharmacists dosing and monitoring direct thrombin inhibitor therapy under an institution protocol for suspected heparin-induced thrombocytopenia	Reduced mean time to attainment of therapeutic aPTT (3.4 hrs. vs. 7.7 hrs.)	p = 0.009
Fall prevention Haumschild MJ, Karfonta TL, Haumschild MS, Phillips SE.[9]	Medication review and written recommendations by pharmacists for all admissions to decrease fall risk in a rehabilitation center	Reduction in the number of falls by 47%	p = 0.05
Polypharmacy management Hanlon JT, Weinberger M, Samsa GP, et al.[10]	Clinical pharmacists meeting with patients 65 years or older for all scheduled visits to evaluate drug regimen and make recommendations to physicians	Decreased inappropriate prescribing scores (24% vs. 6% reduction) Interventions made by physicians from pharmacist recommendation vs. independently (55.1% vs. 19.8%)	p = 0.0006 p < 0.001
Antiepileptic management Bond CA, Raehl CL.[11]	Pharmacists provided management for antiepileptic drugs under a collaborative drug therapy management	Lower (vs. hospitals without pharmacist management): • Death rates by 120.61% • Length of stay by 14.68% • Total Medicare charges by 11.19%; • Aspiration pneumonia rates by 54.61%	 p = 0.014 p = 0.0009 p = 0.0003 p = 0.015

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Parental nutrition in low-birth-weight infants Dice JE, Burckart GJ, Woo JT, Helms RA.[12]	Pharmacists monitoring and management of peripheral-vein total parenteral nutrition in a neonatal intensive care unit	Greater mean weight gain (11.8 g/day vs. 4.9 g/day) Greater amount of protein provided (2.2 g/kg/day vs. 1.9 g/kg/day) Greater number of calories provided/day (63 kcal/kg/day vs. 53 kcal/kg/day) Greater amount of lipid provided (2.0 g/kg/day vs. 1.5 g/kg/day)	p < 0.02 p < 0.01 p < 0.001 p < 0.001
Antimicrobial control program Gentry CA, Greenfield RA, Slater LN, Wack M, Huycke M.[13]	Antimicrobial control program led by a clinical pharmacy specialist with authority and primary responsibility to approve use of restricted and non-formulary antimicrobial agents	Decreased length of hospital stay (10.8 ± 12.7 days vs. 13.2 ± 15.3 days) Reduction in mortality (6.61% vs. 8.28%)	p < 0.0001 p = 0.007
Conversion from IV to PO antibiotics Przybylski KG, Rybak MJ, Martin PR, et al.[14]	Pharmacist led initiative to contact physicians for the conversion of antibiotics from intravenous to oral in select patients	Shorter total number days of therapy by 1.53 days	p < 0.003
Pharmaceutical care Smythe MA, Shah PP, Spiteri TL, Lucarotti RL, Begle RL.[15]	A robust pharmaceutical care system protocol for patients admitted to a step-down unit managed by a critical care pharmacist	Fewer adverse drug reactions requiring treatment (1 vs. 8)	p = 0.027
QTc interval prolongation monitoring Ng TM, Bell AM, Hong C, et al.[16]	Clinical pharmacists on physician teams monitoring patients with QTc interval-prolonging drugs using a standardized algorithm	Lower frequency of QTc interval prolongation (19% vs. 39%) Lower incidence of QTc interval greater than 500 msec (13% vs. 33%)	p = 0.006 p = 0.003
Impact of a pharmacy resident Terceros Y, Chahine-Chakhtoura C, Malinowski JE, Rickley WF.[17]	A pharmacy resident prospectively collecting data on patient demographics and interventions during patient admission and follow-up rounds	Shorter length of hospital stay (7.9 +/- 7.2 days vs. 10.9 +/- 7.9 days)	p = 0.008

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Medication reconciliation Murphy EM, Oxencis CJ, Klauck JA, Meyer DA, Zimmerman JM.[18]	Every inpatient admitted to the hospital provided a comprehensive medication history reconciliation by a pharmacist or their delegate within 24 hours of admission	Medication error reduction: • On surgical unit (47% vs. 90%) • On medicine unit (33% vs. 57%)	 p = 0.000 p = 0.000
Renal dosing adjustment Hassan Y, Al-Ramahi RJ, Aziz NA, et al.[19]	A clinical pharmacist integrated in the nephrology unit team providing dose adjustment recommendations	Less number of suspected ADEs (49 vs. 73)	p < 0.05
Stroke door-to-needle Rech MA, Bennett S, Donahey E.[20]	Pharmacists available bedside during acute ischemic stroke	Pharmacist participation in stroke: • Reduced DTN time (48 min. vs. 73 min.) • DTN ≤ 60 min. in 71% vs. 29%	 p < 0.01 p < 0.01
Stroke door-to-needle Gosser RA, Arndt RF, Schaafsma K, Dang CH.[21]	Emergency department pharmacist's presence for accuracy and timeliness of recombinant tissue plasminogen activator administration	Pharmacist participation in stroke: • Reduced DTN time (69.5 min. vs. 89.5 min.) • DTN ≤ 60 min. in 29.9% vs. 15.8%	 p < 0.0027 p < 0.1087
Pharmacist-managed surgical prophylaxis Bond CAC, Raehl CL.[22]	Pharmacist-managed antimicrobial prophylaxis for surgical and nonsurgical patients	In hospitals that did not offer pharmacist-managed surgical prophylaxis: • Death rates 52% higher (OR 1.54; 95% CI, 1.46-1.63) • LOS 10.2% longer • Infection complications 34.3% higher (OR 1.52; 95% CI, 1.40-1.66)	 p < 0.0001 p < 0.0001 p < 0.0001
Pharmacist-managed direct thrombin inhibitors To L, Schillig JM, DeSmet BD, Kuriakose P, Szandzik EG, Kalus JS.[23]	Pharmacist-directed anticoagulation service for management of patients with heparin-induced thrombocytopenia	• Time to therapeutic aPTT reduced by 12.5 hours • Proportion of time within therapeutic aPTT range increased 32%	p < 0.001 p < 0.001
Anticoagulation services MacLaren R, Bond CA.[24]	Clinical pharmacists' participation with patients in intensive care units with thromboembolic or infarction-related events	ICUs without a clinical pharmacist: • 49% greater incidence of bleeding (OR 1.53; 95% CI, 1.46-1.60) • Higher likelihood for blood transfusions (OR 1.47; 95% CI, 1.28-1.69) • Greater blood product administration (6.8 units/patient vs. 3.1 units/patient)	 p < 0.0001 p = 0.006 p = 0.006

