# ASHP Foundation PHARMACY FORECAST 2018

#### Strategic Planning Advice

## for Pharmacy Departments in Hospitals and Health Systems

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### **Foreword**

The ASHP Research and Education Foundation ("the Foundation") is pleased to present the sixth edition of the annual *Pharmacy Forecast*. While the first 4 editions of the *Pharmacy Forecast* were published as standalone reports, the fifth edition of the *Pharmacy Forecast* was published in *AJHP*. Disseminating the *Pharmacy Forecast* as an element of *AJHP* was incredibly successful, with tens of thousands of downloads over the past year. We are again grateful to the editorial staff of *AJHP* for their support in publishing this year's *Pharmacy Forecast* in the Journal.

The *Pharmacy Forecast* is a vital component of the Foundation's efforts to advance pharmacy practice leadership, and the Foundation appreciates the many pharmacists and others who have contributed to the David A. Zilz Leaders for the Future Fund, which provides the resources to develop the report. The Foundation is also grateful to the many ASHP staff members who support the Advisory Committee and field the survey after it is developed by the Committee.

The *Pharmacy Forecast* could not be created without the support and contribution of the report editor, founding editor, members of the Advisory Committee, Forecast Panelists who responded to the forecast survey, and chapter authors. The Foundation is indebted to those individuals who have helped make the 2018 edition a possibility.

We recognize that the *Pharmacy Forecast* is used by many pharmacy trainees, including pharmacy students in colleges and schools of pharmacy and pharmacy residents in many residency programs. Recognizing the importance of the report to those training programs, we added 2 pharmacy residents this year from Johns Hopkins Hospital as observers to the Advisory Committee. Their contribution to the development of the forecast survey, drawing from their perspectives as new practitioners in training, added substantially to the report. We are grateful to the leaders at Johns Hopkins Hospital for allowing their residents the time to participate in this project.

Over the past 5 years, the Pharmacy Forecast has provided insight into emerging trends and phenomena that have affected the practice of pharmacy and the health of patients in health systems. The value of the report, however, is defined by health-system pharmacists and health-system pharmacy leaders as they use the report to inform their strategic planning efforts. The Pharmacy Forecast is not intended to be a quantitatively or even qualitatively (directionally) accurate prediction of future events. Rather, the report is, at its core, a stimulant for the thinking, discussion, and planning that must take place in every hospital and health system in order to succeed in their mission of caring for patients and advancing the profession of pharmacy. Some may disagree with the opinions of the Forecast Panelists or the positions taken by individual chapter authors with respect to their vision of future events. This is not only acceptable, it is desirable. A person holding a disparate belief regarding future events suggests that the person has his or her own opinion about future events, and as long as that person expresses his or her opinion in the context of his or her organization's strategic planning process and uses that belief to chart a course for that organization, the Pharmacy Forecast has met its objective of encouraging the planning efforts of health systems.

We welcome your comments on this new edition of the *Pharmacy Forecast*. Suggestions for topics that should be considered for future forecasts can be sent to any of the Forecast Editors through the Foundation's *Pharmacy Forecast* website at www. ashpfoundation.org/pharmacyforecast.

Creation of the *Pharmacy Forecast 2018* report was supported by an unrestricted grant from Omnicell, Inc., to the David A. Zilz Leaders for the Future Fund of the ASHP Research and Education Foundation.

## Introduction: Strategic planning in challenging times

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his sixth edition of the *Pharmacy* Forecast is published at a time of considerable uncertainty and turmoil in healthcare. The fate of the Affordable Care Act remains unclear, and the lack of clear direction has put the entire industry in disarray. It is under these exact conditions where strong, deliberate, and disciplined strategic planning becomes a lifeline for leaders charged with the stewardship of healthcare delivery. Pharmacy leaders who have developed strategic plans and revisited them frequently to ensure ongoing fidelity between plan and action are able to make course corrections in their organizations—adjusting (as nimbly as possible) to the frequent changes. Of course, political uncertainty is not the only cause of the current conditions—technology continues to advance more quickly every year, growth in spending on medications has expanded after a few years of relatively slower growth, and our continued mandate to provide safe care to our patients continues to challenge us. This 2018 edition is provided to support the needs of healthsystem pharmacists as we struggle to meet that mandate.

#### **FORECAST METHODS**

The methods used to develop the

Pharmacy Forecast this year were similar to those used in the previous 5 editions, drawing on concepts described in James Surowiecki's1 book, The Wisdom of Crowds. According to Surowiecki, the collective opinions of "wise crowds"-groups of diverse individuals in which each participant's input is provided independently, drawing from his or her own locally informed points of view—can be more informative than the opinion of any individual participant. This process is particularly valuable when addressing phenomena that are not well suited to quantitative predictive methods. A critical requirement for successfully creating crowd-based knowledge is establishing a systematic method of combining individual beliefs into a collective opinion. The Pharmacy Forecast uses a survey of carefully selected pharmacy leaders to derive its environmental scan.

The *Pharmacy Forecast 2018* Advisory Committee (see membership list in the Foreword) began the development of survey questions by contributing lists of issues and concerns they believed will influence health-system pharmacy in the coming 5 years. That list was then expanded and refined through an iterative process, resulting in a set of 8 themes, each with 6 focused topics on which the survey was built. Each of 48 survey items was written to explore the selected topics and was pilot-tested to ensure clarity and face validity.

As in the past, survey respondents— Forecast Panelists (FPs)—were selected by ASHP staff after nomination by ASHP section leaders. Nominations were limited to individuals who had expertise in health-system pharmacy, knowledge of trends and new developments in the field, and the ability to think analytically about the future. The survey instructs FPs to read each of

the 48 scenarios represented in survey items and consider the likelihood of those scenarios occurring in the next 5 years. They were asked to base their response on their firsthand knowledge of current conditions in their region and not on their understanding of national circumstances. The panel was carefully balanced across the census regions of the United States to reflect a representative national picture. FPs were asked to provide a top-of-mind response regarding the likelihood of those conditions being very likely, somewhat likely, somewhat unlikely, or very unlikely to occur.

#### **FORECAST SURVEY RESULTS**

A total of 165 FPs were recruited to complete the survey. Responses were received from 146 FPs (response rate, 88.5%). Most of the FPs (86%) had been in practice for over 10 years, and 50% had been in practice for over 20 years. Many FPs (49%) described their practice setting as a teaching hospital or health system, 16% of FPs were from nonteaching hospitals or health systems, and 18% described their primary organization as academia. FPs reported that their primary organizations offered very diverse services including home health or infusion care (54% of FPs), specialty pharmacy (58%), ambulatory care (80%), pediatric care (59%), and hospice care (47%). Most responses came from the South Atlantic (Maryland, District of Columbia, Virginia, West Virginia, North Carolina, South Carolina, Georgia, and Florida) and Great Lakes (Ohio, Indiana, Illinois, Michigan, and Wisconsin) regions (21% and 24% of total responses, respectively). The proportion of total responses from the other regions ranged from 5% to 11%. Every region was represented by a minimum of 7 FP respondents. Many of the FPs hold the title of chief pharmacy officer or director of pharmacy (19% and 12% of FPs, respectively). Another large group of FPs (19%) listed their primary position as faculty. The remainder of FPs included leaders and practitioners at varying levels and titles. While 24% of FPs indicated that their primary organization was not a hospital, 61% of FPs were employed by hospitals with 400 or more beds, and only 15% of respondents were from hospitals with fewer than 400 beds.

Within each chapter of this report, the results of each survey question are summarized in detail. The results are summarized and discussed in each chapter, along with key strategic recommendations for practice leaders.

## CONTENTS OF THE 2018 PHARMACY FORECAST

The 2018 *Pharmacy Forecast* provides guidance on 8 topics that will affect health-system pharmacy in the coming year. A total of 48 questions were posed in a survey completed by a Forecast Panel, and 8 teams of authors considered the results of the survey and developed 46 key recommendations to stimulate strategic planning.

In a chapter on new technological innovation, Jill Kolesar and Lynn Crismon describe the future impact of genomic advances and the development of new treatments for Alzheimer's disease. They also offer insight into emerging legal and regulatory trends, such as the Right to Try Act of 2017, that will affect the use of new technology for many years to come. Allen Flynn and Jim Stevenson emphasize the importance of intentional planning around data and analytics. In the face of remarkably rapid advancement in information technology, developing and maintaining a purposeful strategy is the only way to be responsive to future change. Falling behind technologically as a consequence of inadequate planning is an avoidable vulnerability that pharmacy leaders can ill afford.

Philip Almeter, Mike Heath, and Tyler Short provide a discussion of trends that will affect the business of

#### **ACKNOWLEDGMENTS**

The editor of the 2018 Pharmacy Forecast Report gratefully acknowledges the contributions of many individuals who have made the 2018 Pharmacy Forecast a success. The members of the *Pharmacy Forecast* Advisory Committee were instrumental in considering hundreds of factors that may influence the future of health-system pharmacy and distilling those ideas into a coherent survey, and the authors of each Forecast chapter took that "crowd wisdom" and created impactful messages and recommendations. Also acknowledged for assistance with various aspects of the process are Steve Allen, Philip Almeter, Dan Ashby, Stacy Boyer, Stephanie Brown, Colleen Bush, David Chen, Dan Cobaugh, Mike Dejos, Erica Diamantides, Mick Hunt, Anita Lonesome, Yvonne M. Yirka, Rohit Moghe, Maryam Mohassel, Barbara Nussbaum, Antoniette Parris, and Abhay Patel.

The author also recognizes the leadership and vision of William Zellmer, the founding editor of the ASHP Research and Education Foundation *Pharmacy Forecast* series. Mr. Zellmer has created a resource for the profession that will have significant lasting value, and I am grateful for his guidance and mentorship in carrying the *Pharmacy Forecast* forward.

pharmacy in the coming years. Predicting the future direction of legislative and regulatory changes is difficult, and pharmacy leaders will be challenged to respond with programs that are financially sustainable, but there will be opportunities to leverage the expertise of pharmacists in pro-

grams aimed at meeting the needs of their patients.

