# PHARMACY FORECAST 2015-2019

# STRATEGIC PLANNING ADVICE

FOR PHARMACY DEPARTMENTS IN HOSPITALS AND HEALTH SYSTEMS



A trends report from the Center for Health-System Pharmacy Leadership, ASHP Research and Education Foundation



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#### PHARMACY FORECAST

2015-2019

STRATEGIC PLANNING ADVICE FOR PHARMACY DEPARTMENTS IN HOSPITALS AND HEALTH SYSTEMS

#### William A. Zellmer, Editor

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# Foreword

harmacy Forecast 2015–2019 stems from the core mission of the Center for Health-System Pharmacy Leadership, which is to advance the development of effective pharmacy practice leaders. Strategic planning is central to effective practice leadership, and environmental scanning is an essential step in strategic planning. At its heart, the annual *Pharmacy Forecast* series is an environmental scan of trends that are likely to have a major impact on the future of health-system pharmacy practice.

The Center is pleased to publish the third edition in this series. The *Pharmacy Forecast* project began with the encouragement of David A. Zilz, who challenged the Center to catalyze pharmacists' thinking about the future, going well beyond the typical focus on near-term operational issues. The report is supported by contributions to the David A. Zilz Leaders for the Future Fund.

This report has been designed to be a strong complement to other practice-advancement initiatives, including the ASHP/ASHP Foundation's Pharmacy Practice Model Initiative (www.ashp/ppmi) and the Center's wide array of leadership-development resources (www. ashpfoundation/leadership). The annual *Pharmacy Forecast* report is released each year at the ASHP Midyear Clinical Meeting.

The number of Web-page visits to the report has reached over 230,000. The report's strategic recommendations have influenced the agendas of ASHP sections and forums, and we have received many favorable comments from pharmacy practice leaders who have used the previous reports in their planning process. Academic institutions and residency programs have also incorporated the reports into their curricula.

Building on the last two years' success, the 2015 report covers new territory. It is an important *addition* to the previous reports, not a replacement or substitute. Pharmacy practice leaders will find value in consulting all three reports in their strategic planning efforts. We encourage pharmacists to share the report with colleagues in medicine, nursing, administration, and other disciplines. The report can be a stimulus for dialogue on pharmacy's role in this time of transformational change in health care.

We welcome your comments on the new *Pharmacy Forecast*. Tell us what you find particularly useful in the report, whether there is anything that falls short of your expectations, and what you would like to see in the next edition. We want to continue to make this series an important resource in your efforts to enhance pharmacy's contributions to your institution's strategic objectives and to the health and well-being of patients.

#### Richard S. Walling, B.S.Pharm, M.H.A.

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# Introduction:

#### CHALLENGES AND OPPORTUNITIES ABOUND IN EMERGING LANDSCAPE FOR PHARMACY DEPARTMENTS

WILLIAM A. ZELLMER, RICHARD S. WALLING, AND DAVID CHEN

#### STAYING AHEAD OF THE CURVE

ow can health-system pharmacy practice leaders stay on top of their game with all the changes afoot in the health care field? How do they know which new developments and emerging trends merit their thoughtful attention? What new strategically important situations that pharmacists are well positioned to see and understand are worth bringing to the awareness of other health-system leaders? These questions, and their continuously evolving answers, are what drive content planning for the annual *Pharmacy Forecast* report.

Through a good strategic planning process, practice leaders can identify their own best answers to key questions, and *Pharmacy Forecast* reports can be an important tool in that process. The 2015-2019 edition of the report includes new thinking about trends that are likely to have a major impact on pharmacy practice in hospitals and health systems over the next five years.

#### **COMMON THEMES**

This report covers 64 potential trends and offers 37 strategic recommendations for practice leaders. Several themes cut across two or more chapters in this edition:

- **1.** It will be difficult for the pharmacy department to achieve its full potential as the voice for responsible use of medicines unless it has a strong clinical presence in the hospital's or health system's ambulatory care clinics and transitions-of-care program.
- **2.** Pharmacy practice leaders have important opportunities to contribute to the strategic imperatives of their institutions through continuous improvement in operations (possibly involving reallocation of resources) and in medicationrelated patient care.
- **3.** Creation of a specialty pharmacy program holds promise as a rewarding opportunity for health systems and larger hospitals, in terms of both patient care and financial benefits.

- **4.** As health systems pick up the pace in applying big-data techniques to improving patient care and operations, pharmacy practice leaders must ensure that the related planning draws on pharmacists' expertise.
- **5.** Likewise, practice leaders must ensure that pharmacy has a voice as institutions tap into the patient empowerment movement by supporting innovations such as medication-related apps for mobile devices and implementing patient portals for access to electronic health records.

#### OTHER KEY TOPICS

Many other topics in this report align sharply with current strategic concerns of practice leaders. Examples include pharmacist involvement in team-based patient care, integrating biomarker and pharmacogenetics information into clinical decision-making, real-time biometric monitoring, future meaningful-use IT requirements, shifting traditional responsibilities in the medicationuse process, relationships with retail clinics,

forestalling a potential crisis in technician training, optimizing the role of students in essential pharmacy activities, and rational planning for sterile compounding.

## STRATEGIC VERSUS OPERATIONAL PLANNING

Most pharmacy departments probably engage in *operational* planning, focused on immediate problems and existing services. It is more difficult to conduct authentic *strategic* planning, which considers how emerging external trends will affect activities over the long term.

A recent article summed up well what is at stake in strategic planning for health-system pharmacy practice: "Failure to take the initiative and seize the opportunities that are presenting themselves at this critical juncture in history is tantamount to professional suicide."

A barrier to strategic planning is often a lack of time and resources for conducting an environmental scan of relevant issues. Here is where the *Pharmacy Forecast* project enters the picture, by filtering the background signals and amplifying those that are likely to have a major bearing on pharmacy practice within the next several years. Through the *Pharmacy Forecast* report, pharmacy practice leaders have ready access to the insights of a group of trend-watchers, and those insights can be used to supplement the wisdom that resides within the pharmacy department to move toward authentic strategic planning.

#### HOW PHARMACY FORECAST REPORTS ARE CREATED

The methodology used to prepare *Pharmacy Forecast* reports is based on research summarized in the book, *The Wisdom of Crowds*, by James Surowiecki (Anchor Books, 2005). The predictions of "wise crowds" are generally more accurate than those of individual experts. By definition, wise crowds are composed of independent, decentralized individuals who have a diversity of opinion and whose private judgments can be aggregated.

The wise crowd in the case of *Pharmacy Forecast* reports is an appointed panel

of health-system pharmacists that are believed to have (1) expertise in institutional pharmacy practice, (2) knowledge of trends and new developments in this area, and (3) demonstrated ability to think analytically about the future of pharmacy practice in hospitals and health systems.

Forecast Panelists (FPs) complete a questionnaire that is developed under the guidance of an advisory committee. The questionnaire is pilot tested with a few health-system pharmacists and refined before launch. The survey asks about the likelihood of certain developments occurring over the next five years. The point of reference for survey items is "the geographic region where you work," which encourages responses based on firsthand knowledge, observations, or experience rather than conjecture about the situation nationwide. FPs are asked to give their top-of-mind responses and not to do any extra reading or research to decide how to respond.

Experts are recruited to write a brief chapter for each domain of the report. Those chapters present the survey results and offer the authors' assessments of the FPs' predictions and express related strategic recommendations for pharmacy practice leaders.

#### THE 2015 REPORT

The following eight topic areas (domains) were selected for the most recent survey: (1) hospital and health-system practices, (2) ambulatory care, (3) quality improvement, (4) technology applications, (5) patient empowerment, (6) health-system work force, (7) drug development and therapeutics, and (8) pharmacy policies and practices. Each domain had eight survey items for a total of 64 questions in the entire survey.

The composition of the 150-member Forecast Panel for the current report was balanced across the census regions of the United States. Sixty-seven FPs were members of the panel for the previous year's survey; they had been nominated for the panel by leaders of the ASHP sections. The remaining panelists were selected from among the graduates of the Pharmacy Leadership Academy, a leadership-devel-

opment program conducted by the ASHP Foundation's Center for Health-System Pharmacy Leadership.

The Web-based survey was launched on May 20, 2014, and closed on June 10, 2014, after three reminders to nonrespondents. The response rate was 88%.

#### HOW TO USE PHARMACY FORECAST REPORTS

As a formal or informal leader in pharmacy practice, you should first scan the report to get a sense of its content and then schedule more thorough review to assess the implications of the report for your activities. You will find it helpful to start by reviewing a chapter's survey questions and the FPs' responses. Look at the distribution of responses to a question and see whether there is a clear consensus in one direction or another. Think about how the panel's response to a particular question compares with your own sense of what is happening in your practice, at your institution, and in your region. Is your department tuned in to this issue? If not, should it be?

After reviewing the survey results, read what the chapter authors have to say about the FPs' predictions. Reflect on the strategic recommendations in the chapter in relation to your own department's situation and plans.

Pharmacy Forecast 2015-2019 can be assigned as required reading for staff members who participate in the pharmacy department's planning process. Staff members, residents, or students can be asked to make a presentation to the department on the whole report or on individual chapters.

Consider sharing the report with the executive and clinical leaders in your institution, and invite their perspectives on the survey findings and the strategic recommendations. Factor those perspectives into the department's planning process.

Consult both the current report and the last two years' editions. For all three reports, FPs were asked to think ahead five years in their predictions, so the previous reports (which cover different issues) are relevant complements to the current report.

#### CONCLUSION

Effective strategic planning requires environmental scanning, not only of the immediate surroundings but also of the horizon. Pharmacy Forecast 2015-2019, complemented by the previous editions of the report, will help your pharmacy department with this essential part of looking and planning ahead.