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Inpatient pharmacist specialties			
Pediatric pharmacists Kaushal R, Bates DW, Abramson EL, Soukup JR, Goldmann DA. [25]	Unit-based rounding and pharmacist's involvement on general and intensive care floors for pediatric patients	Reduction in serious medication errors per patient days (6 per 1,000 patient days vs. 29 per 1,000 patient days) Reduction in net serious medication errors per patient days (33 fewer per 1,000 patient days vs. 10 more per 1,000 patient days)	$p < 0.01$ $p < 0.001$
Heart failure pharmacists Gattis WA, Hasselblad V, Whellan DJ, O'Connor CM.[26]	Clinical pharmacist evaluation, therapeutic recommendation to attending physician, patient education and follow-up telemonitoring for patients with left ventricular dysfunction	Reduction in all-cause mortality and heart failure events (4 vs. 16)	$p = 0.005$
Heart failure pharmacists Sadik A, Yousif M, McElnay JC.[27]	Structured pharmaceutical care service program for patients with diagnosed heart failure	Improvements in a range of summary outcome measures: exercise tolerance (2-min walk test: 1,607.2 vs. 1,403.3 meters/month); forced vital capacity (31.6 liters/month vs. 27.8 liters/month); and health-related quality of life (463.5 units/month [better] vs. 637.5 units/month) Increased number of patients reporting medication compliance (85 patients vs. 35 patients)	$p < 0.05$ $p < 0.05$
Renal transplant pharmacists Chisholm MA, Mulloy LL, Jagadeesan M, DiPiro JT.[28]	Renal transplant patients who received direct clinical pharmacy services, including medication histories, therapy optimization and promotion of adherence strategies	Increased mean medication compliance rate (96.1% vs. 81.6%) Longer duration of medication compliance at 12 months (75% vs. 33.3%) Greater achievement of target levels (64% vs. 48%)	$p < 0.001$ $p < 0.05$ $p < 0.05$
Renal transplant pharmacists Maldonado AQ, Weeks DL, Bitterman AN, et al.[29]	Pharmacists' involvement with the hospital's interdisciplinary kidney transplant team	Decreased mean LOS (7.8 days vs. 3.4 days) No adverse effect on all-cause, 30-,60- and 90-day readmission rates Annual cost savings of $279,180 attributable to shorter LOS	$p < 0.001$ $p > 0.09$
ED pharmacists Brown JN, Barnes CL, Beasley B, Cisneros R, Pound M, Herring C.[30]	Clinical pharmacists assigned to the ED for consultation and other assistance to health care providers during all hours of each shift	Reduction in medication error rate (5.38 per 100 medication orders vs. 16.09 per 100 medication orders)	$p = 0.0001$
Critical care pharmacists Leape LL, Cullen DJ, Clapp MD, et al.[31]	Clinical pharmacist rounding with ICU team for consultation	Decreased rate of preventable ADEs by 66%	$p < 0.001$