Sharon Enright, Pam Ploetz, and Meghan Swarthout contribute a chapter focused on the future leadership challenges that pharmacists will face. Changes in the composition and expectations of health-system executive teams, as well as the makeup and needs of employees, will force pharmacy leaders to think and act very differently, and the challenge of meeting our obligation to prepare the next generation of leaders will be particularly acute. William Zellmer and Rafael Saenz focus their forecast on the future role of pharmacy technicians in health systems. Our ability and willingness to foster the development of technicians will be an essential determinant of success for pharmacy, as all caregivers strive to "right size" their staff and ensure that everyone is working at the limit of their licensure and competence.

James Hoffman and Bill Evans explore emerging public health imperatives that will demand the attention of health-system pharmacy leaders in the future. Our responsibility to provide safe and effective medication therapy will demand greater creativity in the face of rising rates of substance abuse and continuing pressures related to scarcity of resources.

Debra Devereaux and David Zilz offer a discussion of opportunities and challenges pharmacists will face in managing the health of populations. Systematic changes that incentivize value-producing better outcomes per dollar spent-have illustrated the importance of meeting patients' health needs in very different ways than we have in the past. The ability of pharmacists to respond to new models and priorities will be critical in the future. Finally, Scott Knoer and Max Ray delve into the unique challenges that we currently face, specifically due to uncertainty in the current healthcare environment, and offer specific recommendations for leading our organizations through these chaotic times. Never

before has strategic planning been more critical to the success—indeed even the sustainability—of our pharmacy programs in health systems.

Throughout the 8 sections of the *Pharmacy Forecast*, we provide a comprehensive environmental scan of key trends that our authors believe will emerge over the coming years. This scan is intended to catalyze strategic planning processes in health-system pharmacy departments.

## USER'S GUIDE TO THE PHARMACY FORECAST

This advice on using the 2018 *Pharmacy Forecast* is similar to that provided in the first 5 editions of the report. The purpose of this report is to encourage and support active, deliberate strategic planning in hospitals and health systems. It is intended to stimulate thinking and discussion and provide a starting point for individuals and teams who wish to proactively position themselves and their teams and departments for potential future events and trends. This edition of the report differs from the first 5 editions, just as each previous version differed from earlier versions. When using the *Pharmacy Forecast*, it is recommended that planners review at least 1 or 2 past editions in addition to this new report; many of the observations and recommendations that are 1 or 2 years old remain important to consider. All past editions of the Pharmacy Forecast can be found on the ASHP Research and Education Foundation's website at www.ashpfoundation.org/ pharmacyforecast. A recent article on strategic thinking and strategic planning by Boyd et al.<sup>2</sup> is also recommended as an informative guide on this topic.

The process of strategic planning should involve pharmacy staff at all levels—those in formal leadership positions, frontline staff (both pharmacists and pharmacy technicians), and others connected to departments of pharmacy, such as affiliated faculty members and key physician and nursing leaders involved in pharmacy activities. The *Pharmacy Forecast* has been developed to provide guidance to anyone participating in strategic planning activities, and it is recommended that the report be reviewed by all involved.

Importantly, strategic planning should not be limited to an annual process, producing a strategic plan that is then largely ignored until the following year when a revised plan is created. Given the complexity, uncertainty, and pace of change in healthcare today, strategic planning must be a continuous process. Strategic plans should be reviewed frequently, allowing for tactical adjustments in course over time as trends (those discussed in this report and others that were not predicted) emerge. It is only through a continuous process that organizations can be responsive to changes that are sure to affect our profession, organizations, and patients.

During the strategic planning process, the *Pharmacy Forecast* can be used as a provocative springboard for brainstorming and discussion; however, individuals leading strategic planning discussions should be open to opinions that differ from those expressed by the FPs and the chapter authors. Unique characteristics of each hospital and health system may suggest important differences in the potential impact of emerging trends, or individuals may simply disagree with the predictions

made in this report. As a stimulant for thought and discussion, dissenting opinions can be constructive and valuable, provided those who express disagreement are willing to offer alternative views and recommendations for action that support their perspectives.

Those organizations involved in education or training should consider the use of the *Pharmacy Forecast* as a teaching tool. Many educators and residency preceptors use the report as part of coursework, seminars, or journal club sessions to help engage pharmacy trainees in thinking about the future of the profession they are preparing to enter.

Finally, as pharmacists are increasingly relied on to provide systemwide leadership, the Pharmacy Forecast addresses many issues that are relevant well beyond the traditional boundaries of pharmacy and the medication-use process. The content of the report should inform the broadened scope of responsibility that many pharmacists now take. The *Pharmacy Forecast* should be shared with other senior healthsystem leaders and executives as a resource to help them understand the challenges facing pharmacy and recognize how emerging healthcare trends will affect many other areas of health systems.

#### **DISCLOSURES**

The author has declared no potential conflicts of interest.

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# Therapeutic innovation: Impact of precision medicine

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#### **DRIVERS OF INNOVATION**

president Barack Obama launched the Precision Medicine Initiative in his 2015 State of the Union address. Subsequent federal legislation allocated \$200 million for this initiative and the 21st Century Cures Act (the Cures Act). These 2 efforts will have a substantial impact on therapeutic innovation in the future.

#### **NEW MOLECULAR ENTITIES**

Eighty-one percent of Forecast Panelists (FPs) predicted that the annual number of new molecular entities (NMEs) approved by the Food and Drug Administration (FDA) will double by 2022 (Figure 1, item 1). Since 1993, the annual number of approvals of NMEs has ranged from 15 to 53, with innovation peaks occurring in 1996 (53 NMEs), 2004 (31 NMEs), and 2012 (33 NMEs) and 5- and 10-year averages of 35 and 29, respectively.3 Based on 20-year trends, the number of NME approvals will likely remain flat over the next 5 years. However, the gene-editing technology CRISPR (clustered regularly interspaced short palindromic repeat) bears watching.4 CRISPR repairs specific mutations and has entered its first human clinical trial. While CRISPR-based therapy is unlikely to be approved within the next 5 years, this technology could revolutionize cancer treatment by repairing the dozens of individual mutations found in most cancers.

Major drivers of oncology therapeutic innovation are targeted therapies. The first disease-agnostic drug was FDA approved in 2017—the immune checkpoint inhibitor pembrolizumab was approved for any tumor with high microsatellite instability (MSI-High). A recent forecast predicts that by 2024, immune checkpoint inhibitors and targeted therapies will constitute more than 95% of the lung cancer market. As predicted by the FPs, it seems likely that at least 75% of all cancer patients will receive somatically targeted therapies (Figure 1, item 2).

Considering the high cost of targeted therapies with activity that is almost exclusively confined to specific patient subsets, getting the right drug to the right patient has never been more important, and pharmacists are uniquely qualified to serve as precision medicine experts for health systems. If pharmacists are unable or unwilling to lead precision medicine efforts, other healthcare professionals will fill this role.

A majority of FPs indicated that an effective treatment that halts Alzheimer's disease (AD) progress will be approved (Figure 1, item 3). AD is an etiologically heterogeneous disorder but presents with a similar clinical phenotype. Drug development based on a one-size-fits-all approach for treating the clinical syndrome has not produced effective drugs and as a strategy for affecting disease progression is likely doomed to failure. Specific genetic polymorphisms in subpopulations of patients

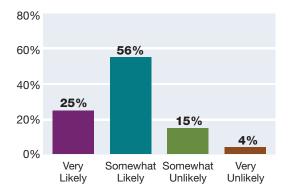
with AD must be identified and then integrated with system-based biology to identify treatments targeted to specific pathophysiologic processes. This may allow precision medicine-based interventions to be implemented years before the onset of symptoms, postponing or possibly even preventing the neuronal destruction associated with AD. The mixed response of FPs on this question is a reflection of the complex nature of these disorders and the challenges in addressing them therapeutically.

# CHANGES IN FDA REGULATION OF DRUG APPROVALS

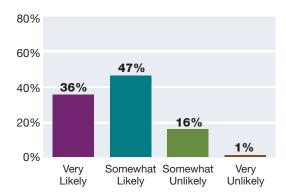
A large majority of FPs predicted that in at least half of future FDA drug approvals, the efficacy requirement will be met by data sources other than large Phase III clinical trials (Figure 1, item 4). This prediction is supported by the Cures Act and the influence of precision medicine on the landscape of drug development. A recent metaanalysis demonstrated that outcomes were significantly improved in clinical trials of precision medicine when compared with clinical trials of nonprecision medicine.7 Precision medicine drugs were approved faster, often with approvals based on Phase II trials.8 The Cures Act overhauls the FDA drug approval process and requires consideration of "real world evidence" (commonly defined as including safety surveillance and other observational studies and registries), in drug approvals, and continues drug development incentives for specific patient populations. FPs indicated that such support is unlikely to stop (Figure 1, item 5). While observational studies cannot completely replace randomized clinical trials, consideration of less-rigorous data presents an opportunity for health-system pharmacists

**Figure 1 (Therapeutic Innovation).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

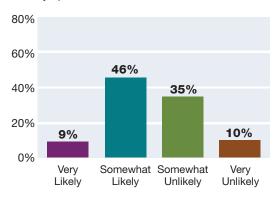
The annual number of new molecular entities, including biologics, approved by the FDA will double by 2022.



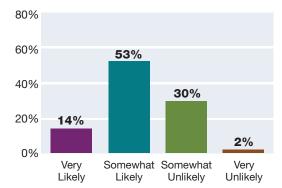
In at least 75% of all cancer patients, the results of genetic testing for somatic mutations will qualify them for specific targeted drug therapy.



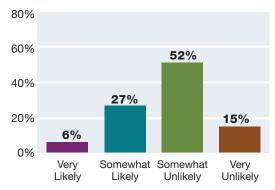
An effective treatment that halts Alzheimer's disease progression will be approved for patients showing initial symptoms of disease.



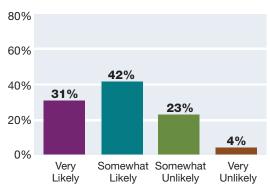
4 In at least 50% of FDA drug approvals, the efficacy requirement will be met by data from sources other than large randomized trials (e.g., data from small-scale targeted clinical trials, "real world evidence," information from patient registries).



The federal government will discontinue incentives for the development of innovative treatments in specific patient populations (e.g., orphan diseases, pediatrics).



