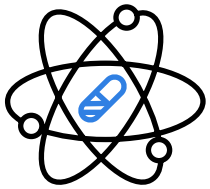


The Autonomous Pharmacy Framework: A Transformative Vision for the Medication Management Process

The Autonomous Pharmacy Framework: A Transformative Vision for the Medication Management Process

MARK SULLIVAN, JENNIFER TRYON, HANNA MAEHLEN,
ALLEN FLYNN, CHRIS NEWMAN, ARASH DABESTANI,
KYLE TOWNSEND, JAMES G. STEVENSON

Executive Summary

Across industries, technological adoption is accelerating and transforming the way products and services are created, delivered, consumed and measured. In healthcare, artificial intelligence, virtual care, and other cutting-edge innovations will continue to have tremendous impact – creating entirely new markets, unleashing powerful insights, and making formerly impossible procedures routine. Despite the pace of change elsewhere, pharmacy systems have lagged, failing to adequately invest in and implement transformational advancements. The overdependence on manual processes and siloed technology in pharmacy operations is one of the biggest challenges facing healthcare systems today, and arguably one of the most overlooked by system leaders.

This paper outlines the ultimate vision for the medication-use process – the Autonomous Pharmacy – and presents a framework to get there. It details how organizations can tangibly drive progress in five key areas of their business to achieve improved outcomes, and demonstrates how the Autonomous Pharmacy will enable health systems to realize optimal performance in key elements such as safety, financial, efficiency, regulatory compliance, and people.

A New Vision for Medication Management

Pharmacy is a critical component of today's healthcare ecosystem. A large health system pharmacy dispenses millions of doses per year and, in 2018, the average US community hospital spent over $550 per inpatient admission on drugs[1], rendering it one of the greatest drivers of cost in a hospital. The strategic importance of pharmacy will only grow as healthcare moves toward more value-based care and as pharmacies play a key role in delivering and improving outcomes.

However, deficiencies in the current medication-use process result in suboptimal outcomes, excess costs, and staff dissatisfaction. With people largely responsible for every task in the process—from procuring to dispensing to administering drugs—pharmacists, pharmacy technicians, and nurses spend a large portion of their time on administrative work, with pharmacists spending only 25% of their time on clinical activities[2]. The reliance on human performance throughout the medication-use process creates a system that is prone to errors, compromising clinical outcomes when patients do not receive the right medication, in the right dose, at the right time. In addition to the challenges posed by dependence on human activity, today's medication management system is challenged by the lack of interoperability and data optimization capabilities. With disjointed and disparate processes and technology, outcomes across the care continuum suffer.

AUTHORS: MARK SULLIVAN, PharmD, MBA, BCPS, FASHP, Executive Director, Pharmacy Operations, Vanderbilt University Medical Center. JENNIFER TRYON, PharmD, MS, FASHP, Associate Vice President and Chief Pharmacy Officer, Wake Forest Baptist Health. HANNA MAEHLEN, Senior Marketing Manager, Omnicell. ALLEN FLYNN, PharmD, PhD, Assistant Professor, Department of Learning Health Science University of Michigan Medical School. CHRIS NEWMAN, PharmD, MSHA, Vice President, Ancillary Services, Archbold Medical Center. ARASH DABESTANI, PharmD, MHA, FASHP, FABC, Senior Director of Pharmacy, NYU Langone Health. KYLE TOWNSEND, PharmD, MBA, BCPS, Former Director of Pharmacy Services, Billings Clinic. JAMES G. STEVENSON, PharmD, FASHP, Vice President of Medication Systems Strategy, Omnicell.

CONTRIBUTORS: CHRIS FORTIER, PharmD, FASHP, Chief Pharmacy Officer, Massachusetts General Hospital. GEEMON MATHEN, Assistant Director of Pharmacy, Texas Children's Hospital. RANEE RUNNEBAUM, PharmD, MHI, FASHP, Medication Safety and Pharmacy Informatics, Louisiana Children's Medical Center. JEFFREY WAGNER, PharmD, MPH, BCPS, Assistant Vice President, Pharmacy, Respiratory Therapy and ECMO Services, Texas Children's Hospital. NILESH DESAI, MBA, BS, RPh, CPPS, Director of Pharmacy, Hackensack Meridian Health at Pascack Valley Medical Center. KEN PEREZ, Vice President Healthcare Policy, Omnicell. DIANE KAYE, Chief Product Officer, Omnicell.

There is an imminent need to transform the medication-use process to improve efficiency and reduce susceptibility to human error.

Transformative change in an uncertain, complex, regulated, and high-risk environment requires the industry to embrace a paradigm shift that elevates and optimizes the medication-use process. As new technologies continue to be introduced at a faster pace each year, it is imperative that leaders in pharmacy and health systems come together to develop a strategic vision to better leverage technology and define the future of pharmacy. Furthermore, as pharmacy practice shifts away from drug distribution and toward patient-centricity, pharmacists, technicians, and nurses need to be equipped with tools and resources so that they can spend more time with patients. With a coordinated and intentional approach, technological advancements can be used to enable pharmacists to provide direct patient care and improve clinical decisions. Additionally, this evolved system would predict and eliminate medication waste and errors, ultimately resulting in better health outcomes and a more efficient system.

The Autonomous Pharmacy is the vision for the future of medication management, replacing manual, error-prone activities with efficient, safe, and automated processes to improve outcomes and reallocate talent to higher-value, more satisfying tasks.

The Autonomous Pharmacy thoughtfully applies and integrates technology into today's medication-use process to realize this goal. Leveraging advanced levels of automation and intelligence, the Autonomous Pharmacy enables pharmacists, nurses, and other clinicians to practice at the top of their license, relieving them of repetitive and administrative activities. By providing robust data intelligence services, the Autonomous Pharmacy improves safety, financial performance, efficiency, regulatory compliance, patient outcomes, and staff job satisfaction. With technology fulfilling previously manual tasks, healthcare providers can focus on zero-error patient care and feel confident that their patients are receiving optimal medication therapy.

The Challenges with Today's System

Today, medication logistics and inventory management are manual processes, requiring human touch and intervention at almost every stage in the medication-use process. The dependence on manual tasks and the lack of robust data collection and integration at the enterprise level pose serious risks and challenges in five key areas: safety, financial, efficiency, regulatory compliance, and people.