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Infectious disease pharmacists Carver PL, Lin SW, DePestel DD, Newton DW.[32]	Infectious disease clinical pharmacist alerting and providing clinical recommendations of therapy for mecA gene test result	Clinical pharmacist in ICU led to reduced time to administration of optimal antimicrobial therapy (64.7 hours vs. 39.3 hours)	p = 0.002
Infectious disease pharmacists Gums JG, Yancey RW Jr, Hamilton CA, Kubilis PS.[33]	Typed consult from infectious disease pharmacy specialist containing rationale and references for clinical recommendations to attending physicians	Decreased length of hospital stay (5.7 days vs. 9 days)	p = 0.0001
Antimicrobial stewardship pharmacists Doernberg SB, Abbo LM, Burdette SD, et al.[34]	Review of antimicrobial stewardship programs throughout the U.S. and associated outcomes based upon pharmacist allocation to the program	Each 0.5 pharmacist FTE increase predicted a 1.48-fold increase in the odds of demonstrating effectiveness (95% CI, 1.06-2.07): • Decreased MDROs, cost savings, decreased antibiotic utilization Recommended minimal pharmacist FTE support by bed size: • 100-300 (1 FTE) • 301-500 (1.2 FTEs) • 501-1000 (2.0 FTEs) • >1,000 (3 FTEs)	
Outpatient pharmacist services			
Lipid management Bogden PE, Koontz LM, Williamson P, Abbott RD.[35]	Pharmacists provided care during 30-minute appointment prior to PCP to provide recommendations to medication therapy	Higher success rate of patients achieving NCEP goals (43% vs. 21%) Decreased total cholesterol levels (44 mmol/L vs. 13 mmol/L reduction)	p < 0.05 p < 0.01
Lipid management Ellis SL, Carter BL, Malone DC, et al.[36]	Patients randomized into intervention group were scheduled for drug assessments by ambulatory care clinical pharmacists who could adjust therapy and order laboratory tests	Higher number of patients with a fasting lipid panel (72% vs. 70%) Greater reduction in total cholesterol (17.7 mg/dL vs. 7.4 mg/dL) Greater reduction in low-density lipoprotein (23.4 mg/dL vs. 12.8 mg/dL)	p = 0.021 p = 0.028 p = 0.042
Diabetes management Anaya JP, Rivera JO, Lawson K, Garcia J, Luna J, Ortiz M.[37]	Patients with diabetes mellitus were referred by physicians to the pharmacist for clinical management and education under a collaborative drug therapy management agreement	Mean reduction in HbA1c by 0.7% Mean reduction in blood glucose by 26.4 mg/dL Lower average costs for inpatient hospitalization and ED admissions ($636 vs. $2,434)	p < 0.001 p < 0.001 p = 0.015

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Diabetes management Kiel PJ, McCord AD.[38]	Pharmacist-coordinated diabetes management program emphasizing inpatient education, medication adjustment and laboratory monitoring via a collaborative practice agreement	Mean HbA1c reduction by 1.6% Increase in percentage of patients with A1c < 7 (50% vs. 19%) Mean LDL reduction by 16 mg/dL Increase in percentage of patients with LDL < 100 (56% vs. 30%)	p < 0.001 p < 0.001 p < 0.001
Diabetes management Choe HM, Mitrovich S, Dubay D, Hayward RA, Krein SL, Vijan S.[39]	Randomized trial evaluating clinical pharmacist assistance to primary care providers in management of type 2 diabetes mellitus	Mean HbA1c reduction (2.1% vs. 0.9%) Process measures conducted more frequently (LDL measurement: 100% vs. 85.7%; retinal exam: 97.3% vs. 74.3%; monofilament foot screening: 92.3% vs. 62.9%)	p = 0.03 p = 0.02
Diabetes management Coast-Senior EA, Kroner BA, Kelley CL, Trilli LE.[40]	Pharmacist management of diabetic patients who were initiated on insulin therapy; pharmacists provided education, medication management, monitoring and adjustments	Mean HbA1c reduction by 2.2% Mean fasting blood glucose level reduction by 65 mg/dL Mean random blood glucose level reduction by 82 mg/dL	p = 0.00004 p < 0.01 p = 0.00001
Diabetes management Cranor CW, Bunting BA, Christensen DB.[41]	Education by certified diabetes educator pharmacists, clinical assessment, monitoring and collaborative drug therapy management	Higher percentage of patients with optimal A1c values (<7%) at first follow-up (57% vs. 42%)	p < 0.0001
Hypertension management Borenstein JE, Graber G, Saltiel E, et al.[42]	Pharmacist comanaged patients and provided patient education, made treatment recommendations and provided follow-up	Reductions in blood pressure (SBP reduction: 22mmHg vs. 11mmHg; DBP: 7mmHg vs. 8mmHg) Higher percentage of patients achieving blood pressure control (60% vs. 43%) Reduced average provider visit costs/patient ($195 vs. $160 reduction)	p < 0.01 p = 0.02 p = 0.02
Hypertension management Vivian EM.[43]	Monthly appointments with clinical pharmacist who adjusted medications and dosages and provided drug therapy counseling	Higher number of patients attaining blood pressure goal (91% vs. 12%)	p < 0.0001
Hypertension management McKenney JM, Slining JM, Henderson HR, Devins D, Barr M.[44]	Pharmacist met with patients monthly to manage antihypertensive therapy and provide recommendations to each patient's physician	Improvement in patient's knowledge of hypertension and its treatment (68% vs. 11%) Increase in the number of patients who complied with prescribed therapy (25% vs. 16%) Increase in the number of patients whose blood pressure was maintained within goal range (42% vs. 14%)	p < 0.001 p < 0.001 p < 0.001