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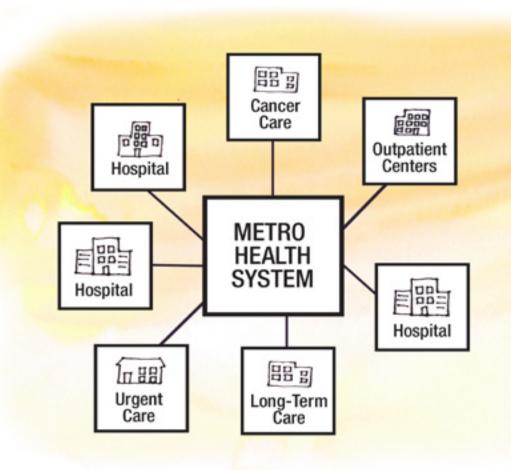
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#### **ACKNOWLEDGMENTS**

The members of the advisory committee (listed on the inside front cover) were instrumental in shaping the Forecast Panel survey. Colleen Bush expertly guided all facets of the survey. We acknowledge with appreciation the health-system pharmacists who served as Forecast Panelists. We also appreciate the support of the following individuals in key aspects of the project: Stephen J. Allen, Beverly Black, Meaghan Cunningham, Bethany Coulter, Bill Fogle, Bruce Gordon, Lynn Hoffman, Mick Hunt, Jaclyn Kruse, Jennifer Perrell, Shekhar Mehta, Steve Pickette, Douglas J. Scheckelhoff, and David Zilz.



# Health-System and Hospital Practices:

CHALLENGES AND OPPORTUNITIES RELATED TO INTEGRATED DELIVERY MODELS

RITA SHANE

#### HEALTH-SYSTEM AND HOSPITAL METAMORPHOSIS

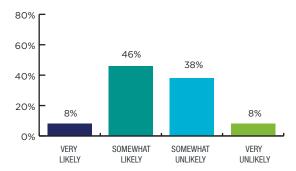
he Affordable Care Act has stimulated **hospital and health-system merg- ers** and acquisitions, creating integrated services across the care continuum.

These actions are based on the premise that larger entities can achieve better outcomes more efficiently, which is critical as financial incentives shift from volume to value. Key components of integrated delivery models include primary, specialty, acute and post-acute services, support for improved population health, acceptance of financial risk, and a sharp focus on improving performance metrics.<sup>1</sup>

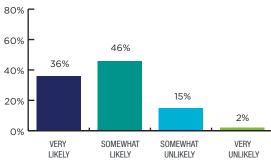
#### HARMONIZATION OF CULTURES AND PRIORITIES

The Forecast Panel had a mixed response related to the prospect of **harmonization of culture** across operational components of health systems, with 54% indicating this was likely and 46% unlikely in at least 25% of health systems over the next five years (item 1). This

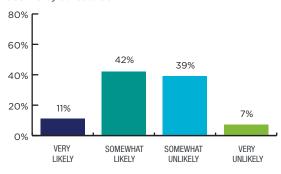
At least 25% of health systems will achieve nearly complete harmonization of organizational culture among all operational components of the system.



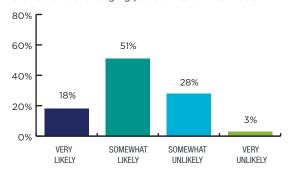
At least 50% of hospitals will continuously examine existing role delineations among all professional and technical personnel throughout the entire medication-use process and make appropriate changes in the interest of efficiency, safety, and cost minimization



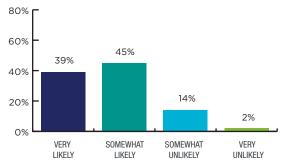
The volume of care provided in anticoagulation clinics that requires the clinical attention of pharmacists will decline by at least 50%.



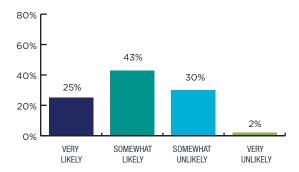
At least 50% of health systems will have formal relationships with retail health care clinics (such as those conducted by chain drug stores, grocery stores, or discount stores) for activities such as patient referrals and exchanging patient health information.



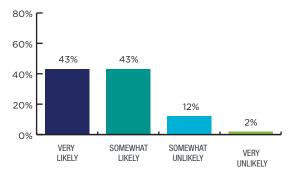
In at least 25% of multihospital organizations, the behavior of individual hospitals will be guided primarily by what is in the best interest of the organization as a whole (rather than what is perceived to be in the best interest of the individual hospital).



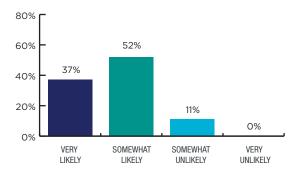
In at least 75% of health systems, physicians will have direct incentives for considering health-system cost in prescribing decisions.



6 Administration of injectable medications (including vaccines) in ambulatory care clinics and infusion centers will increase at least 50%.



The number of ethical dilemmas experienced by health care professionals in health systems and referred to ethics committees for guidance will increase by at least 10%.



response reflects the challenges associated with **change management and standardization** across newly acquired or integrated hospital and health-system entities. Pressures to standardize care come at a time when costly innovations in diagnostics and therapeutics are driving up expenses. Forecast Panelists' (FPs') responses related to **alignment of priorities** across multihospital systems may also reflect the significant effort that will be required to achieve harmonization: 84% of FPs believed this will occur, but for a relatively small percentage of organizations over the next five years (item 2).

## COMPOSITION OF PATIENT CARE TEAMS

**Team-based care** is a key aspect of evolving models of health care delivery. It is anticipated that pharmacists, students, residents, and technicians will be integrated into patient care teams that include nurse practitioners, case managers, and other disciplines along with physicians and nurses. The goal of teambased care is to leverage the knowledge and skills of each member on behalf of the patient while improving efficiency and outcomes. The majority of FPs agreed that at least 50% of hospitals will continuously evaluate roles of team members throughout the medication-use process to ensure efficiency, safety, and reduce costs (item 3). Examples will likely include use of pharmacy technicians to obtain medication histories and pharmacists to support prescribing of medications at discharge or in clinics. It will be challenging, however, to shift responsibilities in the medication-use process across traditional professional boundaries.

#### PHYSICIAN INCENTIVES

Almost 70% of FPs indicated it is at least somewhat likely over the next five years that physicians will have **incentives to support rational prescribing** in at least 75% of health systems (item 4). This perspective is consistent with the increasing number of **hospital-employed physicians**. The number of hospitalists had

grown to 30,000 as of 2012. Hospitalists are expected to expand into areas such as surgery and obstetrics.<sup>3</sup> As more physicians become salaried by health systems, the opportunities increase for aligning their incentives with institutional priorities.

### CHANGING LANDSCAPE IN CLINICS

Slightly more than half of FPs indicated that the anticoagulation clinic volume that requires clinical pharmacists will decline by 50% over the next five years, a prediction that may relate to the increasing number of patients on newer therapies (item 5). Although clinic volume may decrease, periodic evaluation of patients on newer anticoagulants may be necessary to ensure effectiveness and safety. In contrast, administration of injectables in clinics is expected to grow, with 86% of FPs predicting that 50% growth in volume is at least somewhat likely (item 6). This prediction is consistent with the anticipated growth in **specialty medications** for chronic diseases such as rheumatoid arthritis and multiple sclerosis, which are primarily administered by injection.

## RETAIL CLINICS AS A DISRUPTIVE INNOVATION

Nearly 70% of FPs indicated it is at least somewhat likely that most health systems will have **formal relationships with retail clinics** over the next five years (item 7). Retail clinics, which challenge traditional health care delivery systems, are designed to provide care at a cost that is lower than that of emergency departments or physician offices. Agreements between retail clinics and health systems could provide health systems with referrals when patients need a higher level of care. A recent survey indicated that one in four consumers or a member of their household had visited a retail clinic in 2013, and of those that did, 73% would return for care.4 A related trend is the growth of urgent care centers.5 Health systems will be challenged to ensure safe patient handoffs and the flow of essential patient information. Partnerships

between health-system pharmacy and retail pharmacy will need to support safe medication transitions and management of financial risks.

#### ETHICAL DILEMMAS

Almost 90% of FPs indicated it is at least somewhat likely that ethical dilemmas experienced by health care professionals will increase by at least 10% over the next five years (item 8). Given the number of end-of-life issues, the aging population, and decision-making related to costly innovation, health care professionals will inevitably face some level of conflict. It is likely that pharmacists may find themselves ethically challenged when a patient-specific treatment is in conflict with the organization's goals to reduce the cost of care.

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. Establish close alliances with organizational leaders by contributing to initiatives in population health, risk contracting, and strategic partnerships. Lead enterprise-wide efforts to achieve value through standardization and evidence-based decision-making related to both traditional and innovative therapies and diagnostics.
- **2.** Ensure that qualified pharmacists are essential members of clinical teams involved in length-ofstay reduction, transitions-of-care improvement, and end-of-life initia-
- **3.** Collaborate with executive, financial, and clinical leaders to develop incentives to engage physicians in the development and implementation of specialty medication treatment guidelines.
- **4.** Expand transitions of care and ambulatory care clinical services to infusion centers and provide education to pharmacy students and residents in these settings.
- **5.** Contribute to the development of a checklist of key quality, safety, operational, and financial indicators

- to support organizational evaluation of the prospect of **formal relationships with retail clinics.** Determine workflow processes to ensure safe medication handoffs between health systems and retail clinics. Explore opportunities for ambulatory care pharmacists and residents in retail clinics and urgent care centers.
- **6.** Engage staff in regular discussions related to **ethical dilemmas** they encounter in their practice. Include pharmacy residents and students in these discussions.

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# Ambulatory Care: PHARMACISTS WILL PLAY A VITAL ROLE

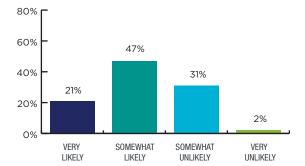
JOEL A. HENNENFENT AND JENNIFER ASKEW BUXTON

s health care reimbursement shifts from fee-for-service to a linkage with quality of care, there will be new clinical opportunities for ambulatory care pharmacists, particularly related to transitions of care, medication adherence, and specialty drug programs. Astute pharmacy practice leadership, including the development of formal business plans related to ambulatory care practice, will be required to capitalize on these opportunities.