Safety

25,000

Errors annually in hospitals

4

Errors per day in outpatient pharmacies

While healthcare professionals are inherently focused on doing no harm, manual, complex medication management processes pose safety risks to patients and healthcare providers. Estimates are that health systems dispensing more than 5 million doses of medication will experience 25,000 errors annually, causing patients to face additional complications and hospital readmissions.[3] In pharmacies dispensing 250 prescriptions or more per day, there are approximately 4 errors made every day, possibly leaving patients with the wrong drug, instructions, quantity, or strength.[4] As explored in "To Err is Human," errors are often the consequence of poor systems, processes, and conditions that then lead people to make mistakes.[5] Additionally, these disparate and disjointed systems prevent the synthesis of data into actionable insights, thus limiting pharmacists from predicting potential medication errors or adverse reactions and proactively acting to improve outcomes.

In addition to medication errors, deficiencies in the security of the medication-use process create opportunities for drug diversion, posing potential safety challenges for providers and patients, and contributing to the opioid crisis. In 2018, approximately 47 million doses were lost due to healthcare employee misuse and theft, and healthcare organizations in the US lost over $450 million to clinical drug diversion.[6] Of these incidents, 94% involved opioids.[7] According to a study published in the Current Opinion in Psychiatry, 10%-15% of physicians, nurses, and other healthcare professionals will develop a chemical dependence during their lifetimes.[8] In a system where drugs are sub-optimally managed and tracking is inconsistent and noncomprehensive, drug diversion is a dangerous reality, causing serious safety and compliance risks.

Outside of the four walls of the hospital setting, medication management systems are also failing to deliver. According to a review in Annals of Internal Medicine, 20%-30% of prescriptions are never filled, and approximately 50% of medications for chronic disease are not taken as prescribed.[9] High medication nonadherence rates lead to poorer health outcomes and costly waste across the system, including 125,000 avoidable deaths annually[10] due to nonadherence and an estimated $300 billion lost due to nonadherence and other suboptimal prescribing, administration, and diagnosis practices.[11] Outpatient programs to improve medication adherence have shown improvements in health outcomes[12], and demonstrate the value of adopting and implementing more advanced medication management processes across the care continuum.

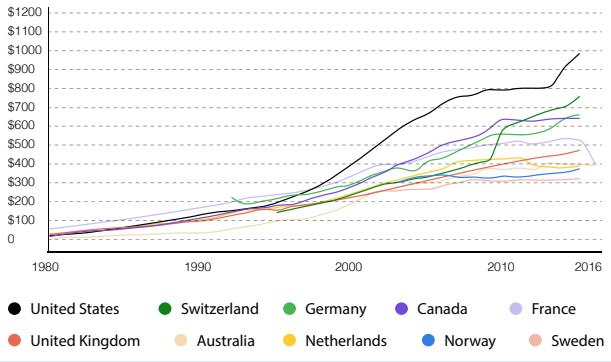
More robust, integrated and automated medication management systems and processes can help safeguard patients across the continuum of care – from inpatient stay, to care transition to post-acute care settings and back into the home.

Sample metrics in this performance element include medication errors, the number of days since the last safety event, and alert overrides.

Financial

In addition to the safety challenges experienced in today's medication management system, healthcare costs continue to rise at an unsustainable rate. The US spends $485 billion dollars on medications per year[13] – about one-seventh of total US healthcare expenditures. Prices of many of the most popular brand-name drugs have risen nearly ten times the cost of inflation,[14] and one in four hospitals have cut staff to account for rising drug prices.[15] When compared to other developed nations, the US spends the most per capita on prescription drugs, with patients paying over twice as much for some of the same medications (e.g., Humira, Januvia, Lantus).[16]

National Trends in Per-Capita Pharmaceutical Spending, 1980-2015



Source: Organisation for Economic Co-operation and Development, 2017.
Data for Australia and Canada from 2014.[17]

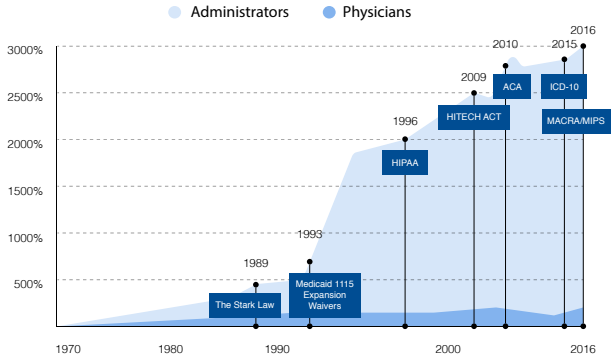
Medications play a critical role in the financial performance of health systems. In the inpatient environment, fixed reimbursement places an emphasis on constraining the cost per case and medications often have a significant impact. In the outpatient environment, medications present a significant revenue and margin opportunity. With expanding drug costs, the optimization of the financial performance of medication management systems has become an essential objective for health systems.

Sample metrics in the financial performance element include the cost per dose dispensed, the pharmacy expense per adjusted patient day, and the pharmacy or drug expense as a percentage of the total system expense.

Efficiency

In addition to compromising patient safety and contributing to rising healthcare costs, today's medication management system is plagued by inefficiencies. As complexities have grown with increasing regulations, drug costs, and other factors, the solution has been to add administrators. Since 1970, the number of administrators in health systems has grown by 3,000%, while the number of physicians has only grown by 200%.[18] This creates a situation of siloed systems and technologies, connected inconsistently by people. In addition to adding administrative roles, health systems have also relied on highly trained professionals to conduct administrative tasks across the system. The reliance on manual labor for medication logistics has left highly trained nurses and pharmacists responsible for ordering, verifying, retrieving, mixing, counting, and dispensing medications. In addition to the suboptimal use of resources, the lack of centralized data or business metrics leads to lost time spent mining for data

Growth in Administrative Roles vs. Physicians



Source: Bureau of Labor Statistics; National Center for Health Statistics; and Himmelstein/ Woolhandler analysis of Current Population Survey (CPS).

across disparate systems, leaving healthcare professionals and leadership without the information they need to act. Without standardized and interoperable information systems across sites of care, management is difficult and inventory visibility is limited. For example, the lack of robust drug tracking in today's medication management systems makes it extremely difficult for health systems to predict and manage medication shortages. Hospitals in the US routinely deal with over 125 drug shortages per year, with an all-time high of 267 shortages reported in 2011.[19]

125+

Drug shortages in hospitals per year

Drug shortages leave healthcare providers without the essential medications they need to treat patients safely, effectively, and efficiently. Without data and visibility into inventory and utilization patterns, health system pharmacists and other personnel require substantial time and effort to manage these drug shortages effectively, putting a significant strain on resources that could otherwise be dedicated to direct patient care.[20]

Sample metrics in this performance element include turnaround times (e.g., from order entry to administration), the number of missing medications per 10,000 doses dispensed, and the number of pharmacist hours worked per 100 orders. In the future, in a more autonomous pharmacy, health systems can look to measure the number of human touches per dispense.