Most health systems will prohibit the use of medications under "Right to Try" regulations unless patients, insurers, or manufacturers have agreed to pay for that care. {Note: "Right to Try" refers to the right of terminally-ill patients to access unapproved medications after approved alternatives and Phase 1 clinical trial options have been exhausted.}



to influence drug development by using evidence-based research methodologies to analyze and apply data stored in their own electronic health records.

The Right to Try (R2T) Act of 2017, allowing unrestricted use of experimental drugs by patients with a terminal illness and no standard therapeutic options, has strong bipartisan support in Congress,9 and 37 states have already enacted R2T laws.10 While the Cures Act will have a profound effect on the types of medications developed, the Right to Try Act could have a similar impact on who has access to them. R2T laws passed by some states are based on the Goldwater Institute's Model R2T suggesting that "terminally ill patients possess a fundamental right of access to investigational drugs which have passed basic safety tests, provided there is a doctor's recommendation, informed consent, and the willingness of the manufacturer to make such drugs available."11 These laws prioritize the right of individual patients to access investigational medications over societal rights to limit access to medications without demonstrated safety and efficacy.11,12 A majority of FPs believe that most healthcare systems will prohibit medication use under R2T regulations unless patients, insurers, or manufacturers pay for care (Figure 1, item 6). This is supported by professional organizations who oppose R2T legislation, based on the legislation being unlikely to improve access to investigational medications, since manufacturers are not required to provide them and insurers are not required to pay for them.13 Eliminating FDA review will likely result in inadequate safety protections for patients.

Strong congressional support and patient demand suggest that legislators and patients may not understand that the benefits of investigational therapies are unproven and associated adverse effects may be worse than no treatment at all. This raises important questions that will need to be addressed in the near future. Is informed

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- Pharmacists must be precision medicine experts and leaders, understanding and applying next-generation sequencing, emerging technologies, and targeted therapies to the care of their patients.
- 2. Pharmacists and health systems must be prepared to tailor the care of patients with AD based on the subpopulations identified by genetic polymorphisms and system biology and our ability to apply precision to address these different AD subpopulations.
- 3. Health systems should enhance the quality, objectivity, and automation of electronic health record documentation to allow for the contribution of mined data to "real world" trials in anticipation of FDA acceptance of those data for new drug approval applications

- and consider the possibility of developing this as a revenue stream.
- 4. Health systems should create institutional policies addressing R2T legislation, allowing expanded access while enrolling in observational registries that may contribute to drug development.
- 5. Pharmacists should collaborate with physicians, other providers, and medical ethicists to develop a program to educate legislators and the public about the potential merits and risks associated with R2T laws.
- 6. Pharmacists should work with physicians and other providers to educate patients about their options so they truly understand the potential implications of a decision to access a medication through R2T laws.

consent possible for a terminally ill patient without therapeutic options? Is it clinically appropriate to treat a patient with a medication of unproved efficacy and safety? Who pays for investigational medications, care associated with their use, and adverse effects caused by the medication? Lastly, the R2T creates an ethical slippery slope that may deteriorate FDA's entire drug approval process.

#### **DISCLOSURES**

The authors have declared no potential conflicts of interest.

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# The future of data, analytics, and information technology

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# PURPOSEFUL STRATEGY TO TRANSFORM PHARMACY PRACTICE

apid advancement of information systems and technology has the potential to transform and improve the delivery of healthcare.1 More data and analytic power bring exciting possibilities to enhance the efficiency and outcomes associated with medication use.<sup>2,3</sup> To date, large investments in information systems and technology have not achieved the degree of improvement in quality and safety that is needed.4 Instead, technology has often introduced new problems and challenges and has limited the movement of pharmacists into more direct patient care roles.5

Too often, pharmacy resources have been focused on the isolated implementation of information technology (IT) without an overarching purposeful strategy to advance practice and patient care. As the pace of the introduction of new technology increases, it is more important than ever that leaders develop a vision and strategic approach (both institutionally and professionwide) to effectively utilize

technology to enable direct patient care services by pharmacists, improve clinical decision support, predict and forestall medication problems and errors, and better prioritize patient care activities resulting in improved health outcomes and efficiency of healthcare delivery.

# PATIENT MONITORING AND OUTCOMES DATA IN PRACTICE

The advent of wearable devices (wearables), mobile apps, sensors, and telehealth has the potential to extend the role of the pharmacist through remote interaction with patients in ways that have previously not been possible.6 Pharmacists should work with patients to use monitoring data to help prevent adverse events and hospital admissions while improving outcomes and overall health. Forecast Panelists (FPs) overwhelmingly predicted that health insurance plans will provide incentives for beneficiaries to document that they meet goals for health behaviors through the use of wearables (Figure 1, item 1). Pharmacy needs a strategy to capitalize on these new data sources by effectively integrating them into the practice model. A majority of FPs believed that some patients will deny their healthcare providers access to data from wearables (Figure 1, item 2). Thus, as part of these efforts, pharmacists must influence health policy by fostering and demonstrating the value of data sharing in improving medication use while ensuring patient confidentiality and respecting patient wishes.7

# USE OF ARTIFICIAL INTELLIGENCE TO INCREASE VALUE

People struggle to perform complex statistical calculations, but machines do them well. Thus, it is no

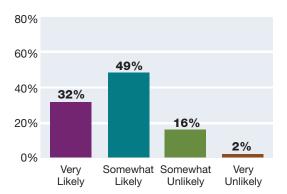
surprise that most data processing can be automated.8 A large majority of FPs predicted that in health systems, advanced data analytic techniques will be employed to guide therapeutic decision-making (Figure 1, item 3). Artificial intelligence (AI) refers to a handful of statistical methods applied to large data sets. AI may allow pharmacists more time for direct patient care. Using AI, machines can do data analytic work continuously in the background and identify potential issues. The "principle of complementarity" suggests that AI and human expert judgment reinforce each other when they are properly coordinated.9 A value-based strategy, unbiased by hype or fear, can upgrade pharmacy practice with AI. There are 3 parts of this value-based strategy: (1) identify time-consuming analytic tasks, (2) use AI to partially automate those tasks while directing pharmacist attention to salient patient issues, and (3) continuously evaluate the effects of AI.

## USE OF STATISTICAL PREDICTION IN PRACTICE

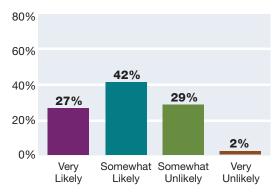
Interest in the use of statistical predictive models to improve clinical decision-making is growing. Models with sufficient predictive power are useful for forecasting the risks and benefits of medication use.10 Healthsystem pharmacists already use predictive models to estimate creatinine clearance, among other things. FPs were less confident that pharmacy departments will primarily employ nonpharmacist data analysts or that pharmacy departments will have their own analytics infrastructure (Figure 1, items 4 and 5). A quarter of FPs responded that these 2 outcomes were somewhat unlikely. This uncertainty among the FPs is understandable-it highlights the need for a national dia-

**Figure 1 (Data, Analytics, and Information Technology).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

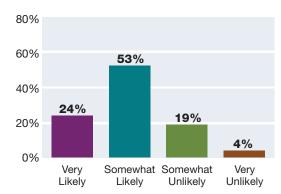
At least 75% of health insurance plans will provide incentives for beneficiaries to meet specific goals for healthful behavior as documented by wearable devices.



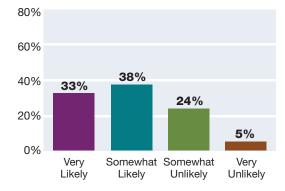
At least 25% of patients will deny their healthcare providers and health systems access to data from their wearable devices.



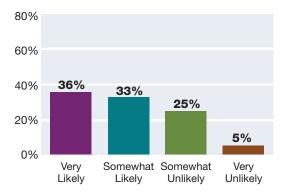
In at least 25% of health systems, advanced data analytic techniques (e.g., cognitive computing, artificial intelligence, machine learning) will be employed to guide therapeutic decision-making.



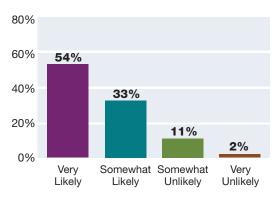
4 Most health-system pharmacy departments will primarily employ nonpharmacists who are formally trained in data architecture and analytics to manage their information systems and data analysis needs.



At least 50% of health-system pharmacy departments will have their own informatics infrastructure (not reporting to IS, finance, etc.) for managing medication-related data analytics and data architecture.



At least 50% of health systems will undertake significant EHR redesign efforts to enhance clinicians' ability to manage patients' medications across the continuum of care.



logue on how best to incorporate statistical prediction into practice for the purpose of informing medication-use decisions. Successful use of statistical prediction requires professionwide efforts to gather and analyze large amounts of data and then rapidly and widely incorporate lessons learned into practice.

Thanks to ultralarge data aggregation projects like FDA's Sentinel Initiative,11 many useful predictive models may soon be available to inform pharmacists' decisions. Two strategies are needed to implement them nationally. The first is to rank predictive models by potential utility. The second is to develop infrastructure (e.g., digital libraries and electronic health record [EHR] deployment capabilities) to facilitate predictive model adoption. Pharmacy requires a platform to share, deploy, and learn from the experience of using predictive models in practice.

## DEVELOPING AN ACTION AGENDA FOR THE HEALTH IT INDUSTRY

The idea that department-level strategy is sufficient for transforming pharmacy practice to improve care with technology should be rejected. Instead, health-system pharmacy leaders must engage in expanding regional-, national-, and internationalscale data analytics and technology initiatives.12 To benefit from the largescale infrastructure needed for success with data analytics, pharmacy must communicate a clear, actionable national agenda, encompassing telepharmacy, AI, and predictive analytics, to our EHR vendors and the rest of the health IT industry. Eightyseven percent of FPs believed it is likely that health systems will undertake significant EHR redesign efforts to enhance clinicians' ability to manage patients' medications across the continuum of care (Figure 1, item 6). These EHR redesign efforts would be more beneficial if they were guided by a national health IT industry "action agenda" that clearly articulates what

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- Develop a vision and strategic approach (both institutionally and professionwide) to effectively utilize technology to improve outcomes and advance practice.
- Develop new methods for monitoring and interacting with patients through technology and implement strategies that integrate these into practice.
- Collaborate with other stakeholders in discussions to improve access to patient information while respecting patient preferences and privacy concerns.
- 4. Apply the principle of complementarity by using AI to

- offload routine analytic work and simultaneously provide pharmacists with the most salient patient information.
- 5. Identify useful predictive models that inform pharmacists about medication-use issues, and collaborate with those who are developing information infrastructures that can generate and update these models on a national scale.
- 6. Initiate and support work that articulates the pharmacy profession's action agenda for the health IT industry to enable the changes needed to achieve technology-enabled practice transformation.

we need the industry to do. Haphazard, small-scale approaches to EHR redesign will fail to bring transformational improvement. With support from ASHP's Section on Pharmacy Informatics and Technology, health-system pharmacy leaders should help lead the development of a national health IT industry action agenda for pharmacy.