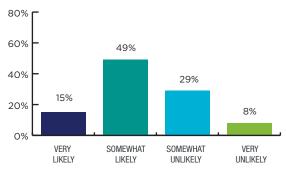
#### SPECIALTY PHARMACY SERVICES

Seventy-nine percent of Forecast Panelists (FPs) said it is at least somewhat likely that one fourth or more of health systems will conduct their own **specialty pharmacy programs** (item 7) within the next five years. Specialty drug products are projected to grow from 24% of total drug expenditures in 2005 to 44% in 2030.¹ In commenting on growing competition among the providers of specialty pharmacy services, an industry report observed, "The new players include specialty pharmacies operated by wholesalers, *large hospital organizations*, physician practices and retail pharmacies" (emphasis added).¹ Health systems that create their own specialty pharmacy programs might derive significant benefits from the perspectives of quality and continuity of patient care, management of costs, and generating financial margin. A key component of this strategy is to place pharmacists and pharmacy support staff in specialty clinics. Health systems that are considering **outsourcing outpatient pharmacy** 

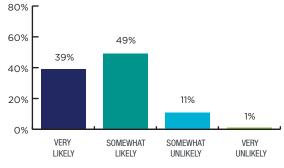
In at least 50% of hospitals, the institution's own pharmacists will be assigned to monitor medication adherence and medication outcomes of discharged patients who are at risk for early readmission.



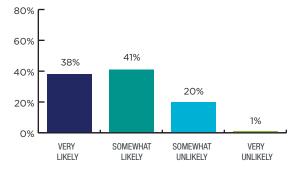
In at least 25% of hospitals, pharmacists will have authority to write discharge prescription orders that reconcile all medication lists, medications taken before admission, and new medications started during hospitalization.



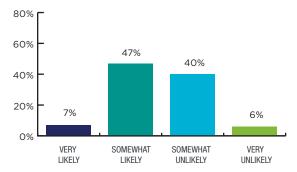
Health systems that provide pharmacist drug therapy management services for ambulatory patients will justify the cost of those services through a combination of fee-for-service reimbursement and demonstration of reduced total cost of care attributable to pharmacist interventions.



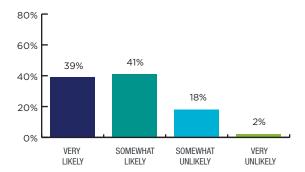
7 At least 25% of health systems will conduct their own "specialty pharmacy" services for at least three specialty medications (versus relying on external specialty pharmacies).



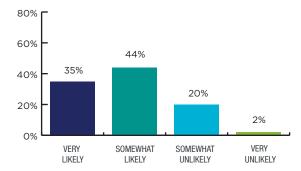
2 At least 50% of hospitals will contract with a corporate entity (e.g., a chain drugstore company) to monitor medication adherence and medication outcomes of discharged patients who are at risk for early readmission.



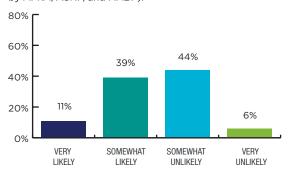
4 At least 50% of health systems will have a formal business plan for expanding pharmacists' clinical services for ambulatory patients.



In at least 50% of health systems, ambulatory care pharmacists will use point-of-care diagnostic testing to monitor response to drug therapy and take appropriate follow-up action.



At least 10% of health-system outpatient pharmacy departments will be accredited by the Center for Pharmacy Practice Accreditation (a body sponsored by APhA, ASHP, and NABP).



services to a retail drugstore corporation should be alert for contract clauses that prohibit the health system from creating a specialty pharmacy program. Hospital affinity groups are offering guidance to health systems in creating specialty pharmacy programs, and ASHP has information available about a wide range of issues associated with specialty drug products.<sup>2</sup>

## MONITORING ADHERENCE AND OUTCOMES

Because hospitals have a financial incentive to foster continuity of care for discharged patients, they should be particularly interested in ensuring that adverse drug events or nonadherence to drug therapy do not contribute to early readmissions. FPs were asked to predict whether hospitals, over the next five years, will engage their own pharmacists (item 1) or will contract with a corporate entity (item 2) "to monitor medication adherence and medication outcomes of discharged patients who are at risk of early readmission." By a 14-point margin, FPs predicted that the dominant approach is more likely to be using the hospitals' own pharmacists rather than a corporate entity for this vital function.

# PHARMACIST PRESCRIBING AUTHORITY

In response to the question asking if pharmacists in at least 25% of hospitals over the next five years will have authority to write **discharge prescription orders**, 64% of FPs said that this is somewhat or very likely (item 3), up from 59% in the previous *Pharmacy Forecast* report. Contributing to the plausibility of this prediction is the growing interest in **pharmacist privileging**, 3 the profession's promulgation of a standardized approach to the patient care process of pharmacists, 4 and expansion of pharmacist **scope of practice** in a growing number of states.

The availability of **point-of-care** laboratory results enabling pharmacists to make immediate clinical decisions has the potential to improve patient care outcomes and reduce health care costs.

Almost 80% of FPs said it is at least somewhat likely that ambulatory care pharmacists in most health systems will be using point-of-care testing over the next five years (item 6).

## BUSINESS PLANS FOR AMBULATORY CARE SERVICES

Eight of every ten FPs believed that at least 50% of health systems will have a formal business plan for expanding pharmacists' clinical services for ambulatory patients within the next five years (item 4). The importance of business plans for building of sustainable ambulatory care practice models was emphasized at the recent ASHP Ambulatory Care Summit, which issued a recommendation that "services provided by (ambulatory care) pharmacists ... should achieve a set of quality and cost measures, be supported by payment model(s), and be valued by demonstrated improvements in patient outcomes" (summit recommendation 3.4).5 A background paper for the summit discussed how to develop sustainable business models for ambulatory care pharmacy practice.6

FPs predicted that health systems will **justify the cost of drug therapy management** services using both revenuegenerating and cost-saving strategies (item 5). The future of fee-for-service models is very uncertain, and as pay-for-performance and global payment models expand, health systems will increasingly give more attention to quality indicators and cost-containment strategies. However, in the view of FPs, a complete shift away from fee-for-service models is not likely in the near future.

## OUTPATIENT PHARMACY ACCREDITATION

Half of FPs said it is at least somewhat likely that 10% of health-system outpatient pharmacy departments will be accredited by the **Center for Pharmacy Practice Accreditation** (CPPA) by 2019 (item 8). CPPA accreditation has the potential for ensuring patients and payers that recognized pharmacies are well

qualified to provide drug therapy management and other patient care services. CPPA standards for community pharmacy practice are applicable to outpatient pharmacies, and a standard for specialty pharmacies is under development (www. pharmacypracticeaccredit.org).

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. Move assertively to engage your pharmacist team in **monitoring** medication adherence and outcomes of discharged patients.
- **2.** Create a **formal business plan** for expanding pharmacists' clinical services in ambulatory care clinics, emphasizing sustainable business models and services that yield a return on investment through a combination of revenue generation and cost-saving initiatives (e.g., decreased readmissions, decreased drug cost, increased physician productivity).
- **3.** Conduct a risk-benefit analysis for establishing a **specialty pharmacy** program in your health system, focusing the evaluation on patient care improvement and financial impact. If indicated, create a business plan to establish a specialty pharmacy program that entails (a) pharmacists and pharmacy support staff practicing in specialty clinics and (b) formal relationships with specialty drug manufacturers and payers.
- 4. Assess the value of pursuing outpatient pharmacy accreditation as a tactic in differentiating your institution from competitors in the eyes of physicians, patients, and payers.

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# **Quality Improvement:**

# OPPORTUNITIES FOR PHARMACIST ENGAGEMENT IN IMPROVING PATIENT OUTCOMES

PAMELA K. PHELPS

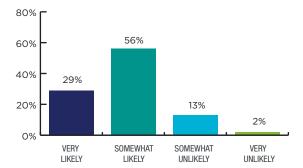
#### FOCUSING SHARPLY ON QUALITY OF CARE

nder the Affordable Care Act (ACA), health systems are challenged with providing a higher quality of care in the face of reduced reimbursement. Health-system executives are now focused more than ever on achieving high quality of care and patient satisfaction. Under the value-based purchasing model, hospital reimbursement is linked to meeting quality-of-care targets for certain medical conditions. The current focus in health systems is on using data-driven processes to improve quality of care, integrate services, and remove waste, and on using physician leadership to reduce clinical variation. Pharmacy leaders should position their departments to contribute significantly to quality-of-care targets.

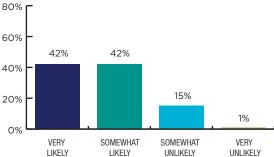
#### PHARMACY-SENSITIVE INDICATORS

A wealth of literature demonstrates the **value of the pharmacist** in the provision of patient care.<sup>3</sup> With the relatively recent emphasis on interdisciplinary, team-based care as a method of fostering patient safety, it becomes more difficult to attribute quality of care directly to the services of the pharmacist vs. the services of the team as a whole.<sup>4</sup> In the view of 85% of Forecast Panelists (FPs), it is at least somewhat likely that over the next five years there will be three or more nationally recognized and validated pharmacy-sensitive indicators that

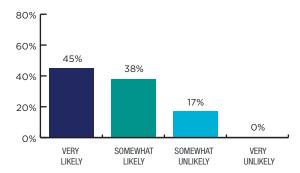
1 There will be at least three nationally recognized and validated pharmacy-sensitive quality indicators that correlate improved patient outcomes with a greater quantity or quality of pharmacist care.



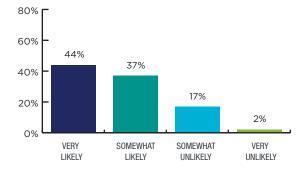
In at least 50% of hospitals, a pharmacist will lead a formal multidisciplinary, systematic process for continuously improving patient safety in all phases of the medication-use process.



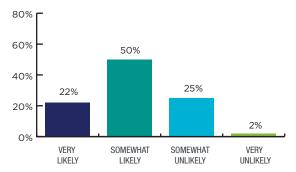
Health systems will increase by at least 25% their investment in building capacity to continuously analyze patient care data for the purpose of gaining insights on how to optimize patient care treatments and interventions.