Regulatory Compliance

To comply with the requirements in today's complex regulatory ecosystem, pharmacists, technicians, and nurses are required to complete and document a significant number of tasks and processes. According to the American Hospital Association (AHA) report, "Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-Acute Care Providers," hospital systems are obliged to meet 341 compliance requirements (as of March 2017).[21] While these regulations have been developed to make healthcare safer and more effective, the costs of maintaining and managing regulatory compliance are immense, and the responsibility often falls on highly trained professionals like pharmacists, nurses, and physicians. The regulatory compliance burden related to medication use is particularly robust, including compliance with accreditation standards of various regulatory bodies such as the Joint Commission, the Food and Drug Administration, Boards of Pharmacy, and the Drug Enforcement Agency. As demonstrated in the AHA report, the healthcare industry spends approximately $39 billion on administrative tasks related to regulatory compliance, and many hospitals and health systems are hiring more employees to maintain regulatory compliance.[22]

341+

Hospital compliance requirements to manage each year

In addition to the monetary cost of managing today's regulatory compliance requirements in medication processes, there are also consequences for the quality of care. In order to stay compliant with constantly changing regulations, hospital staff – physicians, nurses, and pharmacists –spend significant time learning new requirements and completing compliance exams. These activities pull healthcare providers away from patient care responsibilities, leading to a lower quality of care and a potentially overloaded workforce.

Sample metrics in this performance element include the number of controlled substance discrepancies per the number of controlled substances dispensed, the percentage of unit inspections completed on time with no major findings, and the rate of unreconciled waste per dose dispensed. Additionally, health systems that are eligible for the 340B drug discount program have substantial compliance requirements and will need to measure the percentage of required 340B activities that are completed on time and with satisfactory results.

People

Today's medication management system has a dramatic effect on a range of stakeholders, from healthcare providers, to patients and organizations. In today's health systems, 75% of pharmacist time is spent on non-clinical activities.[23] Time required in drug distribution and administrative functions forces pharmacists and nurses to spend less time on patient care - or otherwise practicing at the top of their license. This ultimately increases burnout, decreases employee satisfaction, and adversely impacts clinical outcomes.

A recent study in the American Journal of Health-System Pharmacy (AJHP) reported that 53.2% of health-system pharmacists experience a high degree of burnout on at least 1 subscale of the Maslach Burnout Inventory–Human Services Survey (MBI-HSS),[24] similar to that of physicians (~54%).[25] The ASHP Research and Education Foundation predicted that burnout will raise the annual turnover rate for pharmacists to at least 15% by 2023, from ~8% today.[26] Burnout in turn has negative implications for patient outcomes and satisfaction. A study published in the Journal of the American Medical Association (JAMA) regarding physician burnout demonstrated that providers suffering from burnout are two times as likely to incorrectly diagnose or prescribe medications to patients.[27] It also found that those experiencing burnout are three times more likely to experience low patient satisfaction.[28]

In addition to employees and patients, organizational factors are a key driver of impact – change readiness and leadership effectiveness in implementing strategic initiatives are positively correlated with patient satisfaction.[29] It can be inferred thus, that similar leadership effectiveness and change readiness initiatives will be equally critical in the implementation of strategic pharmacy transformation. With support from automated processes and cognitive intelligence software to augment decision-making, health systems have an opportunity to embrace a more patient-centric pharmacy practice model.

Sample metrics in this performance element include patient and provider satisfaction and engagement scores. Additionally, organizations can look to learn more about employee satisfaction through Net Promoter Scores. Finally, organizations can look to learn more about how prepared employees are for change, by asking questions like "How ready is the organization for change to improve outcomes?" and "How committed is leadership to the change?".

The Solution: The Autonomous Pharmacy

As an industry, we need to embrace transformation and drive toward a solution that addresses these five challenges holistically.

The Autonomous Pharmacy is a strategic vision for the future, in which medication management processes are fully automated, interoperable, and utilize data effectively to provide actionable information - maximizing safety, efficiency, and human potential, ensuring compliance and meeting desired outcomes.

In a Fully Autonomous Pharmacy, we apply connected automation and integrated data intelligence throughout the medication-use process and across care settings, utilizing the full spectrum of technological solutions to complete previously manual tasks. The comprehensive replacement of manual tasks is central to the Autonomous Pharmacy because tasks relying on human performance are what lead to medication errors, lack of satisfaction, operational inefficiency, and suboptimal regulatory compliance and financial outcomes.
The Autonomous Pharmacy is not a replacement for humans; it is a replacement for human error, while reallocating human talent to direct patient care and clinical delivery.
The Autonomous Pharmacy leads to the highest possible levels of safety, financial performance, efficiency, and regulatory compliance—and ultimately enables pharmacy staff and other clinicians to realize the full scope of their role, allowing them to focus on patient care and the core of their clinical role.

The Key Components of an Autonomous Pharmacy

There are five key components when analyzing the capabilities and activities of health system pharmacy: Enterprise Structure, Information Technology (IT) Infrastructure, Automation, Data Intelligence, and Human Activity. These components were developed through collaboration with a group of pharmacy leaders and researchers across the US. They represent the organizational, technological, and human capabilities necessary to move toward the Autonomous Pharmacy vision.

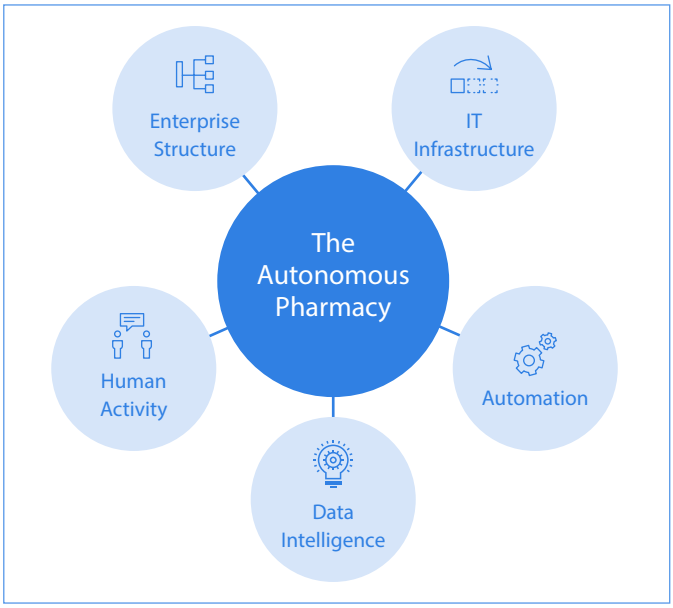
Component 1: Enterprise Structure

Enterprise Structure refers to the degree of operational integration of an organization's pharmacy operations along the continuum of care. All too often pharmacy automation is thought to be confined to the acute care setting, but the truly Autonomous Pharmacy has fully integrated automated technologies across all sites of care including inpatient, specialty pharmacy, community/retail pharmacy, and all other settings. Care is increasingly moving outside the four walls of the hospital. As a result, advanced pharmacy delivery models and technologies that are typically applied in acute-care settings now need to be applied across the continuum of care and extended to the home.