A purposeful technology strategy for pharmacy should focus on transforming practice to improve care. It should include more-frequent remote patient contact supported by new data sources, expanding time for direct patient care using AI, improving the information available to pharmacists using statistical prediction, pharmacist participation in large infrastructure initiatives supporting systematic learning about medication use, and development of a clear and powerful pharmacy action agenda for the health IT industry.

#### **DISCLOSURES**

The authors have declared no potential conflicts of interest.

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## The future business of pharmacy

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## INNOVATION IN BUSINESS STRATEGIES

he business of pharmacy from a health-system perspective continues to be a dynamic, rapidly evolving environment. Health systems are becoming increasingly reliant on pharmacy leaders to create innovative solutions that advance patient care and increase their pharmacy department's contribution to the organization's bottom line. Historically, pharmacy leaders have led costcontainment strategies, which alone have been insufficient to advance pharmacy practice. Health-system pharmacy leaders must demonstrate value by affecting patient outcomes across the continuum of care (well beyond the acute care setting) while finding novel ways of satisfying their fundamental professional responsibility of managing the supply chain.

## STRATEGY FOR EXPANDING AMBULATORY CARE SERVICES

The expansion of ambulatory care services brings the opportunity for increased revenue and further optimization of patient care. While 44% of

Forecast Panelists (FPs) believed that health systems will discontinue drugdispensing services because of insufficient financial margins (Figure 1, item 1), recent trends in ambulatory care pharmacy practice suggest an alternative view. Fueled by specialty pharmacy growth, accounting for 42.6% of net medication spending, drugdispensing services will continue to drive revenue for health systems.1 As health systems continue to enter the specialty pharmacy arena and achieve specialty pharmacy accreditation, practice will evolve from managing acute care needs to serving patients as their comprehensive health delivery hub—a role that must continue to be developed.

A majority of FPs affirmed that the number of health-system pharmacists serving in clinical roles in primary care will increase (Figure 1, item 2). Some FPs may have attributed this growth to increased activity in specialty pharmacy; however, the growing role in specialty pharmacy is unlikely to translate into new primary care pharmacy roles. A larger opportunity for new growth in primary care is through the Centers for Medicare and Medicaid Services' Chronic Care Management Program, which allows billing for services to Medicare patients through pharmacist-physician collaboration.2 Pharmacy leaders should leverage recent improvements in the administration of the program, justifying increased investment by health systems in these collaborations and generating revenue that will drive substantial development of primary care pharmacy programs.

# STRATEGY FOR DEVELOPING PHARMACY BENEFIT MANAGEMENT SERVICES

Over half of FPs indicated that growth will occur in the development of pharmacy benefit management services (PBMs) by health systems to meet their clinical and financial goals (Figure 1, item 3). If the incentives of value-based payment models continue in the future (e.g., accountable care organizations), health systems may be more likely to follow this path. Regardless of the future payment model, health systems must be flexible and responsive to evolving cost-saving strategies driven by existing prominent PBMs.

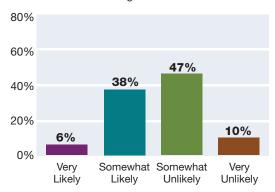
In response to specialty pharmacy growth within health systems, PBMowned pharmacies will continue to focus on recapturing specialty prescription volume. PBM "prescription trolling" or "poaching"—the practice of commercial PBMs actively seeking to have prescriptions transferred to their pharmacies without involving the patient—has created challenges for health-system specialty pharmacies.3 Health-system pharmacy leaders must be proactive in combatting these PBM strategies, countering with programs that leverage technology and giving pharmacists responsibility for responding to prescription refill and transfer requests, thus protecting the continuity of care and patient choice.

A similar phenomenon being driven by PBMs and health plans involves the shifting of expensive infused medications from the medical benefit to the pharmacy benefit. Termed "pharmatization," this practice further fragments the care of patients. This trend should lead health systems to explore new partnerships with local infusion pharmacies.

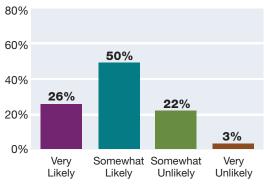
All health systems must be prepared to contend with established PBMs and PBM-owned pharmacies in order to meet the demanding requirements of remaining in network. Future research should compare the outcomes of care delivered by health systems and PBMs, which will likely show that health sys-

**Figure 1 (Business of Pharmacy).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

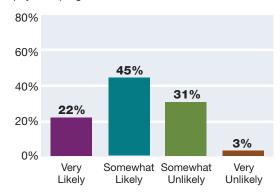
At least 25% of health systems will discontinue (or abandon plans to begin) drug-dispensing services (e.g., ambulatory prescriptions, distribution of specialty or infusion products) because of insufficient financial margins.



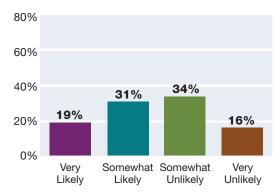
The number of full-time equivalent health-system pharmacists dedicated to clinical roles in primary care will increase by 50%.



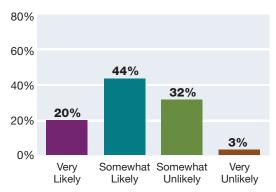
At least 50% of health systems will create their own pharmacy benefit management unit to manage financial risk and continuity-of-care issues for patients covered under capitated or bundled payment programs.



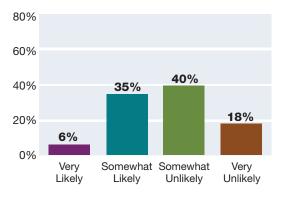
4 At least 50% of health systems will outsource the production of nearly all compounded sterile products.



Most health systems will find that regulatory requirements surrounding the use of opioid medications seriously compromise effective pain management.



The federal government will institute drug price controls, limiting the amount manufacturers can charge any U.S. customer for specific products.



tems demonstrate superior efficiency, customer service, medication compliance, and patient outcomes.

## PHARMACEUTICAL SUPPLY CHAIN DEVELOPMENTS

FPs were divided on outsourcing the production of sterile compounds (Figure 1, item 4). The supply chain of sterile injectable drugs continues to be unstable. The growth of 503B facilities that provide Food and Drug Administration-regulated compounded sterile injectable drugs may present a long-term solution to this volatile market. The 70 503B facilities existing in 2017 are held to higher standards than traditional compounding facilities (Churchill WW, Brigham Health, personal communication, 2017 Jun 20). Seeking supply chain stability, health systems are likely to encourage further growth in the number of dual-registered manufacturers.

Dual-registered corporations operate as conventional manufacturers but are also registered as 503B facilities and may seek partnerships with health systems. For example, Fresenius Kabi USA recently entered into an agreement to be the 503B supplier for a large health system in the Northeast.5 It is likely that such a model will be replicated, given the benefits to both the health system and the dual-registered manufacturer. Health systems will achieve greater supply chain stability for generic injectable medications and less price volatility without compromising quality. Dual-registered manufacturers take advantage of simpler licensing requirements and lower production costs.

As the market share held by dual-registered 503B manufacturers continues to increase, prices are likely to rise. Health systems or their collaboratives may respond to this economic phenomenon by developing their own 503B facilities. The likelihood of disrupting the traditional manufacturer—wholesaler—purchaser model will depend on the cost of entry for 503B facilities by health systems and the continued price and supply volatility they face.

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- Utilize existing data on the cost of chronic diseases to justify the implementation or expansion of primary care clinical pharmacy programs focused on caring for patients with multiple chronic conditions.
- 2. Assertively develop programs to safeguard patients from PBM tactics that increase risk and cost, fragment care, and limit patient choice.
- 3. Quantify the extent to which patients receiving i.v. infusions are impacted by "pharmatization" and coordinate a process

- to facilitate onsite or offsite care after PBM adjudication by the health system.
- 4. Partner with dual-registered manufacturers, or develop local facilities approved under 503B regulations, to increase supply chain stability and manage cost volatility for generic injectable medications.
- Implement and charge opioid stewardship programs under pharmacy leadership to proactively identify, counsel, and direct treatment of patients at risk for opioid abuse.

## LEGISLATIVE AND REGULATORY STRATEGIES

New and pending federal and state legislation responding to the opioid epidemic and continuously increasing drug prices will continue to challenge health-system leaders. Accreditation organizations (e.g., Joint Commission) will continue to refine standards addressing concerns about opioid utilization in pain management.6 Legislative actions that limit prescribing volumes and new regulations that require extensive data collection, monitoring, and analysis will pose challenges as pharmacy leaders struggle to provide effective pain management. Given these new standards and increased scrutiny from the Drug Enforcement Administration, a majority of FPs believe that it is likely that those requirements will seriously compromise patient care (Figure 1, item 5). Many of the efforts by health systems to combat opioid misuse and abuse have been reactionary in nature (e.g., dispensing naloxone). Health-system leaders should seek proactive strategies, such as establishing opioid stewardship programs that use predictive tools to identify and intervene in the care of patients at risk for addiction.

The lack of substantive federal legislation on drug pricing, despite growing public scrutiny, explains the position of 41% of FPs who predicted that the federal government will institute drug price controls in the United States (Figure 1, item 6). Although federal action has not occurred, multiple states have passed legislation aimed at increasing financial transparency and penalizing manufacturers for predatory pricing.7 Further state actions are likely to occur in the next 5 years. Federal legislation affecting the price of generic products may occur in the next 5 years, but political pressure will likely protect branded manufacturers from future price-control efforts.