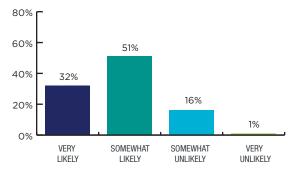
7 The pharmacy enterprise in at least 25% of health systems will employ at least one data-mining expert to aid operational and clinical decision-making.



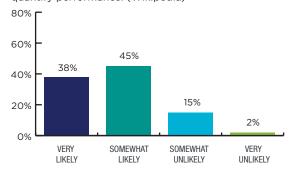
In at least 50% of hospitals, a portion of pharmacy managers' compensation will be based on pharmacy performance in meeting explicit quality-of-care targets (e.g., targets related to patient satisfaction, patient safety, minimization of hospital readmissions).



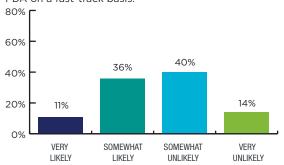
Policies in at least 25% of hospitals will require a pharmacist consultation when complex medication-use problems arise.



Most health systems will have an explicit plan for developing analytics that identify optimal treatments based on patient outcome trends in the health system. Definition: Analytics is the discovery and communication of meaningful patterns in data [that] relies on the simultaneous application of statistics, computer programming and operations research to quantify performance. (Wikipedia)



At least 25% of health systems will create and apply their own rigorous postmarketing surveillance program to monitor patient outcomes from the use of high-risk medications that were approved by the FDA on a fast-track basis.



correlate the services of the pharmacist with improved care (item 1). This survey question stemmed from the work of the National Quality Forum in endorsing nursing-sensitive indicators that directly link nursing care to patient outcomes.<sup>5</sup> The FP prediction seems plausible, given the efforts of the ASHP Pharmacy Accountability Measures (PAM) Work Group to identify measures that establish accountability and demonstrate improvements in clinical outcomes through the patient care contributions of health-system pharmacists.6 These quality indicators can be adopted and put on pharmacy dashboards to reflect pharmacist accountability for improving quality. Measures recommended by the PAM Work Group fall into four clinical domains: anticoagulant safety, glycemic control, antimicrobial stewardship, and pain management.

## ROLE OF THE PHARMACIST IN QUALITY IMPROVEMENT

Eighty-four percent of FPs believed that pharmacists in most hospitals will lead a formal multidisciplinary systematic process for **continuously improving patient** safety in all phases of the medication-use process (item 3). (This compares with 93% of FPs in the previous year's survey who believed that pharmacists would participate in these same functions.) The new prediction seems plausible because pharmacists are skillful at leading process improvement and data collection and analysis. As health-system executives look to physicians to improve the outcomes of care, physicians may increasingly seek out pharmacists to assist with performanceimprovement efforts. Pharmacy practice leaders should continue to build departmental expertise in data analysis and process improvement.

FPs predicted that policies in at least 25% of hospitals will *require* a **pharmacist consultation** when complex medication-use problems arise (item 4). As reported in the 2014 ASHP national survey of hospital pharmacy, pharmacists *routinely* manage dosing and monitoring of anticoagulation therapy in about

one third of hospitals. Common types of pharmacist consultations in hospitals are dosage adjustments, antibiotic therapy, pharmacokinetics, and drug information. These national data suggest a mismatch between current hospital pharmacy practices and the proposed pharmacy sensitive indicators. Pharmacy practice leaders should ensure that department staff has expertise specifically in anticoagulant safety, glycemic control, antimicrobial stewardship, and pain management (domains covered in the report from the ASHP PAM Work Group).

#### HEALTH CARE ANALYTICS

There is a need for analytics to improve quality of care and reduce variation in health systems; with widespread adoption of electronic health records, there is potential for data-mining for the purposes of performance improvement. A large majority of FPs predicted that health systems will build greater capacity over the next five years to analyze patient care data for the purpose of optimizing patient care (item 5). Also, a large majority of FPs thought that most health systems will have an explicit plan for developing analytics that identifies optimal patient treatments based on health-system outcome trends (item 6). FPs also predicted that the pharmacy enterprise in at least 25% of health systems will employ a datamining expert to assist in operational and clinical decision-making (item 7).

These predictions for greater health-system emphasis on analytics seem plausible because of three trends. One trend is the overall downward pressure on health care spending.1 Pharmacy practice leaders will need to understand medication spending more thoroughly to make decisions relating to formulary management. A second trend is FDA approval of medications in a more expedited manner supported by fewer randomized, controlled trials.8 Although most FPs appear to disagree (see item 8), postmarketing surveillance at the health-system level may be advisable to monitor patient outcomes from the use of high-risk medications that were approved

for marketing on a fast-track basis. The third trend is the introduction of **very expensive medications** developed to treat **small numbers of patients.** 9 Robust data analysis at the health-system level might help determine whether these expensive medications are living up to their promised value proposition.

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- **1.** Actively look for opportunities to expand pharmacist involvement in team-based care. Use the quality imperative related to improving medication-related outcomes as leverage in advancing the patient care role of pharmacists.
- 2. Watch for the issuance by ASHP and others of vetted **pharmacy-sensitive** quality indicators. Use these indicators to support pharmacist engagement in patient care activities. Educate health-system executives about the need for pharmacist engagement in patient care services to improve performance on these indicators.
- **3.** Conduct a gap analysis of pharmacist skills and abilities needed to respond to complex medication-related consultations, including antimicrobial management, diabetes therapy, anticoagulation management, and pain management. Take the necessary steps to improve these skills and abilities as indicated by the gap analysis.
- **4.** Develop strong **performance**improvement expertise in the pharmacy department related to medication-use quality. This can be accomplished by (a) building pharmacy staff skills in lean and six-sigma methodologies, data analysis, and performance improvement, (b) creating alignment and partnerships with physician leaders to enhance quality and reduce practice variation, (c) cultivating a strong, constructive relationship with your institution's quality-improvement department to capture appropriate outcome measures for collaborative projects, and

(d) pursuing pharmacist leadership of performance-improvement committees that deal with medication use.

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# Applications: INNOVATIONS CONTINUE TO HOLD

INNOVATIONS CONTINUE TO HOLD PROMISE FOR IMPROVED CARE

KEVIN MARVIN AND KARL F. GUMPPER

#### CONTINUING EFFECTS OF MEANINGFUL-USE REQUIREMENTS

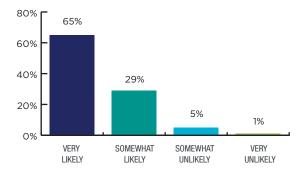
ospitals and health systems have made significant investments in electronic health record (EHR) systems in response to the American Recovery and Reinvestment Act of 2009 (ARRA).¹ The **meaningful-use requirements** for providers to receive ARRA incentive payments will continue to stimulate expansion and optimization of EHR technologies to support safer and more efficient patient care. New and expanded technology use will have a major impact on health-system pharmacy over the next five years.

#### MOBILE-DEVICE HEALTH-RELATED APPS

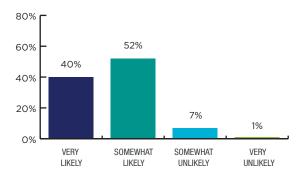
Meaningful-use requirements will foster patient empowerment through the establishment of **Web-based portals** for direct patient access to their own electronic health record and other information. Future stages of meaningful use will require that patients use the portals and that the portals be engaging and user-friendly and support patient-centered outcomes.<sup>2</sup> Access to portals will continue to be enhanced through **mobile-device applications**. Patients will use apps designed to help them manage their health issues. Some apps will facilitate patient communication with clinicians, including pharmacists. More than 80% of Forecast Panelists (FPs) agreed that at least 25% of adult patients taking medications for chronic conditions will use

How likely is it that the following will occur, by the year 2019, in the geographic region where you work?

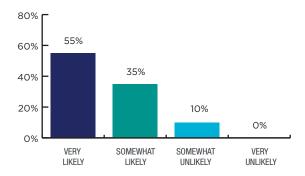
In at least 50% of health systems, pharmacists will use mobile-device applications that are integrated with the organization's information system to improve the efficiency and quality of their clinical practice.



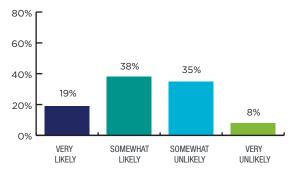
Three or more pharmaceutical companies that market chronic-care medications will disseminate mobile-device applications for use by patients for functions such as accessing educational material and promoting medication adherence.



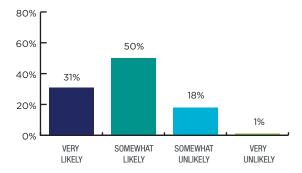
Health systems will increase their investments in information technology (hardware, software, and staffing) by at least 25%.



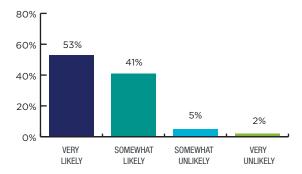
In at least 25% of hospitals, preemptive computerized drug interaction alerts will be replaced by alerts that detect real-time emerging biometric indicators of a drug interaction (e.g., changes in patient vital signs, lab measures, etc.).



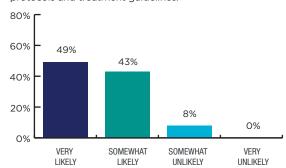
2 At least 25% of adult patients who take medications for a chronic illness will use mobile-device applications for guidance on managing self-care and communicating with their clinicians.



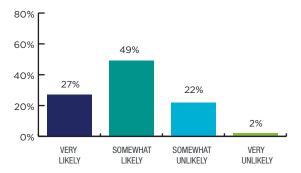
Three or more pharmaceutical companies that market high-cost medications will disseminate mobile-device applications to physicians and other clinicians for disease education, training materials, and tools to guide diagnosis and treatment.



For at least 25% of hospitals, data from the institution's electronic health records will be automatically analyzed and used to develop and continuously refine patient-care protocols and treatment guidelines.