With the increase of integrated delivery networks, the Autonomous Pharmacy allows health systems to seamlessly integrate information and technology, leveraging data and learnings across previously disparate networks. Significant efficiencies can also be realized through standardization and central management of the medication-use process.

Component 2: IT Infrastructure

IT infrastructure is the technological backbone of the Autonomous Pharmacy. It represents an enterprise's entire collection of networks, data centers, facilities, and related equipment used to develop, test, operate, monitor, manage, and support information technology services in pharmacy.



In the Autonomous Pharmacy, IT infrastructure migrates to a cloud-based platform, enabling organizations to be fully integrated and standardized across facilities. Increased automation and the standardization of technology allows health systems to integrate various databases and decrease the administrative effort required to maintain technology and find information. With complete interoperability and centralized IT management, the medication-use process is more efficient and there are fewer opportunities for error.

Component 3: Automation

Automation refers to an enterprise's ability to automate medication management where possible from start to finish. It represents the collection of hardware and software technologies that automate previously manual medication management processes.

The Autonomous Pharmacy adopts a fully automated and predictive medication management process, tracking each dose as node on a network, and removing manual labor from the workflow so that highly trained resources can focus on direct patient care. In order to realize the Autonomous Pharmacy and remove manual intervention, automation needs to be pursued across all elements of the medication-use process, including purchasing, dispensing, delivery, administration, clinical service provision and monitoring, outcomes assessment, and regulatory and administrative monitoring and improvement.

Component 4: Data Intelligence

Data intelligence reflects an enterprise's ability to centralize, standardize, and automate data collection and reporting for maximum operational visibility. It enables organizations to use data to analyze their operations and workforce to make better, real-time decisions, and facilitate process improvements.

In an Autonomous Pharmacy, complete visibility of data allows for real-time workflow optimization for pharmacy technicians, pharmacists, and nurses, and predictive intelligence across the medication management process removes unplanned disruptions and enables risk stratification. Key performance metrics and intelligence help to optimize resources and improve systems over time. Predictive analytics will ultimately be applied to most aspects of the medication-use process to improve clinical, operational, and financial outcomes. To achieve this, data will need to be synthesized into actionable insights and leverage innovations such as machine learning. In order to harness the power of Big Data, health systems will need to be able to contribute data to large scale registries for data aggregation and analysis. These analytics will be accompanied by the return of insights (learnings, analytic results) into the medication-use process. With increased internal and external data sharing, organizations will be better equipped to make key decisions and predict upcoming events to improve outcomes.

Component 5: Human Activity

Human activity captures the human capabilities and tasks involved in work with automated systems, from pharmacists to pharmacy technicians, nurses, and other healthcare professionals. This dimension looks at how every individual's time in the medication-use process is deployed, and details the reallocation that occurs by automating previously manual tasks.

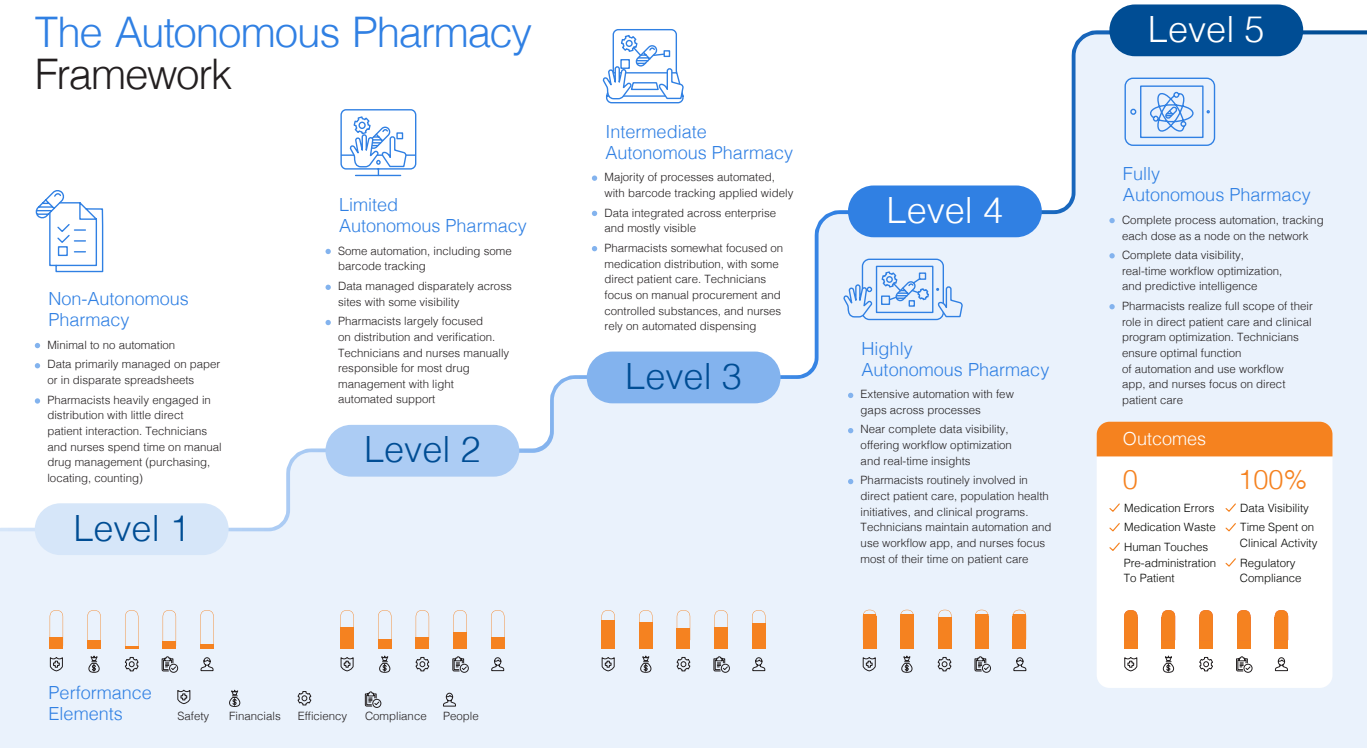
In the Autonomous Pharmacy, pharmacists, technicians, and other health professionals realize the full scope of their role, leading comprehensive medication management for patients and caregivers. Pharmacist talent is reallocated to direct patient care and clinical program delivery. To support this, medication preparation and distribution tasks are transferred to pharmacy technicians supported by technology, who also work to ensure that the automation processes for their traditional role of purchasing, counting, sorting, transporting, billing, repackaging and restocking medications are accurate, efficient, and meeting regulatory requirements. Pharmacy technicians may also be given additional training to support tasks such as medication histories and medication reconciliation.