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Hypertension management Bogden PE, Abbott RD, Williamson P, Onopa JK, Koontz LM.[45]	Pharmacist collaboration with physician to manage medication in patients with uncontrolled hypertension	Higher percentage of patients achieving JNC goals (55% vs. 20%) Reduction in SBP and DBP blood pressure (SBP reduction: 23mmHg vs. 11mmHg; DBP reduction: 14mmHg vs. 3mmHg)	$p < 0.001$ $p < 0.1$; $p < 0.001$
Hypertension management Carter BL, Barnette DJ, Chrischilles E, Mazzotti GJ, Asali ZJ.[46]	Pharmacist met with patients every 3-5 weeks to manage drug therapy and progress	Reduction of SBP (140 mmHg vs. 151mmHg) Improvement in appropriateness of blood pressure regimen (8.7+/- 4.7 to 10.9+/- 4.5) Improvement in quality of life scores after 6 months (physical functioning: 61.6 to 70.7, physical role limitations: 56.8 to 72.8, and bodily pain: 60 to 71.7)	$p < 0.001$ $p < 0.01$ $p < 0.05$
Hypertension management Kicklighter CE, Nelson KM, Humphries TL, Delate T.[47]	Pharmacist management of hypertension medications and monitoring for patients at primary care office	Higher number of patients achieving goal BP (64.6% vs. 40.7%) Higher number of patients receiving a thiazide (68.1% vs. 33.3%)	$p = 0.002$ $p < 0.001$
Hypertension and dyslipidemia management Bunting BA, Smith BH, Sutherland SE.[48]	Pharmacists assigned to patients as their care manager/coach for 30- to 60-minute appointments every 1 to 3 months	Reduction in: • SBP (126 mmHg vs. 137 mmHg) • DBP (78 mmHg vs. 83 mmHg) • Mean LDL (108 mg/dL vs. 127 mg/dL) • Triglyceride (154 mg/dL vs. 193 mg/dL) • Total cholesterol (184 mg/dL vs. 211 mg/dL) Reduction in: • MI events (6 vs. 23) • Non-MI ACS events (37 vs. 58) • Other CAD events (5 vs. 11) Decrease in patient use of EDs and need for hospitalization by 54%	$p < 0.0001$ $p < 0.05$ $p < 0.0001$
Hypertension and diabetes management Garrett DG, Bluml BM.[49]	Community pharmacist patient care services using scheduled consultations, clinical goal setting, monitoring and collaborative drug therapy management with physicians	Reduction in: • Mean HbA1c (7.1% vs. 7.9%) • LDL-C (105 mg/dL vs. 113 mg/dL) • SBP (131 mmHg vs. 136 mmHg)	$p < 0.001$
Asthma management Bunting BA, Cranor CW.[50]	Regular, long-term follow-up by pharmacists using scheduled consultations, monitoring and recommendations to physicians	Improvements in asthma severity scores (3.1 vs. 2.2) Improvements in mean FEV1 over time (90% vs. 81%) Increase in patients with an asthma treatment plan (99% vs. 63%) Decrease in frequency of asthma attacks (2.1 vs. 2.8)	$p < 0.0008$ $p < 0.00001$ $p < 0.0001$ $p < 0.0011$

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Asthma management Barbanel D, Eldridge S, Griffiths C.[51]	Community pharmacist provided self-management advice and counseling when presented to the pharmacy	Improvement in symptom score (20.3 vs. 28.1)	p < 0.001
Asthma management Armour C, Bosnic-Anticevich S, Brillant M, et al.[52]	Pharmacists followed patients for 6 months and counseled on condition, lifestyle, inhaler technique, adherence, detection of drug-related problems and referrals, if needed	Decrease in patients with severe asthma classification (52.7% vs. 87.9%) Increase in patients with adherence to preventer medication (16.6% vs. -1.7%) Decreased mean daily dose of albuterol (mean reduction by 149.1 mcg)	p < 0.001 p = 0.03 p = 0.03
Anticoagulation management Witt DM, Sadler MA, Shanahan RL, Mazzoli G, Tillman DJ.[53]	Anticoagulation therapy managed by centralized, telephonic clinical pharmacy anticoagulation services	Greater number of patients within target INR range (63.5% vs. 55.2%) Lower percentage of INR values ≥ 4.0 or ≤ 1.5 (15.1% vs. 20.4%) Shorter time intervals between INR values ≥ 4.0 or ≤ 1.5 (12% vs. 13.5%)	p < 0.001 p < 0.001 p < 0.03
Anticoagulation management Chiquette E, Amato MG, Bussey HI.[54]	Pharmacist managed warfarin dosage adjustments as clinically indicated	Fewer INRs > 5 and < 2: • INR > 5 (7% vs. 14.7%) • INR < 2 (13% vs. 23.8%) Increased number of patients within INR goal range (50.4% vs. 35%)	 p < 0.001 p < 0.001
Depression management Finley PR, Rens HR, Pont JT, et al.[55]	Pharmacist interview and counseling for patient upon intake and throughout a 24-week process to evaluate medication therapy and provide recommendations to PCP	Increased medication adherence (0.88 vs. 0.81) Higher number of medication switch rates (24% vs. 5%) Greater decline in the number of PCP visits (39% vs. 12% reduction)	p = 0.0005 p = 0.0001 p = 0.029
ADE prevention Schnipper JL, Kirwin JL, Cotugno MC, et al.[56]	Pharmacist reconciled discharge medication and provided education and post-discharge follow-up	Fewer preventable ADEs detected in 30-day post discharge follow-up (1% vs. 11%)	p = 0.01
Medication adherence and effect on SBP and LDL-C Lee JK, Grace KA, Taylor AJ.[57]	Pharmacist managed antihypertensives and cholesterol medications for a 6-month time period	Increased medication adherence after 6 months (96.9% vs. 61.2%): • SBP improvement (130 mmHg vs. 133 mmHg) • LDL-C improvement (86.8 mg/dL vs. 91.7 mg/dL) Persistence of medication adherence change after 12 months (95.1% vs. 69.1%): • SBP improvement (6.9 mmHg reduction vs. 1.0 mmHg)	p < 0.01 p = 0.02 p = 0.001 p < 0.001 p = 0.04