At least 10% of hospitals will use new technology (which was not available in 2014) in the medication-use process that achieves breakthrough advances in patient safety and work force efficiency.



mobile-device apps for self-care guidance and communication with clinicians (item 2).

Health systems and accountable care organizations will partner with software venders and others to provide **health-related apps.** Pharmaceutical manufacturers have created their own apps (sometimes contracting with other companies for technology expertise and content) with the intent of integrating the apps with patient portals or offering them for clinician use.<sup>3,4</sup> Greater than 90% of FPs predicted that pharmaceutical companies will disseminate mobiledevice apps for use by patients (item 3), and 94% agreed that pharmaceutical companies will disseminate mobile-device apps to physicians and other clinicians (item 4).

Before supporting such apps, health systems should review the business model of the vendor partners and assess the clinical content and advertising links. Under the right conditions, these apps can provide a cost effective way of improving patient outcomes and managing treatment costs. Pharmacists are well positioned to advise patients and clinicians on the best sources of medication-related information.

## INFORMATION TECHNOLOGY INVESTMENT

Ninety percent of FPs predicted that health systems will increase their investments in information technology (hardware, software, and staffing) by 25% or more over the next five years (item 5). Considering the large amount that has been recently invested in EHR technology in support of ARRA incentives, an additional 25% is very significant. The value of EHR technology investment is realized after continued refinement and standardization of systems and processes. Pharmacy practice leaders will need to continually advocate for an appropriate number of pharmacists and medication-focused staff to support and enhance these systems.5

# USE OF CLINICAL DATA TO IMPROVE PATIENT CARE

Some hospitals have begun to use "big data" techniques to improve patient care and strategic business decisions.

Health systems with substantial informatics resources will use their patient care data to update and enhance protocols and treatment guidelines. Studies suggest that analytics has the potential to reduce costs through more effective management of readmissions, triage, decompensation, adverse events, and treatment of high-cost patients (including those with diseases affecting multiple organ systems).6 A large majority of FPs predicted that over the next five years 25% or more of hospitals will use big data techniques to develop and continuously refine treatment protocols and guidelines (item 6).

The use of real-time **physiologic** and **biometric monitoring** holds great potential for improving individual patient care. Many patients are willing to monitor and manage their chronic diseases at home. The development of wearable home monitoring devices for patients will require remote linkage with the patient's personal health record and the provider's EHR.<sup>7</sup>

As hospitals integrate mobile devices into their EHR infrastructure, more clinical decision support (CDS) will be used to improve patient care, including medication use. Interoperability of devices with each other and with the EHR will be required. For example, consider a patient on an opioid infusion: physiologic monitoring with a smart pump and a breathing monitor, and an EHR with an intuitive CDS system could add a higher degree of patient safety than currently exists.

#### BREAKTHROUGH ADVANCES

Seventy-six percent of FPs agreed that it is at least somewhat likely within the next five years that 10% of hospitals will use a new **technology not available today,** achieving breakthrough advances in safety and efficiency (item 8). Possible examples include the artificial pancreas,<sup>8</sup> micro devices made possible with 3D printing, genetic and brain mapping, virtual 3D display devices, and improved voice recognition.

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- **1.** Move assertively to position the pharmacy department as a vital contributor to the success of your institution's Web-based patient portal. Among the elements of this imperative are (a) ensuring that the patient portal supports communications with pharmacists, (b) specifying how pharmacists will monitor the patient portal, and (c) establishing performance goals that link pharmacist patient communications through the portal with medication-related outcomes.
- 2. Participate actively in your institution's initiatives related to patientand clinician-focused **mobile-device apps,** including (a) advocating for oversight of the use of medicationrelated apps by the pharmacy and therapeutics committee, (b) ensuring that pharmacists are involved on teams that evaluate and manage medication-related apps (including assessment of vendor businessmodel alignment with your institution's medication-management goals), (c) developing an approved list (formulary) of medication-related apps through multi-disciplinary collaboration, and (d) developing a pharmacy-operated advisory service for patients and clinicians on appropriate medication-related apps and information sources.
- **3.** Ensure that your organization's IT operation includes an appropriate number of pharmacists and medication-focused staff to support the growing complexity of EHR technology systems.
- **4.** Participate actively in your institution's projects that integrate **patient-specific physiologic data** with clinical decision support related to medication use.
- 5. Develop pharmacy department expertise in data analytics to ensure the best use of data to improve individual patient and population-based care.

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# Patient Empowerment:

#### THE PATIENT'S PARTICIPATION IN THE HEALTH SYSTEM

RUSSELL FINDLAY AND LEE C. VERMEULEN

#### THE EVOLVING ROLE OF THE PATIENT

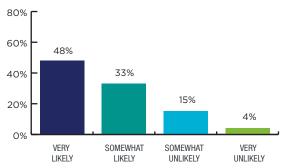
atient empowerment involves self-directed behavior, autonomous action, and critical assessment that results in the capability to manage one's own prospective situations. The landscape of contemporary health care is continuing to align with practices and beliefs that promote patient empowerment. Patient and family engagement is believed to produce better outcomes—fewer adverse effects, lower cost, and higher patient-satisfaction scores. It is imperative that health-system pharmacy leaders and practitioners understand, set strategic plans, and manage enterprise-wide expectations and requirements surrounding the economic, technological, legislative, and cultural aspects of patient empowerment.

A hallmark example of patient empowerment is the addition of former and current patients to committees in health systems. Nearly two thirds of Forecast Panelists (FPs) agreed that most health systems are likely over the next five years to **appoint laypersons** to governance and clinical-policy committees (item 5). Lay members of committees must be prepared by committee leaders in advance of meetings, encouraged to participate in discussions, and must be engaged directly during meetings.

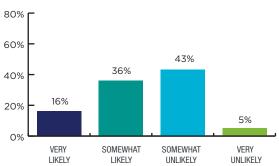
#### THE INFORMED CONSUMER

As health systems assume more risk under capitated reimbursement, there is a renewed focus on addressing the impact of patient behaviors and habits as they affect health status,

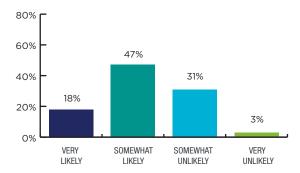
At least 50% of health systems will have Internet-based mechanisms that allow patients to have virtual interactions with clinicians (dealing with, for example, questions related to ongoing care or about new health concerns).



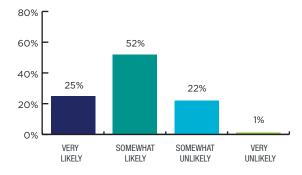
The number of patients who qualify for receiving medications through manufacturer-sponsored patient assistance programs will decline by at least 25% (because of, for example, expanded health insurance coverage).



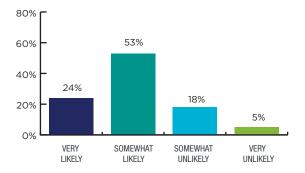
At least 50% of health systems will appoint laypersons who have had experience with the health system to governance and clinical-policy committees.



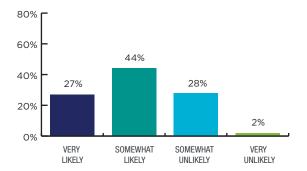
At least 50% of patients, when seeking medical care for which they will incur high out-of-pockets costs (i.e., high deductible or co-pay), will take into account Web-accessible information about the cost and patient outcomes of the providers to which they have access.



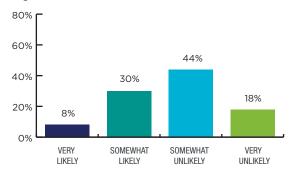
2 The Web sites of 50% of health systems will allow patients to ask a pharmacist specific questions about their drug therapy.



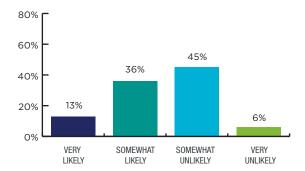
4 At least 75% of insured chronic-care patients will have financial incentives to improve self-management of their illness, including any related drug therapy.



For at least 10% of health systems, readily accessible information about pharmacist services will be a factor in consumer decisions to use the services of the organization.



At least 75% of non-acute and preventive care services will be obtained from non-traditional providers such as retail health care clinics.



especially in primary and preventive care. Nearly three fourths of FPs agreed it is at least somewhat likely that a large majority of insured patients with chronic diseases will have financial **incentives** to improve self-management of their illness, including any related drug therapy (item 4). Additionally, 77% of FPs agreed that most patients, when seeking medical care for which they will incur high out-of-pocket costs, will take into account Web-accessible information about cost and patient outcomes (item 7). These two predictions are plausible given the increase in cost sharing and greater emphasis on transparency in price and clinical outcomes. Patients will increasingly be put in the position of acting as a **classical consumer**<sup>4</sup> in the health care marketplace and to discriminate on the basis of cost and quality. The widespread use of shared decision-making models, in which patients recognize that they have a right to be equal participants in their care, furthers this argument.<sup>5</sup>

# PHARMACY'S VALUE PROPOSITION

Under the premise that patients will increasingly behave like classical consumers in the health care marketplace, consumer demand will drive the financial viability of health care organizations. Pharmacy must be in a position to effectively market its services and advertise its value in order to remain relevant. Three fourths of FPs agreed that Web sites of 50% of health systems will allow patients to ask a pharma**cist** specific questions about their drug therapy (item 2). In spite of this, nearly two thirds of FPs disagreed that in at least 10% of health systems, readily accessible information about pharmacist services will be a factor in consumer decisions to use the services of the organization (item 6). If patients do not consider the value of pharmacy services in their decisionmaking, further marginalization of pharmacy practitioners is likely. Strategic plans of departments of pharmacy should include goals of increasing visibility of

pharmacists, emphasizing the contribution that pharmacists make to the care of their patients, and increasing accessibility of pharmacists to patients and families. Pharmacists must become as **indispensable to patients** as doctors and nurses currently are.