#### **DISCLOSURES**

The authors have declared no potential conflicts of interest.

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## Complex times: Leaders thinking and acting differently

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## LEADERSHIP FOR THE FUTURE

ontemporary problems facing ✓ health-system pharmacy leaders are increasingly "wicked"—problems that are hard to diagnose and involve multiple stakeholders and domains.1 Wicked problems are relentless. Solutions are temporary, as issues constantly morph into new problems with no obvious solutions and profound implications. Leaders must become wicked-problem solvers, relying less on top-down commandand-control wisdom and increasingly on cross-boundary team-based collaboration, rapid-cycle experimentation, and validation of the next best step in the right direction as they explore solutions to seemingly unresolvable issues.2 Today's pharmacy leaders face perplexing demands for a different approach to strategy, decision-making, and workforce leadership and engagement and for new approaches to not only responding to change but creating it to radically transform the care delivery system.

#### **EXECUTIVE LEADERSHIP**

Physicians are assuming executive leadership in increasing numbers as organizations tackle clinical integration, management of population health, and performance improvement. This broader emphasis on clinical leadership places enormous demand to move strategy in a totally different direction. Physicians' skills, experiences, and medical knowledge may be extremely beneficial to achieving patient-centric safety and quality goals and clinical change.3 Preliminary research suggests that physicians' clinical experience and insight into frontline issues will change the decision-making lens to one that is more decisive and focused on the execution of change.4

Forecast Panelists (FPs) believed that physician leadership will definitely create new opportunity and advantage to influence strategic and clinical issues (Figure 1, item 1). This will enhance the opportunity for strong clinical and business expertise across an executive team, regardless of experience and credentials. Pharmacy leaders must be positioned and prepared to influence that team and shape pharmacy enterprise strategies within organizationwide goals to advance both business and patient care improvement initiatives within the prevailing C-suite team, regardless of its constituents. The pharmacy enterprise is material to the profitability of every healthcare organization and offers a unique opportunity for new business, new service lines, and new patient service and convenience, resulting in a positive contribution to the bottom line.

#### **WORKPLACE EXPECTATIONS**

Workplace expectations have changed dramatically for both em-

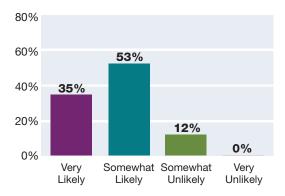
ployers and employees. Lean organizations must find agile solutions for a growing number of wicked problems-all placing unprecedented pressures on employees. Work-life balance has become an acute problem. For seasoned leaders, this may well mean leaving positions earlier due to the stress of complex demands and conflicting pressures, as a majority of FPs noted (Figure 1, item 2). For employees, regardless of generation, this translates to the growing need for more personal control over their work. While FPs were divided in their predictions of changes needed to accommodate the expectations of younger pharmacists (Figure 1, item 3), it seems clear that leaders must respond to the needs of millennials as they become the majority of the workforce within the next few years. The disconnect in work-life balance expectations between employers and employees will need to be addressed in order to attract, retain, and effectively develop talent.

Beyond generational expectations is the issue of gender. With more women in the workforce, combined with the continuing social expectation that they shoulder most of the responsibility for family needs, the issue of balance becomes more acute.

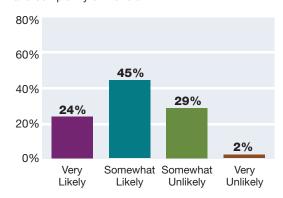
The language we use to frame these issues is important—balance suggests a fulcrum-based relationship between life and work—a zero-sum game, something we want but cannot achieve. The concept of work—life fit has been adopted by the American Psychological Association and Society for Human Resource Management<sup>5</sup> to emphasize flexibility and reduce emphasis on "the inconvenient fact that some people have children" and to emphasize flexibility for all workers as a means to enhance performance and joy in work.<sup>6</sup>

**Figure 1 (Pharmacy and Health-System Leadership).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

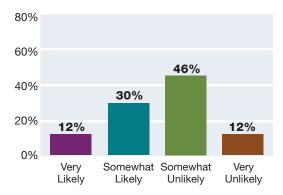
In at least 50% of health systems that appoint physicians to executive leadership positions, pharmacists will gain important new opportunities to influence strategic and clinical issues.



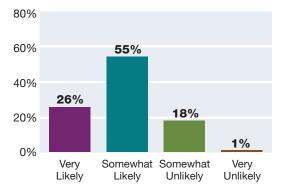
At least 25% of seasoned leaders of health-system pharmacy enterprises will leave their positions earlier than expected because of increasing stress and complexity of the role.



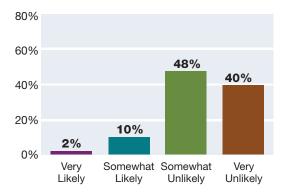
At least 25% of health systems will explicitly redefine the requirements and expectations of pharmacy practice leaders to better accommodate the work–life balance expectations of younger pharmacists interested in taking on leadership roles.



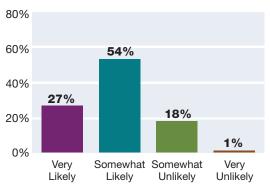
4 Most health systems will invest in coordinated action to give more staff members leadership opportunities in order to facilitate succession planning and improve employee engagement and retention.



The number of health systems with unionized pharmacists will increase by 25%.



Most pharmacy leadership development programs (including residencies) will significantly expand their training in emotional intelligence.



#### **NEW LEADERSHIP**

Many of the changes inherent in the transformation of care fall outside the top-down leadership skills of the past. This transition creates challenges for many positional leaders, adding to the complexity and stress of the leader role, including dealing effectively with a radically changing environment. The functional redesign of service mix and rapid response to environmental changes introduce another level of risk and entry into new areas of practice, often without certainty or experience. Managing the complicated challenges of day-to-day practice, while simultaneously envisioning innovative solutions for a transformed care delivery process, is daunting but essential.7 Engaging team members in this vision and fostering a sense of ownership in goal achievement substantially add to the forward momentum and creativity essential to transformation.8,9 Often, leaders respond to being overwhelmed in this new environment by the adoption of quick actionable fixes, oversimplification, and reflexive reactions. "Living in the question," letting go of control, finding new paths, and collaborating for solutions outside traditional boundaries and in the broader community are the tactics of necessity.

#### **BENCH STRENGTH**

As seasoned leaders contemplate retirement or reduced commitment to their role, investment in leadership development and succession planning are essential. A clear majority of FPs expected organizations to increase their focus on succession planning (Figure 1, item 4). Clearly, too few organizations have made substantial investments other than at senior levels of leadership, and this must become a priority. As we recognize the importance of dispersed leadership at every level of the organization—particularly the need for skilled clinical leadership in the coordination of team-based, cross-boundary care-the need transcends succession to senior leadership, underscoring the need for dis-

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- Establish strategic engagement with executive leaders that is focused on rapid response to wicked problems, adopting a system- and results-focused mindset and emphasizing a patient-centric focus.
- 2. Pursue succession planning at every level of the pharmacy enterprise, coupled with leader assessment and individual skills development, as a standard practice.
- 3. Work with senior leaders and human resources to proactively make work-life fit a fundamental workplace issue. Facilitate work redesign and new metrics for collaborative team performance.
- 4. Require training and development at all levels to include

- self-awareness, emotional and cultural intelligence, and skills development focused on leading self and others and creating transformational change within the larger organization.
- 5. Using innovative communication tools and channels, increase focus on the shared purpose of enhancing patient outcomes to affect organizational culture and employee morale and engagement and to foster joy and resilience in the workforce.
- 6. Expand leadership development to provide continuing, career-long personal commitment to expanding leadership skills at all levels.

persed leadership throughout the organization.

Paradoxically, leadership skills development is inadequate in our education and training, and few of our highest potential talents are equipped to handle emerging leadership responsibilities. Knowledge of the business aspect of healthcare and the pharmacy enterprise remains important, but, as noted by the FPs, self-awareness and emotional intelligence for influence, lateral leadership, and the ability to advance agile, flexible, and adaptable strategy are essential leadership survival skills (Figure 1, item 6).10,111 Strong people skills are vital. Effective communication, the building of trust and engagement, ownership of commitment, and the willingness to take risks (and to fail) are essential while seeking innovation and transformation. Leaders must be skilled to move strategy forward while teaming effectively, often on the fly, across boundaries and in conditions of uncertainty.2

#### **DISCLOSURES**

The authors have declared no potential conflicts of interest.

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## Advanced pharmacy technician roles: Professionalizing pharmacy's technical workforce

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## EXPANDING PHARMACY'S CAPACITY

There is growing understanding in all sectors of pharmacy that advancement of the profession's capacity to promote health and well-being depends in part on the professionalization of pharmacy technicians. For pharmacy to be truly faithful to the public interest, it must ensure that its technical workforce is well educated, tested for competency, and sufficiently compensated to attract bright, career-oriented individuals.

A recent stakeholder conference identified an agenda for pursuing uniform national standards for entry-level pharmacy technicians.<sup>3</sup> Achievement of that agenda will bolster pharmacists' confidence in delegating much more responsibility to technicians, thereby freeing themselves for a larger role in patient care. These developments will stimulate innovation in advanced roles for pharmacy technicians, which is the primary focus of this chapter.

## REQUIRING ACCREDITED EDUCATION

A large majority of Forecast Panelists (FPs) predicted that by 2022 at least half of health systems will require ac-

credited education for new entry-level pharmacy technicians (Figure 1, item 1). Currently, only 18% of pharmacy technicians in hospitals have received accredited education.4,a However, it seems plausible that more new technician hires will be required to have completed accredited education, which would allow them to become fully productive more quickly. It also seems likely that accredited education will generally be a prerequisite for advanced roles for technicians. In the near term, access to standards-based technician education will expand by (1) tapping the underused capacity of existing accredited programs, (2) launching new programs, and (3) fostering innovations in distance education.3

## PREPARING TECHNICIANS FOR ADVANCED ROLES

Opportunities for technicians to prepare for advanced and specialized roles in health-system pharmacy are likely to grow. Might accredited residency education become part of such opportunities within the next 5 years? One fourth of FPs said this is "very likely" to happen and one-third said "somewhat likely" (Figure 1, item 2). At least 1 technician residency program already exists.5,b The prevailing association of the term residency with postgraduate physician and pharmacist education might inhibit widespread creation of technician residencies. More important than the nomenclature of educational programs will be clarity in career paths (and related qualifications) for technicians who have the desire and aptitude for expanded responsibilities.