Indicators			
Study source	**Pharmacy-related interventions**	**Outcomes**	**Statistical significance**
Pharmacist consultation Jameson J, VanNoord G, Vanderwoud K.[58]	Pharmacist consultation to physicians regarding pharmacotherapy regimens for patients in the primary care setting	Decreased number of medications by 1.1 meds Decreased number of doses per day by 2.15 doses	p = 0.04 p = 0.07
Pharmacist consultation Galt KA.[59]	Interdisciplinary pharmacist-directed pharmacotherapy consult clinic in the primary care setting	Reduction in average number of medications/patient by 2.4 meds Decreased average number of doses/patient/day by 6.9 doses	p < 0.001 p < 0.0001

Abbreviations: ACS = acute coronary syndrome; ADE = adverse drug event; ADR = adverse drug reaction; aPTT = activated partial thromboplastin; BP = blood pressure; CAD = coronary artery disease; CI = confidence interval; DBP = diastolic blood pressure; DOT = directly observed therapy; DTN = door-to-needle; ED = emergency department; FTE = full-time equivalent; ICU = intensive care unit; INR = international normalized ratio; JNC = Joint National Committee; LDL = low-density lipoprotein; LDL-C = low-density lipoprotein cholesterol; LOS = length of stay; MDRO = multidrug-resistant organism; MI = myocardial infarction; NCEP = National Cholesterol Education Program; OR = odds ratio; PCP = primary care physician; QTc = corrected QT interval; SBP = systolic blood pressure; UFH = unfractionated heparin

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Appendix B

Core pharmacy services

Pharmacy-sensitive indicators (PSIs) reflect evidence-based pharmacist patient care services and interventions associated with improved patient care, safety and/or financial outcomes.

The following is a list of comprehensive inpatient and transitional care pharmacy services that should be provided in a contemporary HVPE.[1,2,3]

Patient care services

- Pharmacists collaborate with patients, families and caregivers to ensure that treatment plans respect patients' beliefs, values, autonomy and agency.
- Pharmacists provide reliable drug information to physicians, nurses, patients, caregivers and other members of the health care team to promote the safe, effective, efficient and patient-centered use of medication therapy.
- Pharmacist services align with organizational quality requirements and population health initiatives.
- Pharmacy services provided for all inpatients include the following:
  - Upon admission:
    - A pharmacist or a delegate under the supervision of a pharmacist reviews each patient's medical record and ascertains an accurate admission medication history.
    - The medication history includes, but is not limited in reviewing:
      - Prescription medications
      - Nonprescription medications
      - Herbal medications
      - Assessment of medication adherence
      - Recent medication use
      - Past medical history and history of present illness
      - Allergies and the patient's reactions
      - Actual or potential adverse drug reactions
      - Immunization history
    - Pertinent patient-specific information that may affect current or future drug therapy is documented.
    - Pharmacists adjust medication start times to reflect appropriate continuity of care based upon medication history information.
    - This medication history is used by the pharmacist and other providers to reconcile medication orders throughout the admission to improve accuracy and quality at transitions of care.
  - Ongoing:
    - Pharmacists routinely assess pertinent patient information, including:
      - Demographic data
      - Vital signs
      - Laboratory values
      - Medication regimens
      - Medication compliance
      - Health insurance coverage
    - Pharmaceutical needs of the patient are reassessed on an as-needed basis as the patient's condition changes through:
      - Patient interviews
      - Participation on interdisciplinary patient care rounds
      - Review of the EMR
      - Daily review of medication profiles and laboratory data
    - Pharmacists initiate drug therapy regimens as authorized by delegation protocols and/or collaborative practice agreements.
    - Pharmacists order and evaluate laboratory tests to monitor drug therapy for safety and efficacy.
    - Medication orders are reviewed for appropriateness by a pharmacist to determine the presence of medication therapy problems in a patient's current medication therapy, including any of the following examples:
      - Inappropriate indication
      - Medical conditions lacking corresponding necessary therapies
      - Incomplete immunization status
      - Inappropriate medication therapy regimen (dose, dosage form, duration, schedule, route of administration, method of administration)
      - Therapeutic duplication
      - Clinically significant drug-drug, drug-disease, drug-nutrient, drug-allergy, or drug-laboratory test interactions (or potential for such interactions)
      - Interference of prescribed therapies with nontraditional drug use
      - Need for additional laboratory tests or assessments to ensure safe and effective medication use
      - Subtherapeutic medication dosing or inadequate response to therapy

- Inability for patients to access medications because of the cost of therapies
- Patients lacking understanding of medication therapy
- Patient medication non-adherence
- Adjust doses for altered renal function, intermittent dialysis and continuous renal replacement therapy

▪ Pharmacists coordinate the following to optimize care:

- Convert routes of medication administration
- Modify therapy to standardized doses as needed
- Ordering, timing and evaluation of serum drug concentrations
- Provide recommendations for pharmacokinetic follow-up for appropriate drugs

▪ Pharmacists work to discontinue medication regimens that are ineffective.