# IMPACT OF LEGISLATION AND INSURANCE COVERAGE

The Patient Protection and Affordable Care Act (PPACA) is intended to increase access to health care services. Expanded insurance coverage, combined with flagging profit margins in the pharmaceutical industry, may limit manufacture-sponsored **patient assistance programs**. Half of the FPs predicted this is unlikely to occur in the short term (item 3), but pharmacy practice leaders should remain aware of this potential, as patients who lose access to key medications often end up consuming more costly care.

#### LEVERAGING TECHNOLOGY

Increases in the size of insured patient pools, together with heightened accountability for quality and performance metrics, have increased pressure on health systems to apply technology to accommodate more patients at a lower cost without compromising quality. FPs indicated a strong belief that a majority of health systems will have Internet-based mechanisms that allow patients to have virtual interactions with clinicians (item 1). This is consistent with a statement by the Federation of State Medical Boards endorsing the removal of regulatory barriers to facilitate the widespread and appropriate adoption of telemedicine technologies.6 Bolstered by favorable clinical evidence in both inpatient and outpatient arenas,7,8 telemedicine advancement is both feasible and imminent and is certain to disrupt classic brick-and-mortar health care delivery.

#### THE CHANGING PRIMARY AND PREVENTIVE CARE MARKETPLACE

Health systems must also consider the growth of **nontraditional providers** 

in non-acute and preventive care niche markets. Surprisingly, half of FPs disagreed that 75% or more of primary and preventive care services will be obtained from nontraditional providers such as retail health care clinics (item 8). It is unclear whether the magnitude of nonacute and preventive services (i.e., 75%) or the idea of a shift from traditional to nontraditional providers influenced the FPs' responses. Regardless, health systems must recognize the role retail health clinics will play in the accountable care organizations (ACOs) and non-acute health care marketplace.

The future of pharmacy can be bright if the profession leverages the growing importance of patient empowerment.

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- **1.** If your institution has not yet made an authentic **commitment to patient empowerment,** consider ways in which the pharmacy department could make initial steps into this arena. For example, develop a patient advisory panel for the outpatient pharmacy or appoint a layperson to a quality council.
- 2. Develop a plan for patient and provider access to your pharmacy department through Internet-based media.
- **3.** Assist your institution in strategizing about how to respond to chain drugstores' business model of penetrating or creating ACOs and competing with health systems in the non-acute and preventive-care markets.
- **4.** Develop and implement a plan to establish the role of the pharmacist in the minds and hearts of patients such that it is inconceivable to receive care at your institution without a pharmacist's involvement.

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# Health-System Work Force:

#### IN PURSUIT OF A CONSTRUCTIVE REMIX

WILLIAM A. ZELLMER AND DAVID CHEN

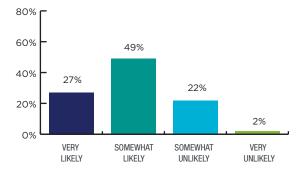
#### RE-EXAMINING TRADITIONAL ROLES

urbulence in health care financing and delivery has created a climate conducive to **re-examining roles and responsibilities** in the provision of patient care. This re-examination has created an opportunity for health-system pharmacy to define itself more clearly and distinctly as a patient care profession. Astute planning by pharmacy practice leaders will be required for this potential to become a reality for the benefit of patients and health systems.

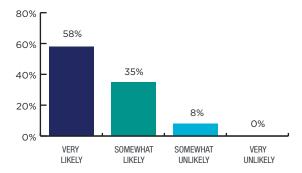
#### THE PATIENT CARE WORK FORCE

Three fourths of Forecast Panelists (FPs) said that it is likely within the next five years that nurse practitioners and pharmacists, in at least 25% of health systems, will provide most **therapeutic guidance** after the diagnosis and initial treatment plan have been established by a physician (item 1). This prediction seems entirely plausible (both in inpatient and outpatient care) for several reasons, including the persistent shortage of physicians, the advantages of team-based care, and strong evidence linking improved patient outcomes to clinical engagement by pharmacists and nurses. The recent initiative by national pharmacy organizations to foster a standardized approach to the patient care process of pharmacists will serve over time to make other health professionals more aware and more accepting of pharmacists' role on patient care teams.

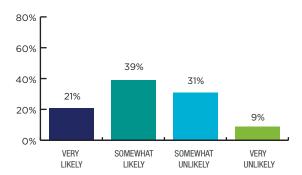
On at least 25% of health-system patient care teams, nurse practitioners and pharmacists will provide most therapeutic guidance after the diagnosis and initial treatment plan have been established by a physician.



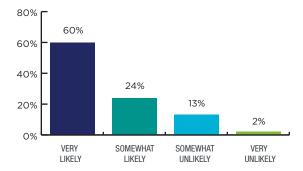
In essentially all health systems that have pharmacy residents, the residents will provide essential patient care services (i.e., if the residents were not there, additional pharmacist staff would have to be hired for these essential services).



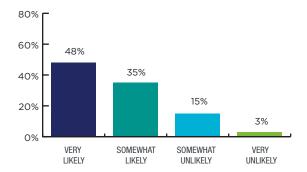
The salaries for newly hired entry-level general-practice pharmacists in health systems will decline by up to 10%.



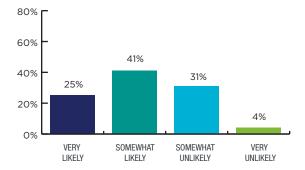
In 50% of health systems all newly hired pharmacy technicians will have completed accredited training and PTCB certification.



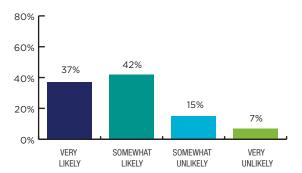
2 At least 50% of health systems will require accredited residency training for entry-level clinical positions in pharmacy practice.



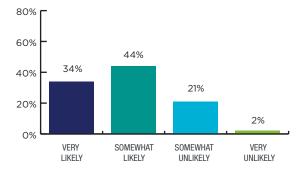
In at least 50% of health systems, pharmacy students on experiential rotations will provide essential patient care services (i.e., if the students were not there, additional pharmacist staff would have to be hired for these essential services).



At least 50% of hospital pharmacy departments will use primarily technicians to check the accuracy of dispensing by other technicians ("tech-check-tech").



At least 25% of health systems will have one or more pharmacists who devote full time to patient care issues in the use of specialty pharmaceuticals.



#### THE PHARMACIST WORK FORCE

Greatly expanded annual output of pharmacy graduates, increased use of technicians and technology in retail and institutional dispensing operations, and other factors have converged to produce an ample supply of pharmacists for healthsystem entry-level positions nationwide.5 This suggests the prospect for **erosion** of starting salaries for pharmacists and, indeed, 60% of FPs said that it is at least somewhat likely that salaries will decline by up to 10% over the next five years for newly hired entry-level general-practice healthsystem pharmacists (item 5). One potential effect of this disquieting prediction is that pharmacists might become better positioned for patient care positions that have a heavy medication-management component.

ASHP estimates that 22% of hospital pharmacists have completed PGY1 **residency training.**<sup>6</sup> FPs predicted that by 2019 at least half of health systems will *require* a residency for entry-level clinical positions in pharmacy practice (item 2). Applicants for health-system pharmacist positions who have completed a residency will likely have an edge over other recent graduates regardless of whether or not such training is a formal job requirement.

FPs expected that both **pharmacy residents and students** will have a sizable role in providing essential patient care services in health systems (items 3 and 4). The percentage of FPs in the most recent survey that expected this of students was 8 points higher than last year. Students on experiential rotations can play an important role in obtaining medication histories and conducting medication reconciliation. The value of pharmacy residents in assessing and capitalizing on new opportunities to improve patient care is widely recognized among residency training programs.

The continuity, safety, effectiveness, and cost-efficiency of patient care are often challenged when vital treatments are available only through commercial **specialty pharmacies**, <sup>7,8</sup> and health systems have begun to dedicate specific pharmacist resources to the issue. <sup>9</sup> Hence, it is not surprising that one third of FPs said it is *very likely* over the next

five years that "at least 25% of health systems will have one or more pharmacists who devote full time to patient care issues in the use of specialty pharmaceuticals" (item 8).

## THE PHARMACY TECHNICIAN WORK FORCE

More than three fourths of FPs said it is at least somewhat likely that in 50% of hospitals over the next five years technicians will check the accuracy of dispensing by other technicians (item 6). (Last year, about the same proportion of FPs said that this would occur in at least 25% of hospitals.) This predicted rate of adoption of **tech-check-tech**, although strongly desirable from the perspective of optimal use of time and talent, seems extraordinary in that only about 16% of hospitals in the 2013 ASHP national survey reported having implemented tech-check-tech to any extent.<sup>a</sup>

Although more than 70% of hospital pharmacy technicians are PTCB certified, fewer than 10% of hospitals use primarily an ASHP-accredited program for training technicians.6 Hence, it is striking that 60% of FPs predicted that within the next five years it is very likely that in half of health systems all newly hired pharmacy technicians will have completed accredited training and PTCB certification (item 7). Beginning in 2020, to qualify for taking the PTCB exam applicants will have to first complete accredited training.<sup>b</sup> There is nowhere near sufficient capacity among current accredited training programs to meet the demand that is implied by this 2020 requirement.

# STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- 1. Assertively advocate for expanded pharmacist engagement in
- a. Scheckelhoff DJ, personal communication, 2014 Jul 11. (Data not reported in the published report.)
- This requirement specifically refers to ASHPaccredited technician training. That ASHP program is now jointly sponsored with the Accreditation Council for Pharmacy Education.