Only 12% of FPs said it is very likely that even a small proportion of health systems within the next 5 years will require certified technicians to have a bachelor's degree for advanced roles (Figure 1, item 3). Nevertheless,

if pharmacy makes progress in professionalizing the occupation of the pharmacy technician (including substantially increasing compensation), more college-educated individuals will be attracted to the field. Further, for certain advanced technician functions, some health systems might give priority to individuals who have earned a college degree.

#### **MANAGING ROBOTICS**

Robotic automation is becoming a dominant approach to medication distribution. When coupled with the use of barcode verification, robotic systems have demonstrated a reduction in the rate of medication-distribution errors. The sophistication of these systems is eliminating the need for pharmacist verification of final products.

Management of robotics will be a growing responsibility of technicians. FPs agreed: 90% predicted that at least some of pharmacy technician time will be dedicated to managing robotic applications in medication preparation and distribution within the next 5 years (Figure 1, item 4). Some state boards of pharmacy have already reduced requirements for pharmacist oversight of technicians managing robotic systems.<sup>7</sup>

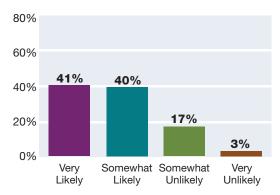
## SUPERVISORY RESPONSIBILITIES

Increasingly, leaders of the pharmacy enterprise are focusing on interdisciplinary clinical quality and safety initiatives, leaving less time for oversight of core operational functions. In light of this development, it is encouraging that many health systems have created pharmacy technician career ladders that lead to advanced responsibilities (including supervision).

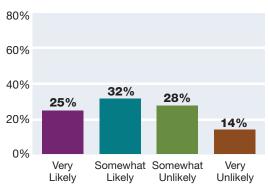
ASHP data indicate that technicians supervise other technicians

**Figure 1 (Advanced Pharmacy Technician Roles).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

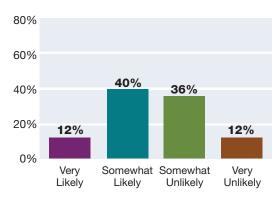
At least 50% of health systems will require accredited education and training for new entry-level pharmacy technicians. {Note: This is a separate issue from certification. In the 2015 ASHP national hospital survey, 18% of all hospital pharmacy technicians had received accredited education and training.}



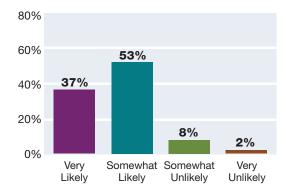
Formal accredited technician residency programs will exist to prepare pharmacy technicians for advanced roles.



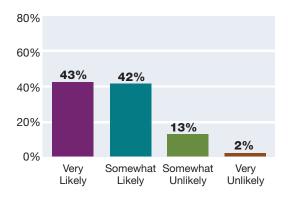
At least 10% of health systems will require certified technicians to have a baccalaureate degree for advanced roles.



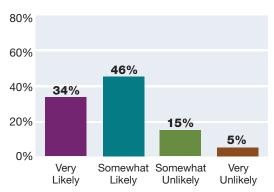
4 At least 25% of pharmacy technician time in health systems will be dedicated to managing robotic applications in medication preparation and distribution.



In 75% of health systems, entry-level pharmacy technicians will be supervised by senior pharmacy technicians.



In 50% of health systems, pharmacy technicians will collect patient information and document it in electronic health records to facilitate clinical decision-support systems.



in about one third of hospitals.<sup>4</sup> Advanced-level technicians will increasingly supervise entry-level technicians in areas such as job training, staffing assignments, performance assessment, and compliance with basic employment requirements. This would be consistent with the prediction of FPs: 85% indicated that in at least three fourths of health systems, entry-level pharmacy technicians will be supervised by a senior pharmacy technician (Figure 1, item 5). A technician supervisor could effectively become a pharmacist–leader extender.

#### **CLINICAL DECISION SUPPORT**

Technicians can also become pharmacist-clinician extenders. Those trained to collect medication histories and document this information in the electronic health record (EHR) can improve the productivity and efficiency of pharmacist clinicians.8 FPs predicted that pharmacy technicians in at least half of health systems within the next 5 years will collect patient information and document it in EHRs to facilitate clinical decision-support systems (Figure 1, item 6). Technicians in about 30% of hospitals already collect medication histories.4 In about 9% of hospitals, pharmacy technicians are involved in facilitating transitions of care and in criteria-based screening of patient records to identify medication-related problems for pharmacist follow-up; in about 5% of hospitals, technicians prepare clinical monitoring information for pharmacist review.4

<sup>a</sup>Among all hospital pharmacy technicians, 78% are certified by the Pharmacy Technician Certification Board.

<sup>b</sup>There is no accreditation program for pharmacy technician residencies.

#### **DISCLOSURES**

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#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. In your department's strategic plan, give priority to achieving a high level of professionalization, job satisfaction, and career commitment of technician staff. Recognize that this will probably require a formal career ladder that specifies how technicians can advance in their responsibilities and compensation.
- Collaborate with the leaders of the human resources department to ensure that pharmacy technicians are compensated equitably, taking into account their credentials, level of responsibility, and parity with technical personnel in other disciplines.
- 3. Establish a date by which all new pharmacy technicians in your department will be required to have completed accredited entry-level education as well as certification.

- 4. Convene major employers of pharmacy technicians in your region, in all sectors of practice, and assess the extent to which your state laws and regulations related to pharmacy technicians require modification in the interests of public safety and pharmacy's alignment with public needs. Develop strategy and tactics to pursue necessary changes.
- 5. Assess whether sufficient opportunities exist in your region for accredited pharmacy technician entry-level education, taking into account the needs in all practice sectors, the emergence of distance education, and potential partnerships with high schools and community colleges. Develop strategy and tactics to close any gaps.

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# Population health management: A community imperative

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#### **HEALTHCARE VERSUS HEALTH**

Population health has various meanings for different audiences. For the purpose of this chapter, we have used the Kindig and Stoddart<sup>1</sup> definition, which (in the context of a forecast for pharmacy leaders) focuses on a comprehensive approach to caring for patients in full consideration of determinants of health beyond care delivery. As hospitals and health systems engage in at-risk contracts for patient lives, managing what happens to the patient outside the acute care setting and during transitions of care is key to achieving optimal outcomes.

## FORMULARY STANDARDIZATION

A majority of Forecast Panelists (FPs) predicted that medication formularies will be standardized across the continuum of care (Figure 1, item 1). In 2012, the Centers for Medicare and Medicaid Services (CMS) finalized the Hospital Readmissions Reduction Program, which is used to calculate a hospital's excess readmission ratio. Hospitals are penalized if patients with any 1 of 6 different conditions are readmitted within 30 days. Standard-

ized medication formularies across acute and outpatient health-system settings have the potential to decrease transitions-of-care issues and support efforts to decrease readmissions.<sup>2</sup>

## "CERTIFICATE OF NEED" PROGRAMS

FPs were almost evenly split (51% versus 49%) on whether states will require certificate-of-need (CON) programs for healthcare facilities (Figure 1, item 2). CON programs originated to regulate the number of beds in hospitals and nursing homes and prevent purchasing more equipment than necessary. Currently, 35 states and the District of Columbia have CON regulations that prohibit entry or expansion of healthcare facilities.3 The original intent of CON regulations 40 years ago (improve access and quality and decrease costs) has not been met, and more states will repeal their CON restrictions in the next 5 years. Pharmacy leaders should monitor their specific state's CON status, and stay abreast of all health entity growth in their area.

## HEALTH-SYSTEM FUNDING OF COMMUNITY PROGRAMS

Many small rural hospitals are the centerpiece of their community and actively engage in community health programs such as diabetes education, immunization initiatives, and nursing services in public schools (Barron C, Fort HealthCare, personal communication, 2017 Oct 26).4 Their efforts to improve their employee wellness spill over into the community. FPs almost evenly predicted that it was either somewhat likely or somewhat unlikely (45% versus 37%) that health systems would fund community programs (Figure 1, item 3). Health systems will increasingly support (either

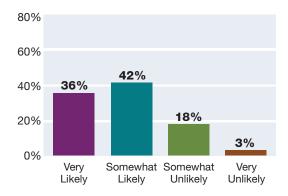
through direct sponsorship or through their foundations) community health programs such as running or biking events and needle exchange programs; however, line-item health system budgets will not regularly include community health programs unless there has been a proven return on investment. Pharmacy leaders should look for opportunities in their communities for themselves and staff to engage in population health initiatives.

#### COMMUNITY HEALTH-IMPROVEMENT COLLABORATION

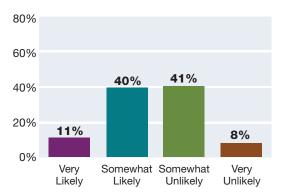
Eighty percent of FPs predicted that it was very or somewhat likely that competing entities (e.g., health systems, retail pharmacy chains, physician practices) in 25% of healthcare markets will collaborate on community health-improvement initiatives (Figure 1, item 4). Retail pharmacy chains can provide primary care services to patients, including laboratory tests, immunizations, preliminary diagnoses, and medication prescriptions. In May 2017, the CMS Innovation Center launched a 5-year, \$157 million test of a payment model called the Accountable Health Communities program. It selected 32 "hub" organizations (hospitals, health systems, local government agencies, foundations) to support in an initiative to screen patients and coordinate care in their community and surrounding area (physician practices, behavioral health providers, clinics, and hospitals).5 The degree of alignment with mission and vision among entities will likely determine the success of these initiatives. There are also future technology (e.g., big data)6 and organization (e.g., Amazon)7 disruptions that will affect collaborations between competing entities.

**Figure 1 (Population Health Management).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

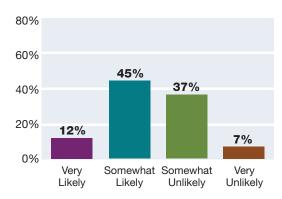
Most health systems that offer insurance products will standardize their medication formularies across the continuum-of-care (i.e., same inpatient and outpatient formularies).