The Journey to the Autonomous Pharmacy

Like the autonomous vehicle, the Fully Autonomous Pharmacy is an ambitious vision for the future that cannot be realized with the technology available today. The path to achieve this vision has been defined based on the components and outlined in 5 Levels of progress. Organizations should aim to move across the spectrum to increase their level of autonomy in the medication-use process. The value of a framework is to assist organizations in assessing their current status and to serve as an aid in their strategic planning to advance care and outcomes through more effective technology utilization.

Furthermore, it is anticipated that there will be an ability to estimate the incremental benefits that could accrue to an organization through advancement in the framework, and this information can help inform resource allocation and prioritization decisions.

At each level in the journey, organizations share some general automation and intelligence characteristics detailed below.



Level 1: Non-Autonomous Pharmacy

Enterprise Structure	IT Infrastructure	Automation	Data Intelligence	Human Activity
Disconnected care settings	IT managed locally and separately	Minimal to no automation	Data managed on paper or disparately	Pharmacists heavily engaged in distribution. Technician and nurse time spent on manual drug management

Health systems at Level 1 in the Autonomous Pharmacy Framework are largely non-autonomous, relying on manual processes and paper-based information systems. In terms of their Enterprise Structure, facilities across the health system lack standardization and interconnectivity. The IT Infrastructure is similarly stratified, with limited to no Electronic Health Record (EHR) systems in place and medication management IT being managed disparately by local teams.

When it comes to the automation of the medication management processes, Level 1 pharmacy systems rely on manual processes and rarely leverage automated hardware or software. With limited or no barcode medication dispensing and administration systems, and central pharmacy storage on shelving, the pharmacy system lacks robust medication tracking and secure management of controlled substances. IV compounding is done manually, and medications are repackaged on an as-needed bases by highly trained staff. Data Intelligence follows a similar pattern, with all data being managed on paper or in disparate spreadsheets, and minimal electronic systems supporting providers. Data cannot be effectively leveraged for data-driven decision making.

In a Level 1 context, pharmacists are heavily engaged in medication distribution and order verification, while pharmacy technicians are responsible for manual purchasing, counting, sorting, transporting, billing, repackaging, and restocking medications. Given the lack of transparency across the medication management system and the highly administrative roles taken on by pharmacists and pharmacy technicians, nurses are often tasked with manually locating and administering medications in the right dose, to the right patient, at the right time. Nurses are accountable for identifying incompatible drug combinations or possible allergic reactions and may not have sufficient time to provide comprehensive medication education to patients and caregivers.

Due to the manual and disconnected processes in a Level 1 pharmacy setting, highly trained professionals across the care continuum spend their time on administrative and repetitive tasks, and the dominance of manual medication management processes creates opportunities for human error and waste. At Level 1, the pharmacy is seen as a cost center and not recognized as a key element of the enterprise's management and financial outcomes. The pharmacy leader has access to minimal metrics and benchmarks to assess and improve performance in important domains.

Level 2: Limited Autonomous Pharmacy

Enterprise Structure	IT Infrastructure	Automation	Data Intelligence	Human Activity
Somewhat connected care settings	IT somewhat connected across facilities	Some automation, with barcode tracking	Data managed disparately, with some visibility	Pharmacists engaged in distribution & verification. Light automated support for techs and nurses

Level 2 Limited Autonomous Pharmacies leverage some automated systems but still largely rely on manual processes for medication management. While some facilities have integrated operations and processes, the Enterprise Structure component remains immature without standardized automation and information systems across sites of care. The IT Infrastructure in a Level 2 system is often behind in the latest capabilities, with only basic EHR or other information management systems, and with information stored across multiple locations. Software is disparate and locally managed, resulting in redundant application overlap in some areas and gaps in others.

Level 2 health systems incorporate more mature automated equipment for medication tracking and dispensing than Level 1 health systems, using central pharmacy storage with some barcoding and secured safes for controlled substances. Bar coding is used for almost all medication administration and dispensing, and there are automated dispensing systems on nursing floors. IV compounds are generally prepared by the manufacturer, outsourced, or prepared manually without IV workflow solutions. Medication repackaging remains a manual process. In terms of Data Intelligence, the lack of centralized data and the disparate documentation across sites leads to low data visibility. With computerized provider order entry (CPOE), e-prescribing, and some clinical decision support (CDS) capabilities, Level 2 systems leverage more data-driven and electronic mechanisms, but business metrics are still limited. Even with support from some automated medication management capabilities, pharmacists at Level 2 health systems remain involved in medication distribution, as well as order and dispensing verification.

Pharmacists are also responsible for managing disparate and non-standardized medication procurement processes, narcotics discrepancies, and varying levels of electronic data across facilities. Pharmacy technicians continue to be responsible for manually purchasing, counting, sorting, billing, transporting, repackaging, and restocking medications. They work to maintain medication management technologies that are in place, acting as a bridge for data to move from one system to another given lack of interoperability. One formulary change can require updating more than 40 different systems manually. Nurses play key roles in medication collection and administration in Level 2 facilities, manually programming IV pumps, tracking IV volumes, conducting manual countbacks for narcotics, and ensuring the right medication administration and sufficient patient education. With limited standardized electronic and data-driven capabilities, nurses must manage disparate documentation systems, sometimes relying on manual documentation and other times using EHR systems. With slightly more automated systems in Level 2, pharmacists and nurses can focus less on administrative tasks, and the health system leadership has more data visibility than in Level 1. Additionally, pharmacy has more exposure with the leadership team, and there are more opportunities for clinical collaboration.

Level 3: Intermediate Autonomous Pharmacy

Enterprise Structure	IT Infrastructure	Automation	Data Intelligence	Human Activity
Connected acute care settings, disconnected non-acute settings	IT standardized across most facilities and somewhat centralized	Majority use of automation and barcode tracking applied throughout	Data integrated across enterprise, with visibility	Pharmacists engaged in distribution, and some direct patient care. Techs focus on manual procurement/ controlled substances. Nurses supported by automatic dispensing

Level 3 pharmacies are considered Intermediate Autonomous Pharmacies, leveraging more automated and data-driven capabilities across the system. The Enterprise Structure at Level 3 includes a significant pharmacy presence existing outside of acute care. While most acute care facilities have integrated operations and processes, non-acute care facilities are still managed separately. The IT Infrastructure is similarly more mature, leveraging standardized EHR systems across most facilities and including capabilities that are interoperable with the medication management infrastructure. Data is more centralized than in Level 2 and, while most systems are managed through abstracted cloud infrastructure, the enterprise still maintains multiple servers for information storage. Additionally, in Level 3 pharmacies, the best-of-breed architectures are identified across facilities, and the standardization of IT applications is in progress to limit redundancies and wasteful overlap.