- **team-based care** as your institution re-examines role delineation and process improvement in patient care.
- **2.** Ensure that human resources personnel in your institution understand the **functional distinctions** between pharmacists in hospital/health-system practice versus other sectors, which will allow them to appropriately interpret regional pharmacist salary-survey data.
- 3. Strongly consider establishing a pharmacy residency program, or expanding an existing program, as a means of increasing the pharmacy department's capacity to capitalize on opportunities to improve patient care.
- **4.** Ensure that your department is optimizing the role of pharmacy students in essential pharmacy activities such as obtaining medication histories and conducting medication reconciliation.
- **5.** Actively assess, with the use of resources from ASHP and hospital/ health-system alliances, whether it is desirable (from patient care and financial perspectives) for your health system to establish a **specialty** pharmacy service.
- **6.** Build a coalition in your state to pursue regulatory authority (if it does not already exist) to permit PTCB-certified pharmacy technicians to prepare and check unit doses. In view of the favorable economics and safety of this practice, include high-profile health-system executives and consumer advocates in this advocacy initiative.
- **7.** Give high priority to collaborating with key stakeholders in your geographic area to expand accredited pharmacy technician training to ensure that an adequate number of graduates will be available to pursue PTCB certification by the 2020 mandate for accredited training as a prerequisite for certification. Bring into this collaboration leading hospitals, chain drugstore corporations, and technical/community colleges.

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# Drug Development and Therapeutics:

CHANNEL SHIFTS AND NEW REGULATIONS WILL CHANGE THE STATUS QUO

EDWARD LI

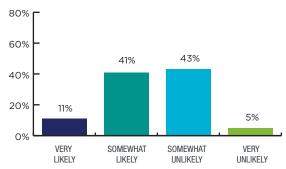
#### TRENDS IN THE BIOPHARMACEUTICAL PIPELINE

he management of many diseases is highly dependent on the commercial availability of high-quality, safe, and effective pharmaceuticals. Accordingly, **new** and emerging therapies will have the potential to significantly affect how care is delivered to patients, especially if these therapies challenge the status quo in how they are prescribed, distributed, and administered. In recent years, we have seen a trend within the biopharmaceutical pipeline from traditional drugs to biologics and specialty products.¹ These products are also being FDA-approved with a "companion diagnostic," which is an "in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product."² These companion diagnostics can be used to assess the genetic status of the patient to inform treatment selection; one example is a test to detect BRAF V600E mutations in order to identify melanoma patients who qualify for treatment with BRAF inhibitors.

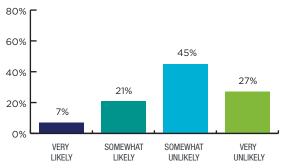
#### DRIVERS AND INCENTIVES FOR PERSONALIZED MEDICINE

Recent FDA policy states that a companion diagnostic requires concurrent FDA approval with a therapeutic product if the clinical use of the drug depends on the results of the

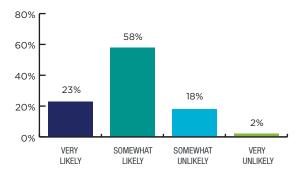
At least 75% of new breakthrough therapies will have a biomarker test that enables patient selection or optimal dosing (or both) based on the patient's genetic characteristics.



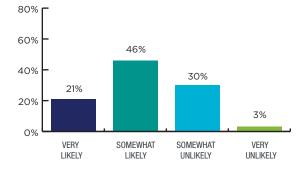
There will be at least two examples of recently marketed high-cost drug products for which the supplier offers a "money-back guarantee" if the desired therapeutic outcome is not achieved and there is proof that patient selection and dosing were consistent with the results of biometric testing.



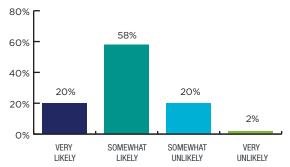
There will be at least three new breakthrough medications on the market reflecting major advances in neuroscience (e.g., for Alzheimer's disease or Parkinson's disease).



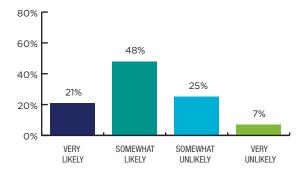
In at least 50% of cancer patients, the primary chemotherapy agent will be self-administered as an oral medicine.



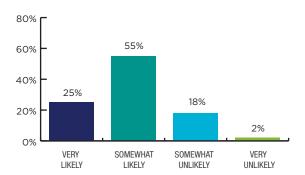
New high-cost chemotherapy agents will be covered by most insurance plans only if a biomarker test indicates high likelihood of treatment success and low likelihood of toxicity.



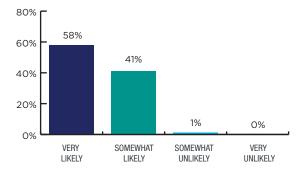
At least five medications will be in a new "behind the counter" category (an intermediate classification between nonprescription and prescriptiononly) that requires patient assessment by a pharmacist before sale of the medication



6 At least two new breakthrough medications for lung cancer will be marketed.



At least 50% of health systems will have implemented a process for adding biosimilars to their formularies and for monitoring their utilization.



companion diagnostic; this is one factor driving practice towards "personalized medicine."<sup>2</sup> Since the issuance of this draft guidance in 2011, the labeling of 13 FDA-approved products reference a companion diagnostic for patient selection or monitoring purposes.<sup>3</sup> About half of Forecast Panelists (FPs) believed that a large majority (75% or more) of new therapies over the next five years will have a biomarker test (item 1).

Another major driver towards the implementation of personalized medicine is drug reimbursement policies. More than three fourths of FPs believed that insurance plans will pay for highcost chemotherapy agents only if the results of a **biomarker test** indicate that favorable clinical outcomes are likely (item 2). Indeed, such practice is already evident by the incorporation of genetic biomarker information within a tumor pathway developed by a major oncology pathway provider.4 In this regard, the requirement for prior authorizations of specific agents is likely to proliferate and the adherence to guidelines for biomarker testing will be monitored.

According to the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics approved in June 2014, pharmacogenomic testing can improve clinical outcomes and, thus, pharmacists "have a fundamental responsibility to ensure that pharmacogenomic testing is used to optimize medication therapy." 5

#### **OUTPATIENT SERVICES**

In the next five years, it is likely that emerging therapeutic agents will challenge the dynamics of existing **outpatient clinical programs**. In particular, 69% of FPs thought it is at least somewhat likely that five or more medications will be in a new FDA-designated **"behind-the-counter"** category that requires patient assessment by a pharmacist before dispensing the medication (item 4). Examples of drug categories that may be appropriate for this designation include those to treat hyper-

tension, dyslipidemia, asthma, gastroesophageal reflux, and migraines.<sup>6</sup>

The 2013-2017 edition of *Pharmacy* Forecast discussed a trend toward oral administration of anti-cancer medications, and two thirds of FPs in the latest survey believed that in the next five years the primary chemotherapy agent administered to most patients will be a self-administered oral agent (item 7). Thus, pharmacist interaction with cancer patients will be important to manage medication adherence to improve patient outcomes.<sup>7</sup> It is notable that cancer therapy continues to be an area of development, with 80% of FPs predicting that there will be two more breakthrough medications to treat lung cancer (item 6).

A large majority of FPs (81%) also predicted that there will be at least three new breakthrough medications FDA-approved for treating **neurological disorders** (e.g., Alzheimer's disease, Parkinson's disease) (item 5). New breakthrough therapies in these areas will increase the need for pharmacist clinical engagement in ambulatory care.

#### PHARMACY WILL DRIVE THE BIOSIMILAR PROCESS WITHIN HEALTH SYSTEMS

By 2019, the patents for 12 biologics will have expired, opening opportunities for **biosimilars** of these products to enter the U.S. marketplace.8 Notably, many of these biologics are used to treat cancer and other diseases. Accordingly, almost all FPs believed that at least half of health systems will have implemented a process for adding biosimilars to their formularies (item 8). The need for the formulary system to address biosimilars within health systems was emphasized by the National Comprehensive Cancer Network Biosimilar White Paper in 2011.9 Specific recommendations in each of the medication management process areas (i.e., formulary analysis, order management, inventory management, financial analysis, education) have been published. 10

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- **1.** Evaluate your institution's process for incorporating biomarker information into clinical decision-making and reimbursement. This evaluation should assess (a) the health system's capacity to integrate biomarker data within electronic medical records and clinical decision-support tools into structured data fields (providers and managers should be able to easily document and retrieve biomarker results), (b) the ability of pharmacy staff to understand and communicate each payer's drug reimbursement policies to stakeholders (including providers) and whether biomarker results are required by the payer before administering the drug, (c) the process for continually measuring (when relevant) whether a biomarker is evaluated before a drug is prescribed, and (d) the potential for establishing a pharmacist-managed clinical pharmacogenomic service.
- 2. Actively assess opportunities to expand pharmacist patient-care engagement in ambulatory care, including the development of novel services such as fostering adherence to newer oral anti-cancer agents and monitoring use and outcomes of new breakthrough therapies in areas such as neurology.
- **3.** Ensure that your health system has developed a method for incorporating biosimilars into the medication use process, including (a) clinical review of the biosimilar vs. reference product, (b) therapeutic interchange and guided-use policies, (c) a process of inventory management and incorporation into information systems, (d) financial implications to the health system and patients, and (e) education of providers. These processes should also take into consideration any potential challenges with transitions of care and the ability to correctly attribute any adverse effects to the specific manufacturer of the biologic.

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# Pharmacy Policies and Practices:

#### **NEW CHALLENGES REQUIRE NEW STRATEGIES**

JOYCE A. TIPTON

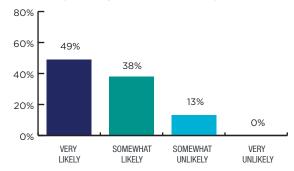
#### "BIG C" CHALLENGES

n this era of new models of health care delivery and financing, pharmacy practice leaders must navigate numerous disruptive changes. Two types of change and challenges can be described. There are "little c" challenges associated with the daily routine. Then there are "Big C" challenges associated with upheaval.¹ Pharmacy leaders will be faced with the need to let go of what worked in the past and focus clearly on the desired future and the actions required to achieve it. Forecast Panel predictions about resource allocation and budgets might seem incongruous with predictions about expanded pharmacist engagement in patient care. Therein resides the "Big C."