– Upon discharge:

▪ The pharmacy workforce collaborates with patients, caregivers, payers and health care professionals to establish consistent and sustainable models for transitions of care, including, but not limited to:

- Educating patients and/or caregivers
- Facilitating safe transitions of care
- Assisting with medication access
- Providing medication adherence aids
- Providing handoffs to community pharmacies

▪ Pharmacists provide prescriptions and medications to patients and/or primary support at the time of discharge, when appropriate.

▪ Pharmacists reconcile discharge medication orders with the patient's inpatient and pre-hospitalization home medication regimens to assure safe transitions of care and appropriateness of medication use to reduce the risk of readmissions due to inappropriate medication use or follow-up.

Medication use safety and quality

- Pharmacists assist in the monitoring, prevention, reporting and coordination of performance improvement activities across the continuum of care.
- Pharmacists provide oversight for ADEs, drug interactions and medication errors.
- Pharmacists develop, maintain, monitor and enforce medication use policies, guidelines and formulary restrictions to decrease variability, improve quality and decrease costs.
- Patient population assessments are accomplished through medication use evaluation studies and by reviewing compliance with established therapeutic and clinical guidelines.
- All medication-related information distributed within the health system is reviewed by the pharmacy department to ensure accuracy of information and consistency with restrictions, guidelines and standards of practice.
- Pharmacists direct appropriate medication use and administration through the development and maintenance of clinical tools (order sets, clinical practice guidelines, delegation protocols, practice protocols, collaborative practice agreements and clinical policies).
- Established policies, procedures, protocols, therapeutic guidelines and standards of pharmacy practice are followed as part of the care services process.
- Pharmacists control drug distribution systems to ensure that the right medication and dose are administered via the right route to the right patient at the right time, while maintaining the safety and efficiency of the medication use system.

Information systems

- The pharmacy workforce is competent in health IT.
- Pharmacists assist in the development, implementation and maintenance of CDS, assisting with enforcing standards of care, institutional guideline adherence and regulatory compliance.
- Pharmacists assist in optimizing the use of automation and IT to further enable development of the professional roles of the pharmacist, pharmacy technician and pharmacy support personnel, as well as the services they provide by promoting the efficient use of health care resources.
- Pharmacy establishes standards for the application of artificial intelligence (AI) in the various steps of the medication use process, including prescribing, reviewing medication orders and assessing medication use patterns in populations.

Education

- Pharmacists educate future professionals by precepting pharmacy students and pharmacy residents and are involved with continuing education through the provision of in-services for pharmacists and other health care professionals.
- Pharmacists take an active role in providing medication therapy teaching to medical residents and other professional students in interdisciplinary care settings.
- Pharmacy technicians, interns and students assist in the delivery of pharmaceutical care under the supervision of a pharmacist.

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Appendix C

Pharmacist impact on disease state management

The following references display excellent examples of the impact pharmacist collaborative practice has on disease state management in the ambulatory care setting. As pharmacist resources are finite, it is important that the HVPE has a system in place to identify patients with the greatest need for pharmacist intervention. These references are not intended to be an all-inclusive list, but rather a guide for diseases where pharmacists may have the greatest impact on patient outcomes, health care costs and/or improving access to care.

Study source	Pharmacy-related interventions	Outcomes	Statistical significance
Patient-centered medical home model Matzke GR, Moczygemba LR, Williams KJ, et al. [1]	Collaborative care group vs. usual care group within 12 months of enrollment	Mean change in A1C: -0.46% vs. -0.08% Mean change in systolic blood pressure: -6.28 mmHg vs. -1.05 mmHg Mean change in diastolic blood pressure: -2.69 mmHg vs. -1.23 mmHg Reduction in all-cause hospitalizations: 23.4% vs. 8.7% Net savings of collaborative care: $4,681,604 ($2,378 per patient) Return on investment: 504%	P < 0.0001 P < 0.0001 P = 0.0071 P < 0.001
Telehealth primary care Litke J, Spoutz L, Ahlstrom D, et al. [2]	Chronic disease management program, including clinical pharmacy specialists	Mean absolute HbA1c reduction (mean follow-up 4.8 months): 1.61% Mean systolic blood pressure reduction (mean follow-up 2.9 months): 26 mmHg Mean diastolic blood pressure reduction (mean follow-up 2.9 months): 11 mmHg 82% were discharged on a goal-indicated statin dose 42% achieved tobacco cessation (mean follow-up 3.6 months)	95% CI 1.39-1.83% 95% CI 22.99-28.50 mmHg 95% CI 9.41-13.41 mmHg
Diabetes Benedict AW, Spence MM, Sie JL, et al.[3]	Pharmacist-managed diabetes care vs. usual care in patients with type 2 diabetes and A1C ≥ 8%	Goal A1C achieved at 3 months: 27.86% vs. 14.39% Goal A1C achieved at 6 months: 37.35% vs. 31.63% Mean (SD) time to reach goal A1C: 3.4 (2.7) months vs. 4.6 (2.7) months Change in baseline A1c at 3 months: -0.95% vs. -0.54% Change in baseline A1C at 6 months: -1.19% vs. -0.99%	OR 2.44 (95% CI 1.93-3.10) OR 1.32 (95% CI 1.08-1.61) P < 0.0001 P < 0.0001 P = 0.009
Hypertension Weber CA, Ernst ME, Sezate GS, et al.[4]	Pharmacist-physician collaborative management vs. usual care at 9 months	Overall 24-hour change in systolic blood pressure: -14.1 mmHg vs. -5.5 mmHg Overall 24-hour change in diastolic blood pressure: -6.8 mmHg vs. -2.8 mmHg Blood pressure control at the end of the study: 75% vs. 50.7% Physicians accepted and implemented 95.9% of pharmacist recommendations	P < 0.001 P < 0.001 P < 0.001