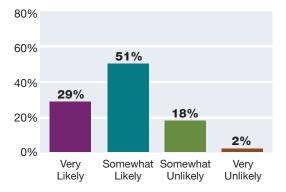
Nearly all states will require certificate-of-need (CON) programs for healthcare facilities, in order to reduce technology and service redundancies and manage costs. {Note: As of the summer of 2016, 15 states had folded their CON programs since the federal CON mandate was repealed in 1986.}



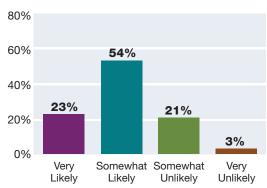
At least 25% of health systems will fund community health programs (e.g., improving air quality, food security).



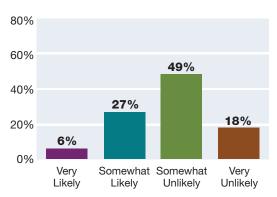
4 Competing entities (e.g., health systems, retail pharmacy chains, physician practices) in 25% of healthcare markets will collaborate on community health-improvement initiatives.



Evidence will exist that accountable care organizations lower the trajectory of cost increases (bend the cost curve).



6 Federal regulations will mandate reduced use of heroic measures in end-of-life care.



#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. Understand that *population health* is a global term, whereas *population health manage- ment* emphasizes financial and
  clinical outcomes.
- Monitor population health programs that are being developed within health systems and incorporate pharmacyand medication-related influences that will improve healthcare outcomes.
- 3. Include education and training activities that create pharmacy-centric data and programs to support population health efforts throughout the health system.

- 4. Identify the department or person in your organization who monitors "certificate of need" regulations and be positioned to react to changes.
- 5. For institutions that have an independent ACO, consider creating an ACO chief pharmacy officer position.
- 6. Develop a program for pharmacy staff to participate competently and confidently in end-of-life and palliative care issues, discussions, and programs.

## ACCOUNTABLE CARE ORGANIZATIONS

To date, accountable care organizations (ACOs) have had variable success in saving healthcare dollars. A total of 20 ACOs in the Pioneer program (a CMS pilot of the ACO model that ran from 2012 to 2016) and the 333 ACOs in the shared-savings program reported total savings of \$411 million.8 However, after paying bonuses, the ACOs recorded a net loss of \$2.6 million to the Medicare trust fund. a fraction of the half-trillion dollars Medicare spends on the elderly and disabled each year. The FPs predicted that it is likely or somewhat likely that ACOs will be able to demonstrate cost-effectiveness in the future (Figure 1, item 5). Difficulties have arisen in the transition from a provider feefor-service model to a value-based, atrisk model. Hospital-based ACOs have incentives to increase population size. In an ACO model of reducing costs, hospitalizations, and high-cost specialists and tests, hospital incentives are not aligned. The ACOs that are able to enhance their marketing and business practices, as well as maximize the

use of ambulatory care pharmacists and nurse practitioners, will be able to improve quality and bend the cost curve. An ACO chief pharmacy officer would be able to implement pharmacy services that will contribute to overall positive financial outcomes.

#### **END-OF-LIFE CARE**

Of particular interest is the number of states<sup>9</sup> that have approved, via referendum, "assisted suicide." Five states (California, Colorado, Oregon, Vermont, and Washington) and Washington, D.C., legalized physicianassisted suicide via legislation; physician-assisted suicide was made legal in Montana via a court ruling. A majority of FPs predicted that it was unlikely that federal regulations will mandate reduced use of heroic measures in end-of-life care (Figure 1, item 6). Religious and cultural beliefs are the primary drivers for voter opinions on this issue. Beginning in 2016, Medicare pays providers for discussions with patients about advance care planning and advanced directives as well as hospice and palliative care. Additional, more-specific federal regulations will likely not be crafted. Spending on Medicare beneficiaries in their last year of life accounts for about 25% of total Medicare spending on beneficiaries age 65 years or older.<sup>10</sup>

#### **DISCLOSURES**

The authors have declared no potential conflicts of interest.

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## Public policy imperatives to improve medication use

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## PHARMACY IN THE PUBLIC HEALTH SPACE

pharmacists are widely accessible in their communities and health systems, and their unique expertise make them well suited to address emerging public health challenges. As medications will remain an essential component of successful care, the importance of pharmacist's expertise in pharmacology, therapeutics, drug interactions, pharmacokinetics, and pharmacogenomics will continue. There are ongoing opportunities for pharmacists to optimize medication use and mitigate medication misuse.

## ADDRESSING THE OPIOID CRISIS

The devastating impact of abuse and misuse of opioids is clear, and the Forecast Panelists (FPs) clearly see that pharmacists can play an important role in implementing various solutions. Immediate access to naloxone to treat opioid overdoses can be lifesaving. Most FPs were confident that states would make naloxone available without a prescription, and at least 46 states have at least 1 law expanding access to the drug (Figure 1, item 1). As these regulations develop,

pharmacists will need to establish procedures to appropriately provide naloxone without a prescription per their state's requirements. Given the increasing cost of naloxone, doing the right thing for public health may come at a substantial cost for some pharmacies. Pharmacists should be prepared to promote changes in the reimbursement paradigm for naloxone.

For health systems and the community, FPs thought it was likely that opioid stewardship programs would become more common. A clear majority of FPs predicted that it was likely or very likely that at least 50% of health systems will participate in a formal communitywide opioid stewardship program (Figure 1, item 2). Stewardship programs incorporate leadership commitment for the target area and a team with relevant expertise to prioritize, act, track, report, and educate in defined areas to improve medication use.2 Pharmacists have vast experience designing and maintaining stewardship programs in other areas, most notably antimicrobials and anticoagulation. As standards for antimicrobial stewardship programs have emerged, a designated pharmacist is a requirement, and the same approach should be taken as opioid stewardship programs are established.3 Further, pharmacists could bring value across the health system by establishing standards for medication stewardship programs that would be relevant across all therapeutic areas.

The opioid crisis has led to more patients who need addiction treatment, and pharmacists could play a larger direct patient care role in providing these services. Many FPs predicted that pharmacists in at least 25% of health systems will manage the care of patients with addiction (Figure 1, item 3). Historically, substance abuse treatment has not been an area of focus for pharmacist education and

training.<sup>4</sup> Currently, this is an area of practice with few defined training pathways, so pharmacists will need to develop their competencies and skills to care for these patients through lessformal mechanisms such as self-study and site visits to established practices.

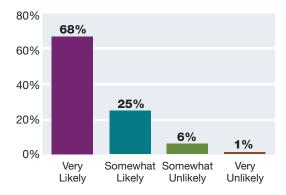
## A NEW CHRONIC DISEASE EMERGES

As new therapies for cancer continue to be approved and the use of current treatments is optimized, the paradigm of cancer treatment is changing. While the ultimate goal should be cure, in an increasing number of cancers cure may not be achieved with newer "targeted agents," which are designed to control the proliferation of cancer cells, as opposed to cytotoxic anticancer agents that kill tumor cells. The consequence of this paradigm change is that some cancers are now treated with medications over many years, analogous to chronic conditions like diabetes and hypertension. Most FPs thought it was likely that at least 50% of newly diagnosed and treated cancer patients will survive and require ongoing cancer care for 10 years or longer (Figure 1, item 4). This new reality offers pharmacists a range of opportunities to optimize the care of these patients, including selection of optimal medications based on a patient's cancer genome and education of patients about the critical importance of medication adherence over many years.

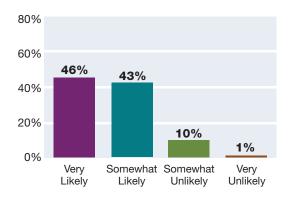
Much of the progress to make cancer a chronic condition may be fueled by precision medicine approaches, such as selecting medications based on the somatic genetic variation in the patient's cancer cells. One recent review listed over 20 different actionable genetic variants for cancer with many more corresponding therapies, and the number of variants and medications will grow in the coming years.<sup>5</sup>

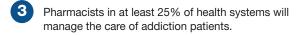
Figure 1 (Public Policy Imperatives). Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

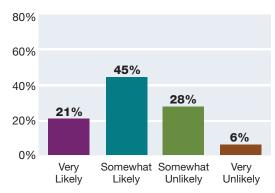
At least 90% of states will allow patients to obtain naloxone without a prescription.



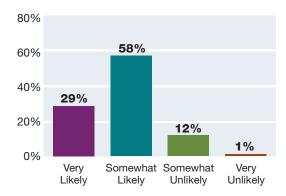
At least 50% of health systems will participate in a formal communitywide opioid stewardship program.



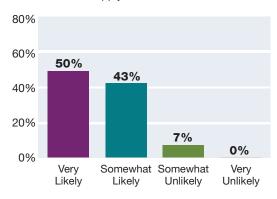




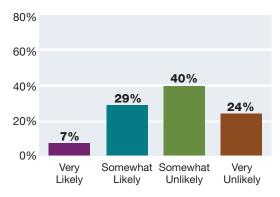
4 At least 50% of newly diagnosed and treated cancer patients will survive and require ongoing cancer care for 10 years or longer.



At least 50% of health systems will have policies addressing the rationing of effective antimicrobials that are in short supply.



At least one consortium of health systems will begin manufacturing generic medications from raw ingredients for sale to its individual member facilities in response to price increases or shortages.



A defined process to carefully select medications that are optimal based on the patient's somatic and germline genetic variants while also considering the patient's medications for the management of comorbid conditions is an evolving challenge for healthcare professionals, including pharmacists, oncologists, and pathologists. An increasing number of organizations are establishing "molecular tumor boards" to manage these processes, and pharmacists are integral to the success of that strategy.<sup>6</sup>

As cancer evolves into a chronic condition, cost will become a driving concern, and the current specialty pharmacy response to high-cost care will fragment the care of cancer patients. Pharmacists must play a leading role in helping patients navigate the complex system to access these life-sustaining medications and enhancing programs to promote the continuity of medication use.