In Level 3 health systems, more automated technologies are applied to medication tracking, storage, dispensing, preparation, data collection, and intelligence. Central pharmacy storage and barcode technology is applied to all dispensing, including BCMA for all medication administration. Medication dispensing is largely automated on patient care units using a standard automated system, and technicians are responsible for restocking medications using barcode technology for verification. Controlled substances are secured and managed disparately using hardware solutions. IVs are prepared by manufacturers, outsourced, manually compounded with some being supported by IV workflow technology, and/or prepared by a compounding robot, and the health system uses intelligent IV pumps for most IV administration. Oral medications are repackaged into unit-doses through semi- or fully automated systems, standardizing a previously manual process.

Throughout the system, data is mostly normalized, and documentation is standardized, with CPOE for all orders and e-prescribing for the majority of outpatient orders, and some clinical decision support. The health system has partial and disparate data visibility, which allows for some reporting and actionable information. There is an increased focus on operational metrics and continuous improvement, including the utilization of tools to manage the regulatory compliance requirements.

Supported by more advanced autonomous systems and capabilities, pharmacists at Level 3 health systems have the time to increase direct patient care activities, including responding to codes, prescribing medications according to protocol, and providing medication education for targeted patients. Medication verification is still largely done by pharmacists with standard decision support, and some IVs are prepared and verified remotely with the help of IV workflow solutions, allowing pharmacists to redirect their time to patient care and delivering clinical services. Additionally, pharmacy technicians leverage more automated systems to order medications. Significant manual processes and data collection and analysis are still required during drug shortages. Similarly, standard drug diversion surveillance solutions are in place but require significant manual effort to follow up on reports and discrepancies. Meanwhile, some regulatory compliance activities are scheduled and collected electronically.

In Level 3 health systems, nurses continue to carry frontline responsibility for the administration of the right medication, in the right dosage, at the right time. Nurses input administration documentation into the system and the documentation is automatically sent to EHR, standardizing and centralizing patient information and decreasing the time spent on administrative tasks. While medication preparation, dispensing, and documentation systems are increasingly automated, nurses still rely on manual processes to program IV pumps for non-database compounds and conduct countbacks of narcotics. With pharmacists playing a more central role in patient care, and automated pharmacy capabilities providing more actionable data to leadership, pharmacy in Level 3 becomes more involved in medication safety and clinical outcomes. Pharmacy may also be able to focus more on ambulatory programs such as specialty pharmacy to drive revenue for the health system.

Level 4: Highly Autonomous Pharmacy

Enterprise Structure	IT Infrastructure	Automation	Data Intelligence	Human Activity
All acute and most non-acute settings connected	IT mostly centralized and standardized, with some cloud storage	Automation used across medication management, but not integrated	Almost complete data visibility, enabling workflow automation & real time insights	Pharmacists mostly engaged in direct patient care, population health, and clinical programs. Techs largely focus on automation maintenance. Nurses mainly focus on patient care

Health systems at Level 4 on the Autonomous Pharmacy Framework are considered to have Highly Autonomous Pharmacies. With more mature automation and data intelligence capabilities across the system, the entire pharmacy system is less dependent on human intervention and open to fewer opportunities for error and inefficiency. In terms of the Enterprise Structure, all acute facilities have integrated their operations and processes, and most non-acute settings are also interconnected. The IT Infrastructure relies on most of the systems being centralized and integrated through an abstracted cloud platform, while still maintaining some servers in a centralized data center. Most of the IT and automated systems are standardized across the enterprise, including a fully implemented and integrated EHR system.

Medication tracking, storage, and dispensing leverage more integrated technology than in Level 3 pharmacies, with automated medication dispensing across all floors and restock automation capabilities. All medication dispensing and administration uses barcoding, which is then fed automatically into all systems and tracked routinely. Level 4 pharmacies include capabilities that allow most controlled substances to be automatically secured and tracked through the entire medication-use process. IVs also require almost no manual preparation, either being prepared by manufacturers, outsourced, prepared with IV workflow, or with IV robots. Smart pumps are used for IV administration, including data feedback that allows the system to automatically and proactively reorder new IV compounds. The repackaging of oral medications into unit doses is an automated process, liberating pharmacists and pharmacy technicians from medication preparation processes.

Data Intelligence in Level 4 pharmacy systems is more robust, with increased data visibility enabling some workflow optimization and providing action-oriented recommendations based on insights. Inventory data is integrated across the pharmacy ecosystem, helping to track and manage medications throughout the journey, including with IV pumps, IV workflow management solutions, medication kits and trays, pharmacy robots, and dispensing cabinets. Some actions can be automatically transferred to hardware and software upon the approval of key decision-makers, further automating and streamlining processes.

In addition to automating the medication management workflow, the data intelligence capabilities in Level 4 include a range of tools to help manage and navigate the complex regulatory compliance process.

With more support from automated systems and data intelligence, pharmacists at Level 4 health systems are increasingly involved in direct patient care, prescribing the right medications according to protocols, responding to codes, monitoring responses to drug therapies, and leading comprehensive medication education and discharge counseling for patients. Additionally, they can reallocate time that had historically been spent on administrative tasks to focus on population health initiatives, clinical programs, and process optimization. The increased data visibility allows pharmacy technicians at Level 4 health systems to be equipped with workflow apps that provide real-time direction. While relying on automated ordering based on current stock, utilization, expiration, and other variables, pharmacy staff continues to conduct order verification, although more sophisticated clinical decision support and machine learning is being integrated to make the verification process safer and more efficient.

Nurses in Level 4 health systems, better supported by pharmacists and automated medication preparation systems, can focus on direct patient care, and the careful and correct administration and monitoring of medications. With automated IV preparation and mixing capabilities, nurses spend less time reordering IV bags. Similar to Level 3, nurses input administrative documentation that is then automatically sent to EHR. However, in Level 4 health systems, automated capabilities are also able to calculate and document waste, which is then reviewed by nurses to address exceptions. Drug diversion surveillance actions and data needed for regulatory requirements are more automated and efficient. With highly accessible data across the medication management system and an increasingly visible role in patient care, pharmacy is viewed as a key strategic partner, and shares accountability for medication safety and clinical outcomes.