Study source	Pharmacy-related interventions	Outcomes	Statistical significance
Chronic heart failure Jackevicius CA, de Leon NK, Lu L, et al.[5]	Multidisciplinary heart failure post-discharge clinic vs. historical controls	90-day heart failure readmission: 7.6% vs. 23.3% All-cause mortality: 1.4% vs. 5.3% Combined 90-day heart failure readmission or all-cause mortality: 9% vs. 28.6%	aHR 0.17 (95% CI 0.07-0.41); ARR 15.7%; NNT= 7 aHR 0.12 (95% CI 0.02-0.93) aHR 0.14 (95% CI 0.06-0.31); ARR 19.6%; NNT= 6
Chronic heart failure Donaho EK, Hall AC, Gass JA, et al.[6]	Outcomes of multidisciplinary allied health clinic over 2 follow-up visits within 6 weeks of hospital discharge	297 medication errors identified Average number of medication reconciliation errors decreased from 2.1 to 0.8 between visits 1 and 2 All cause 30-day and readmission: 12.3% for intervention group vs. 22.1% for heart failure patients at the medical center (hospital average) Clinic intervention resulted in a 44.3% reduction in 30-day readmissions	
Anticoagulation Hall D, Buchanan J, Helms B, et al.[7]	Pharmacist-managed anticoagulation service vs. usual care	Anticoagulation-related adverse events: 5.1% vs. 15.4% Anticoagulation-related hospital admissions: 3 vs. 14 Anticoagulation-related emergency department visits: 58 vs. 134 Percentage of time INR values were in range: 73.7% vs. 61.3% Expenditure for anticoagulation care (based on paid medical claims): $35,465 vs. $111,586 Total expenditures of all medical care: $754,191 vs. $1,480,661 Overall net medical care cost savings in the anticoagulation service group during 1-year study period: $647,024	P < 0.0001 P < 0.00001 P < 0.00001 P < 0.0001
Hepatitis C Yang S, Britt RB, Hashem MG, et al.[8]	Economic, clinical and safety parameters associated with pharmacy-led hepatitis C direct-acting antiviral utilization management	Overall cost ratio of total drug spend to cure rate: $40,135.22 At the time of the study, the national cost per treatment regimen ranged from $25,126 to $164,225 Overall cure rate (including patients who discontinued treatment): 94.1% Total calculated medication possession ratio: 98.7% (±0.13)	
Cancer Sweiss K, Wirth SM, Sharp L, et al.[9]	Collaborative clinic model vs. ad hoc pharmacist consultation model over 12 months	Adherence to bisphosphonates: 96% vs. 68% Adherence to calcium and vitamin D: 100% vs. 41% Appropriate antiviral prophylaxis: 100% vs. 58% Appropriate to Pneumocystis jirovecii pneumonia prophylaxis: 100% vs. 50% Appropriate thromboembolism prophylaxis: 100% vs. 83% Median time to appropriate initiation of bisphosphonate: 5.5 days vs. 97.5 days Median time to appropriate initiation of Pneumocystis jirovecii pneumonia prophylaxis: 11 days vs. 40.5 days	P < 0.001 P < 0.001 P < 0.001 P < 0.001 P = 0.0035 P < 0.001 P < 0.001

Study source	Pharmacy-related interventions	Outcomes	Statistical significance
Infectious disease Klepser DG, Klepser ME, Dering-Anderson AM, et al.[10]	Outcomes from a collaborative streptococcal pharyngitis management program	93.8% of patients testing positive for group A streptococcal pharyngitis reported feeling better 24-48 hours after initiating antibiotics 43.2% of tested patients had no primary provider 43.9% of tested patients visited the pharmacy outside of established physician's office hours Authors noted a 55% reduction in antibiotic use compared with historical control groups	

Abbreviations: aHR = adjusted hazard ratio; ARR = absolute risk reduction; CI = confidence interval; INR = international normalized ratio; NNT = number needed to treat; OR = odds ratio; SD = standard deviation