## TOUGH CHOICES FOR SCARCE MEDICATIONS

Pharmacists work constantly to prevent patient harm from the shortages of vital medications that continue to plague the United States. A clear majority of FPs thought it was likely or very likely that at least 50% of health systems will have policies addressing the rationing of effective antimicrobials that are in short supply (Figure 1, item 5). Proactively establishing explicit policies to guide the difficult choices that occur with drug shortages will facilitate effective allocation of available medications. Ethical dimensions of the rationing scheme should be considered, and some models are available.7 By establishing best practices, pharmacists could have a broad impact on healthcare.

Ultimately, more creative solutions will be needed for obtaining expensive and scarce medications. FPs thought it

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. Pharmacists must accept and act on their responsibility to leverage their unique skills in response to public health challenges.
- 2. Pharmacists should lead the development of best practices for ensuring access to naloxone without a prescription as soon as legally authorized, and conduct an assessment of other pharmacist contributions to combat opioid misuse and addiction treatment.
- Develop overarching standards for medication stewardship, drawing from successful programs in antimicrobial and anticoagulation management, and apply those standards to addiction care and other

- conditions that warrant close attention by pharmacists.
- 4. Identify and implement programs that manage an increasing number of cancer patients who will need care over many years, focusing on medication selection and access, patient monitoring, adherence support, and continuity of care.
- Pharmacists should lead the development of best practices for "molecular tumor boards" without ignoring these patients' other chronic comorbid conditions.
- 6. Develop policies and practices for managing drug shortages that address the ethical concerns of rationing scarce medications.

was very or somewhat unlikely that a consortium of health systems would begin to manufacturer generic medications from raw ingredients as a response to shortages or price increases (Figure 1, item 6). Bold moves such as this may be needed to provide lasting solutions.

#### **DISCLOSURES**

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## Coping with uncertainty and chaos: Leading in ambiguous times

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## **LEADING IN AMBIGUOUS TIMES**

he 2016 U.S. presidential and congressional elections were bitterly contested events, underscoring the extent to which American society had become polarized into conservative and liberal camps. The outcome—Republican control the White House and both houses of Congress-portends substantial shifts on a number of social and political issues, including healthcare reform. The uncertainty arising from these shifts has led to instability and chaos in the world of healthcare finance. Understandably, many Americans feel less certain about how healthcare will be provided and paid for in the future.

To explore this mood of ambiguity, the 2018 *Forecast* survey included a set of items related to the potential impact of uncertainty on dimensions of health-system pharmacy, including healthcare financing, population health, the new drug approval process, drug costs, and future practice roles of pharmacists. We have a leadership imperative to guide health-system pharmacy strategically through these ambiguous times. These *Forecast* results are intended to help us in this endeavor.

#### **HEALTHCARE FINANCING**

Given the chaotic climate in healthcare today, it is understandable that Forecast Panelists (FPs) appeared pessimistic about the potential to create new programs and about the financial viability of some health systems. A clear majority of respondents predicted at least a 25% reduction in investment in new programs (Figure 1, item 1). This is particularly significant for pharmacy departments, given the costs of initiatives (e.g., compliance with United States Pharmacopeia chapter 800) and the capital investment required to develop projects to improve efficiency (e.g., shared service centers). In addition, 61% of FPs felt that the annual number of hospital and health-system bankruptcies will increase by at least 25% over the next 5 years (Figure 1, item 2). The implications of this forecast are stark: potential citations for regulatory noncompliance, inability to "grow" the pharmacy enterprise, and-most importantly-a likely downturn in access to and quality of patient care services.

As of this writing (July 2017), the fate of the Affordable Care Act (ACA) remains uncertain, as does the prospect of replacing it with an alternative plan for affordable insurance. As a result, exchanges are in shambles, and insurers offering ACA plans are leaving the market. By 1 estimate, over 400 counties nationwide (mostly rural) will likely not have a single ACA plan by 2018, and almost 1,800 counties will have greatly reduced coverage.1 It is not surprising, therefore, that 80% of FPs predicted a significant upturn in the amount spent by health systems on unreimbursed charity care (from the current 3% to 10%) (Figure 1, item 3). This would stretch most health systems to the breaking point, resulting

in draconian cuts in pharmacy personnel and substantial declines in the quality of patient care.

#### **DRUG COSTS AND RISKS**

Drug price increases continue to outpace broader inflation statistics, although wages and the consumer price index have been relatively stagnant.<sup>2</sup> Since insurers are unwilling to absorb all of these increases, hospitals are faced with even lower margins and a greater challenge to their fiscal viability.<sup>3</sup>

Current congressional efforts to reduce regulatory barriers to the drug approval process will likely result in the release of more (and more expensive) drugs, as well as increased risks associated with drug use. Most FPs felt that health systems will significantly expand risk-management strategies in their formulary review process (Figure 1, item 4). One important implication is that health systems will be required to develop programs aimed at smarter use of high-cost resources (including drugs).

Adding uncertainty is the proposed executive order on drug prices, which would strengthen patent protection and withdraw parts of the 340B Drug Pricing Program, creating greater financial risks for many disproportionate share hospitals.

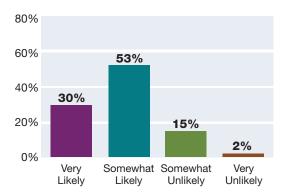
Drug shortages created by the pharmaceutical industry (e.g., i.v. sodium bicarbonate) have created further chaos for health-system pharmacists. However, such crises may actually present an opportunity for expanded pharmacy services such as creating 503B compounding facilities.

#### OTHER SURVEY FINDINGS

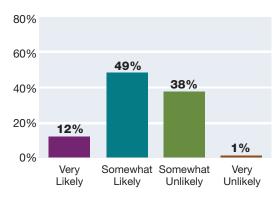
Over the past decade, healthcare in the United States has been moving

**Figure 1 (Coping With Uncertainty and Chaos).** Forecast Panelists' responses to the question, "How likely is it that the following will occur by the year 2022 in the geographic region where you work?"

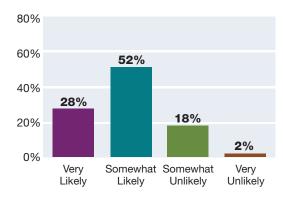
Uncertainty in healthcare financing will lead healthsystem executives to reduce investment in new programs by at least 25%.



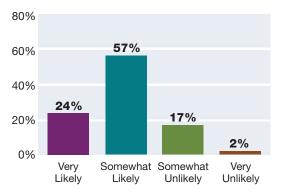
The annual number of hospital and health-system bankruptcies will increase by at least 25%.



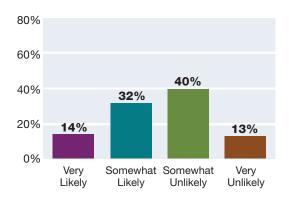
Unreimbursed charity care will consume 10% of health-system spending. {Note: According to a 2013 report from the Kaiser Family Foundation, the cost of "uncompensated care" provided to uninsured individuals was \$84.9 billion, approximately 3% of total national health expenditures that year. Uncompensated care includes healthcare services without a direct source of payment.}



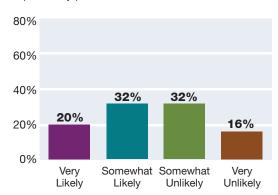
Due to a reduction in regulatory rigor around new drug approvals, 75% of health systems will significantly expand risk-management strategies in their formulary review processes.



5 Life expectancy at birth for Americans will decline at least 1 year.



At least 50% of states will loosen regulation related to pharmacy practice.



#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. Plan for uncertainty. Develop strategic plans with an awareness of the ambiguity associated with today's healthcare environment. Develop a process of continuous reexamination of plans that allows an immediate response to changing conditions in the health system.
- 2. Focus on the basics. Be prepared for significant reductions in revenue by ensuring good stewardship of your organization's financial resources and focusing on core business operations such as sterile products production, safe automated distribution, and optimal inventory management to reduce waste of expensive products.
- 3. Continually remind your administration of the value of a well-managed pharmacy enterprise (both its financial value

- and its contributions to patient care outcomes). Stress the importance of a strong professional pharmacy staff that ensures that the health system derives optimal value from drugs.
- 4. Engage your health system's media and government relations team in supporting state and federal legislation to combat drug price inflation and allow pharmacists to practice at the "top of their license."
- Remain focused on the continuum of care. Resist pressures to abandon population health management principles in the pursuit of short-term, metric-driven goals.
- 6. Harness the chaos for good. Quickly identify and seize opportunities to advance services and create successful business lines.

gradually from a fee-for-service payment model to a population healthmanagement model. In this new model, providers receive financial incentives to achieve optimal patient care outcomes and are penalized for poor outcomes. If the country returns to short-term transactional payment models (as some proposals in Congress seem to imply), there will be a shift in priorities from preventive care and wellness maintenance to episodic disease management. This would be a major reversal of the healthcare gains that have been made under value-based payment models. Although the impact of such a chaotic state on morbidity and mortality might be difficult to forecast, it is worth noting that 46% of FPs predicted that life expectancy at birth for Americans will decline by at least 1

year within the next 5 years (Figure 1, item 5). This concern underscores the need for health-system pharmacists to remain focused on principles of population health management, notwithstanding the pressures to meet specific, short-term, metric-driven goals.

Despite federal inaction, there are still positive steps that can be taken at the state level. Since pharmacy is primarily regulated by states, there is an opportunity to broaden pharmacist scope-of-practice laws and authorize the expanded use of technicians. Many FPs felt that at least half of states will loosen regulation related to pharmacy practice over the next 5 years (Figure 1, item 6). This could have a very positive impact on health-system pharmacy: much more cost-effective use of all pharmacy personnel.

## IMPORTANCE OF STRATEGIC PLANNING

The forecasts set out in this chapter have profound implications for strategic planning. All health systems must plan with an awareness of the uncertainty associated with today's healthcare environment. Appropriate metrics must be established for the evaluation of progress in achieving goals and integrate continuous quality improvement into the process. Although goals must be based on our best interpretation of current conditions, those goals should be able to be reset on short notice. Plans should be updated at least every 6 months to maintain relevance. While longterm plans are essential in setting an overall trajectory for the department, 6-month and 1-year objectives are critical. Failure to meet milestones should prompt a reexamination of the assumptions on which those goals were based. Long-term objectives (achievable in 3-5 years) should be thought of as aspirational and subject to modification when the shorterterm objectives are adjusted.

#### **DISCLOSURES**

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