Level 5: Fully Autonomous Pharmacy

Enterprise Structure	IT Infrastructure	Automation	Data Intelligence	Human Activity
Fully integrated automated technology across all care settings	Decentralized IT infrastructure that is fully integrated, using cloud platform as service	Fully automated and predictive management process, with each dose tracked	Full visibility of data, enabling real-time workflow optimization & predictive intelligence	Pharmacists realize full scope of provider role in patient care and clinical activities. Techs maintain optimal function of automation. Nurses focus on direct patient care

As today's health systems develop more mature pharmacy automation and data intelligence capabilities, they continue to progress towards the vision outlined in Level 5 of the Autonomous Pharmacy Framework: The Fully Autonomous Pharmacy. While technologies available today are key building blocks to achieving this vision, the necessary set of comprehensive technologies and systems is still being imagined and created. But, the vision for the Autonomous Pharmacy is clear. While empowering pharmacists and leadership with the right tools and information to make the best decisions, the Autonomous Pharmacy has the potential to play a major role in solving the problems facing pharmacy and healthcare today.

In a Level 5 organization, the Enterprise Structure includes automated technologies that are fully integrated across all facilities. Dispensing processes are completely automated across settings, including inpatient, infusion pharmacy, specialty pharmacy, retail pharmacy, and other sites of care. In terms of the IT Infrastructure, the enterprise no longer needs servers for pharmacy operations, relying on a decentralized IT infrastructure that is abstracted through a cloud platform as a service. All systems are completely integrated, using one formulary and other datasets that are globalized throughout all systems, and relying on edge capabilities for instantaneous decision-making.

In terms of the medication management automation and intelligence capabilities that define the Fully Autonomous Pharmacy, Level 5 health systems are empowered to view every dose within their system as a node on a network, with full inventory visibility and automated medication management. Medication procurement is fully automated and predictive, streamlining the process and protecting against harmful drug shortages. Medication storage is also highly automated, with fully automatic medication receiving, returns, and acceptance. Batching medications for dispense to patients and medication repackaging for all form factors are also fully automated processes. IVs are prepared by the manufacturer, IV workflow, or robots, and IV smart pumps are used for all IV administration and programmed automatically, using data feedback loops to prepare new IV compounds and provide restock alerts. Medication dispensing is a fully automated process, including restock automation capabilities.

Predictive, prescriptive, and precision intelligence across all medication management processes removes unplanned disruptions (i.e., drug shortages) and eliminates errors. Using automatic and continuous multi-echelon inventory optimization capabilities, facilities and providers can optimize their storage locations to meet their specific needs. Similarly, care transition tools, such as patient data tracking across the care continuum, allow care providers to understand their patients' histories and needs, and meet them at every stage in their journey. Risk stratification and patient acuity scoring, available through increased data collection capabilities and analytics, focus pharmacists' clinical activities to maximize clinical outcome improvements, including population health and medication adherence strategies implemented for targeted high-risk patients.

In a Fully Autonomous Pharmacy, comprehensive, real-time, and customizable data intelligence is used to inform decisions, analyze performance against key metrics, and provide actionable insights. One way that the data can come to life for providers is in the ability of Level 5 health systems to provide full, real-time workflow optimization for all pharmacy technicians, pharmacists, and nurses. Analytics tracking medication use equip professionals with the tools they need to develop data-driven cost containment initiatives. The metrics available in a Fully Autonomous Pharmacy setting allow care providers and leadership to assess the pharmacy enterprise's performance in all of the aforementioned performance elements: safety, financial, efficiency, regulatory compliance, and people.

Equipped with fully automated medication management systems and comprehensive data visibility, the Fully Autonomous Pharmacy enables pharmacists, technicians and nurses alike to realize the full scope of their roles. Pharmacist talent is reallocated to direct patient care and clinical program delivery and optimization, allowing pharmacists to lead comprehensive medication management for patients and caregivers, monitoring drug therapies, providing medication education, and extending coverage through telepharmacy capabilities and providing greater care to patients at home. Pharmacists can also leverage analytics for population health management purposes, as well as leading data-driven revenue cycle optimization efforts. As for pharmacy technicians, time is no longer spent procuring, preparing,

and verifying medications; rather, they work to better support the transition of care, medication histories, and medication reconciliation. Equipped with a workflow app, pharmacy technicians are provided real-time task execution guidance, helping to ensure efficiency and accuracy at
every step.

The Fully Autonomous Pharmacy equips pharmacists and pharmacy technicians to better serve their patients and enables nurses, physicians, and other caregivers to provide the full breadth of care they were trained to provide. With peace of mind that every medication is the right one, in the right dose, to the right patient, nurses confidently administer medications to patients and focus their time on direct patient care. By limiting human touches throughout the process until the medication is delivered to the patient, the Fully Autonomous Pharmacy creates a system where pharmacists and other healthcare professionals are always available to patients and there are no medication errors, diversion instances are easily identified, medication waste is minimized, and drug shortages are more efficiently managed. The entire medication management system is safer, more efficient, and less costly, and the accessibility of data across the pharmacy system equips leaders with the tools they need to make decisions, elevating pharmacy to be a key strategic leader in the health system.

Conclusion

In summary, while pharmacies are still operating with largely traditional manual methods, progress is well within reach. The journey has begun and there are clear steps that organizations can take immediately to dramatically improve the performance of health system pharmacies along several dimensions. The key to progress will begin with mobilizing the industry around a unified vision for the future, leveraging diagnostics to evaluate where an organization lies on the journey today, and identifying the key gaps to address within each component. With this roadmap, we can leverage technology to fully unlock human potential and support the delivery of superior patient care.

The Autonomous Pharmacy Framework

Level 1

Non-Autonomous Pharmacy

- Minimal to no automation
- Data primarily managed on paper or in disparate spreadsheets
- Pharmacists heavily engaged in distribution with little direct patient interaction. Technicians and nurses spend time on manual drug management (purchasing, locating, counting)

Level 2

Limited Autonomous Pharmacy

- Some automation, including some barcode tracking
- Data managed disparately across sites with some visibility
- Pharmacists largely focused on distribution and verification. Technicians and nurses manually responsible for most drug management with light automated support

Level 3

Intermediate Autonomous Pharmacy

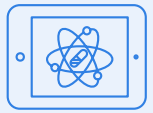
- Majority of processes automated, with barcode tracking applied widely
- Data integrated across enterprise and mostly visible
- Pharmacists somewhat focused on medication distribution, with some direct patient care. Technicians focus on manual procurement and controlled substances, and nurses rely on automated dispensing

Level 4

Highly Autonomous Pharmacy

- Extensive automation with few gaps across processes
- Near complete data visibility, offering workflow optimization and real-time insights
- Pharmacists routinely involved in direct patient care, population health initiatives, and clinical programs. Technicians maintain automation and use workflow app, and nurses focus most of their time on patient care