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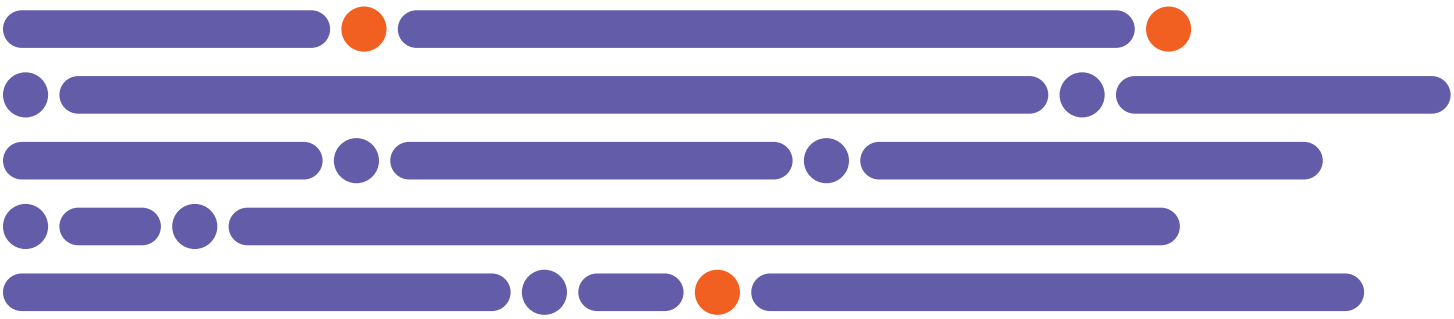
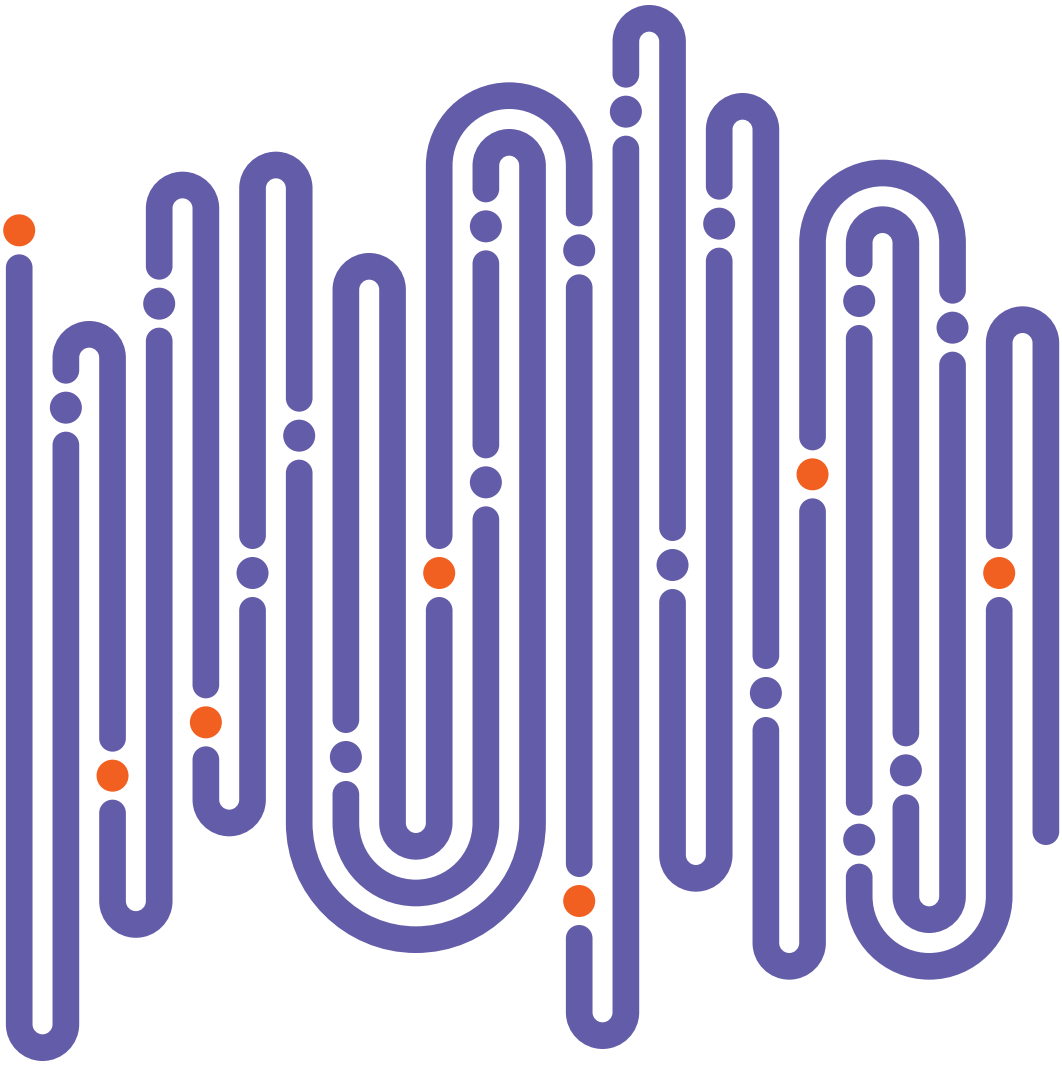
Appendix D

Expanded pharmacy technician roles and responsibilities to support advanced pharmacy practice

- Allergy preparation
- Billing and reimbursement
- Business integrity analysis
- Clinic medication control
- Controlled substances system integrity
- Customer service assurance
- Decentralized medication distribution
- Discharge medication access coordination
- Diversion prevention/internal auditing
- Drug compounding
- Drug shortage surveillance
- Education and training
- Hazardous sterile product preparation
- Informatics technology design and analysis
- Inventory management and control
- Investigational drug services
- Medication access
- Medication histories
- Nuclear medicine preparation
- Operating room drug distribution
- Patient assistance program
- Patient care advocacy
- Prior authorization coordination and benefits investigation
- Purchasing (supply chain optimization)
- Regulatory compliance assurance
- Reimbursement auditing and maximization
- Revenue cycle integrity
- Tech-check-tech
- Technology/automation oversight





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