Level 5



Fully Autonomous Pharmacy

- Complete process automation, tracking each dose as a node on the network
- Complete data visibility, real-time workflow optimization, and predictive intelligence
- Pharmacists realize full scope of their role in direct patient care and clinical program optimization. Technicians ensure optimal function of automation and use workflow app, and nurses focus on direct patient care

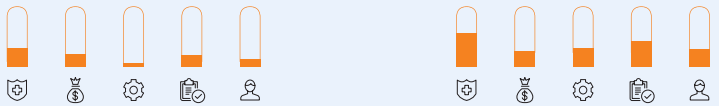
Outcomes

0

- ✓ Medication Errors
- ✓ Medication Waste
- ✓ Human Touches Pre-administration To Patient

100%

- ✓ Data Visibility
- ✓ Time Spent on Clinical Activity
- ✓ Regulatory Compliance



Performance Elements

Safety · Financials · Efficiency · Compliance · People

Contact Us

Please send any comments regarding the Autonomous Pharmacy Framework to joinus@autonomouspharmacy.com

1 Recent Trends in Hospital Drug Spending and Manufacturer Shortages. NORC at the University of Chicago. January 15, 2019.

2 Schneider PJ, Pedersen CA, Ganio MC, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: workforce—2018. American Journal of Health-System Pharmacy. 2019;76(15):1127-1141.

3 Poon EG, Cina JL, Churchill W, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. Ann Intern Med. 2006;145:426-434.

4 Flynn EA, Barker KN, Carnahan BJ. National observational study of prescription dispensing accuracy and safety in 50 pharmacies. J Am Pharm Assoc. 2003;43:191-200.

5 Kohn, L. T., Corrigan, J., & Donaldson, M. S. (2000). To err is human: Building a safer health system. Washington, D.C.: National Academy Press. https://www.ncbi.nlm.nih.gov/pubmed/25077248.

6 Protenus, Inc. report: 2019 Drug Diversion Digest. https://www.abn.alabama.gov/wp-content/uploads/2019/07/2019-Drug-Diversion-Digest.pdf

7 Protenus, Inc. report: 2019 Drug Diversion Digest. https://www.abn.alabama.gov/wp-content/uploads/2019/07/2019-Drug-Diversion-Digest.pdf

8 Bennett J, O'Donovan D. Substance misuse by doctors, nurses, and other healthcare workers. Current Opinion in Psychiatry. May 2001;14(3):195–199.

9 Brody JE. The cost of not taking your medicine. New York Times. April 17, 2017.

10 Burrell CD, Levy RA. Therapeutic consequences of noncompliance. In: Improving medication compliance. Proceedings of a symposium. Washington, DC: National Pharmaceutical Council; 1984:7-16.

11 New England Healthcare Institute. Thinking Outside the Pillbox. August 2009.

12 Pinto S, Simon A, Osundina F, Jordan M, Ching D. Study to Measure the Impact of Pharmacists and Pharmacy Services (STOMPP) on Medication Non-Adherence: Medication Adherence and Clinical Outcomes. Innovations in Pharmacy. 2018;9(1).

13 The Global Use of Medicine in 2019 and Outlook to 2023. January 2019, IQVIA Institute for Human Data Science. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf?&_=1555970409763

14 U.S. Senate Committee on Homeland Security & Governmental Affairs. Brand-name drugs increasing at 10x cost of inflation, McCaskill report finds. March 26, 2018. https://www.hsgac.senate.gov/media/minority-media/breaking-brand-name-drugs-increasing-at-10x-cost-of-inflation-mccaskill-report-finds

15 Recent Trends in Hospital Drug Spending and Manufacturer Shortages. NORC at the University of Chicago. January 15, 2019.

16 Sarnak, D., Squires, D. and Bishop, S. Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?. The Commonwealth Fund. October 5, 2017. https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier

17 Sarnak, D., Squires, D. and Bishop, S. Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?. The Commonwealth Fund. October 5, 2017. https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier

18 Bureau of Labor Statistics; National Center for Health Statistics; and Himmelstein/Woolhandler analysis of Current Population Survey (CPS).

19 American Society of Health-System Pharmacists. Drug Shortages Statistics - ASHP. 2019. https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics

20 Kaakeh R, Sweet BV, Reilly C, Bush C, DeLoach S, Higgins B, Clark AM, Stevenson J. American Journal of Health System Pharmacy. Impact of drug shortages on U.S. health systems. https://www.ncbi.nlm.nih.gov/pubmed/21930639

21 Regulatory Overload Report: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Care Providers. American Hospital Association. October 2017. https://www.aha.org/guidesreports/2017-11-03-regulatory-overload-report

22 Regulatory Overload Report: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Care Providers. American Hospital Association. October 2017. https://www.aha.org/guidesreports/2017-11-03-regulatory-overload-report

23 Schneider PJ, Pedersen CA, Ganio MC, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: workforce—2018. American Journal of Health-System Pharmacy. 2019;76(15):1127-1141.

24 Mary E. Durham, Paul W. Bush, Amanda M. Ball, Evidence of burnout in health-system pharmacists, American Journal of Health-System Pharmacy, Volume 75, Issue 23_Supplement_4, 1 December 2018, Pages S93–S100, doi.org/10.2146/ajhp170818

25 Stephen Swensen, Tait Shanafelt, Namita Seth Mohta. Leadership Survey: Why Physician Burnout is Endemic, and How Health Care Must Respond. Catalyst New England Journal of Medicine. December 8, 2016. https://catalyst.nejm.org/physician-burnout-endemic-healthcare-respond/

26 Lee C Vermeulen, Natalie D Eddington, Michelle A Gourdine, et al. ASHP Foundation Pharmacy Forecast 2019: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, American Journal of Health-System Pharmacy, Volume 76, Issue 2, 15 January 2019, Pages 71–100, doi.org/10.2146/sp180010

27 Panagioti M, Geraghty K, Johnson J, et al. Association Between Physician Burnout and Patient Safety, Professionalism, and Patient Satisfaction. JAMA Intern Med. 2018;178(10):1317-1330. doi:10.1001/jamainternmed.2018.3713

28 Panagioti M, Geraghty K, Johnson J, et al. Association Between Physician Burnout and Patient Safety, Professionalism, and Patient Satisfaction. JAMA Intern Med. 2018;178(10):1317-1330. doi:10.1001/jamainternmed.2018.3713

29 Caldwell D, Chatman J, O'Reilly C, et. Al. Implementing Strategic Change in Healthcare System: The Importance of Leadership and Change Readiness. Healthcare Management Review. 2008; 33(2), 124-133