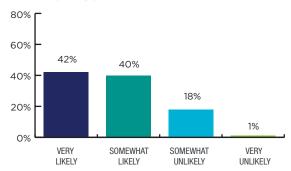
#### REALLOCATING RESOURCES

Eighty-seven percent of Forecast Panelists (FPs) believed that in at least 50% of health systems, pharmacy departments will actively **reallocate discretionary resources** to higher priority activities within the next five years, and three fourths said at least 25% of hospital pharmacy departments will reduce nondrug operating budgets by 10% or more (items 1 and 2). Compare these predictions with the results for items 3, 4, and 5, where about 80% of FPs said there will be **expansion of pharmacists' patient care roles.** To manage this incongruity, practice leaders must be rigorous in conducting operational and true strategic

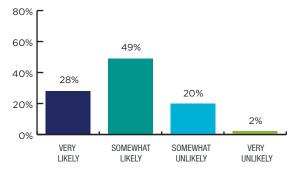
Pharmacy departments in at least 50% of health systems will engage in an ongoing, proactive process of reallocating discretionary resources from activities that have declined in importance to higher-priority activities that are more likely to contribute to the strategic imperatives of the organization. ("Discretionary" resources are those that are not subject to legal or accreditation requirements.)



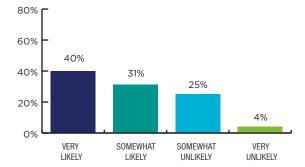
At least 50% of community hospitals will have a formal plan for expanding the engagement of pharmacists on multidisciplinary patient care teams.



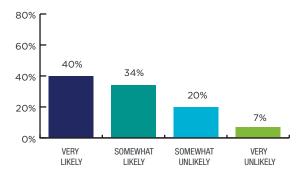
At least 25% of health systems will employ one or more clinical pharmacy specialists for the management of acute and chronic pain among patients in all settings including inpatient care, ambulatory care, palliative care, and end-of-life care.



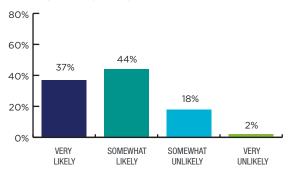
The pharmacy departments in at least 50% of hospitals will be responsible for preparing nearly all compounded sterile products needed by the hospitals' patients (versus outsourcing this function).



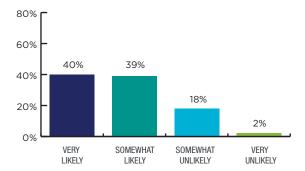
The pharmacy departments of at least 25% of hospitals will reduce their operating budgets (excluding the cost of medications) by 10% or more.



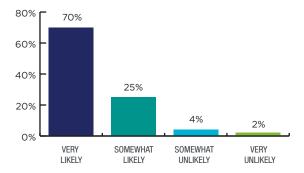
4 At least 25% of health systems will have a formal privileging process for authorizing individual pharmacists to provide specific patient-care activities.



At least one academic medical center in the region will have a formal pharmacy-based pharmacogenetic information/consultation service for health professionals and patients.



At least 90% of hospitals that outsource any of their non-patient-specific compounded sterile products will require that the supplier(s) be registered by the Food and Drug Administration.



planning, which will entail being assertive in challenging every sacred cow related to the pharmacy enterprise.

# PHARMACIST PATIENT CARE ENGAGEMENT

While it is common for pharmacists in academic medical centers to be full-fledged members of **multidisciplinary patient care teams**, this is less prevalent in the more numerous nonacademic community hospitals. FPs predicted that at least 50% of community hospitals within the next five years will have a formal plan for expanding the engagement of pharmacists on multidisciplinary patient care teams (item 3). Elements of such plans might include creation (or expansion) of a pharmacy residency program and systematic efforts to enhance the clinical skills of the current staff.

An important tool for expanding clinical engagement of health-system pharmacists is a **privileging process** that authorizes a pharmacist to perform specific advanced functions based on documented qualifications.2,3 Eighty-one percent of FPs said that it is at least somewhat likely that one fourth or more of health systems will have a formal pharmacist-privileging process (item 4). Several questions will have to be addressed by pharmacy leaders who move in this direction. Should the privileging process be identical to that used by the medical staff, or something different? What credentials are needed for specific clinical activities? Some guidance is available from ASHP on these questions.4

Prescription medication abuse is well recognized in the pharmacy community and is receiving greater national focus, including a Summit on Opioids hosted by the Obama Administration in July 2014. The Centers for Disease Control and Prevention reports that the number of drug overdose deaths doubled between 1999 and 2010, many from prescription opioids.<sup>5</sup> Facets of this issue include both over-prescribing and under-prescribing. The expertise of pharmacists is essential in addressing this public health problem. More than three fourths of FPs said it is at

least somewhat likely that 25% of health systems will employ one or more clinical pharmacists for the **management of acute and chronic pain** in all settings, including inpatient and ambulatory care (item 5). The 2013 ASHP national survey of hospital pharmacy reported that pharmacists provide pain management consultation in 45.7% of hospitals; however, of the hospitals with pharmacists practicing in outpatient clinics only 9.8% of such clinics were in pain management.<sup>6</sup> Pharmacists have untapped potential for improving pain management, particularly in ambulatory care.

# EMERGING ROLE IN PERSONALIZED HEALTH CARE

Educational programming for pharmacists has begun to address integration of **pharmacogenetics** knowledge into clinical practice.<sup>7</sup> In response to item 6, 79% of FPs predicted that at least one academic medical center in their region will have a formal pharmacy-based pharmacogenetic information/consultation service for health professionals and patients within the next five years.

#### STERILE COMPOUNDING: THE ONGOING SAGA

Following the publication of a recommendation on sterile compounding in the previous edition of *Pharmacy* Forecast, the federal Drug Quality and Security Act was signed into law. Under Section 503B of this law, a compounder can become a registered "outsourcing facility," which entails compliance with good manufacturing practice requirements and FDA inspections.8 Hospital pharmacies continue to face critical decisions regarding insourcing vs. outsourcing of sterile compounding. FPs predicted that at least half of hospitals will prepare most of their own compounded sterile products (item 7), and 95% believed that at least 90% of hospitals that outsource any non-patient-specific compounded sterile products will require the supplier to be registered by FDA as an outsourcing facility (item 8).

#### STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

- **1.** Give high priority to **systematic strategic planning** that includes careful consideration of emerging issues and trends that might affect the department in the future (such as issues highlighted in *Pharmacy* Forecast reports). Be assertive in initiating actions that will position the department well for contributing to the imperatives facing the institution as a whole.
- 2. Engage the pharmacy staff in effective change-management techniques, including analysis of operational issues, brainstorming solutions to the issues, and building buy-in for the changes required.
- **3.** Include, as an integral part of your strategic plan, assertive communications related to the role and value of the pharmacist in emerging health care delivery models. Make use of the materials in the ASHP Foundation C-Suite Tool Kit (http://www. ashpadvantage.com/ppmitoolkit). Help the leaders of your institution understand why pharmacist engagement in patient care is critical in achieving the required quality outcomes that drive the financial security of the organization. Focus on areas of particular need, such as pain management. Shift the demonstration of pharmacist value from drug expense reduction to improved patient outcomes.
- **4.** Demand that **suppliers of sterile** compounded products for your patients be registered by the FDA under the provisions of the Drug Quality and Security Act.

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# All Three *Pharmacy Forecast* Reports Have Value in Strategic Planning

his third edition of the annual *Pharmacy Forecast* report builds on the previous editions, each of which takes a five-year perspective in its predictions and strategic recommendations. All three reports are applicable to current environmental scanning and strategic planning by pharmacy practice leaders. All of the reports are accessible at www.ashpfoundation/pharmacyforecast.

Below are representative examples of strategic recommendations (SRs) from the previous two reports.

#### EXAMPLES FROM THE 2014-2018 REPORT

- Approach cost containment efforts in a manner that assumes all medication expense is borne by the provider organization, not reimbursed in a feefor-service fashion. Prepare for the emergence of risk-bearing by aggressively eliminating inefficient medication use, even when that medication use is still covered by insurance. (Page 8, SR 4)
- Identify medication-related quality-of care measures within your institution and develop an action plan for the pharmacy department to improve performance on those measures. Develop a pharmacy department dashboard of indicators that document pharmacists' contribution to improving the quality of care. (P 12, SR 1)
- Assume that drug shortages will continue to **affect your operations** for the foreseeable future. Therefore, implement or shore up the following procedures: (a) conduct a communications program (including training materials) to ensure that hospital staff is aware of the alternative regimen in use and is well versed in handling products that may be less familiar to them than the usual treatments, (b) document the chain of custody of each limited-supply product to ensure the acquisition of unadulterated product from a legitimate supplier, (c) closely monitor drug products purchased outside the usual supplier system for adverse events or outcome failures, and take corrective action as necessary, and (d) document the increased costs associated with drug shortages and report this information to executive leaders. (P 19, SR 1)
- Identify patient care priorities in your institution that
  can be advanced by redeployment of pharmacists to
  patient care teams and develop business cases to
  garner the support of executive and clinical leaders for allocation of resources to pharmacy practice
  advancement. This planning should be preceded by
  completion of the PPMI Hospital Self-Assessment,
  with its accompanying action plan. (P 24, SR 1)

#### EXAMPLES FROM THE 2013-2017 REPORT

- Develop specific plans for stepping up the pharmacy department's efforts to improve the continuity of care for patients discharged from the hospital, with special focus on patients with diagnoses that are covered (or may be covered in the future) by bundled payment to providers. Include in your plans how you will document the results of pharmacy's efforts in this area. (P 8, SR 4)
- Establish a sound process for (a) identifying the **competency requirements** of pharmacists and technicians for specific responsibilities, (b) assessing every staff member for compliance with competency requirements, and (c) continuous professional development of each pharmacist and technician related to competency requirements. Ensure that executive and patient-care leaders in your institution are aware of this process and how it relates to plans for advancing the roles of pharmacists and technicians. (P 12, SR 5)
- Capitalize on the growing availability of **clinically competent pharmacists**. Assume that you will be able to (a) be more selective than in the past in hiring top clinical talent and (b) make aggressive plans for expanding the contributions of pharmacists to improved outcomes of your patient population. (P 15, SR1)
- system strategic plan that includes short-term and long-term objectives toward achieving an ideal medication-use process. Define measures of success in advance for all medication-use system projects. Objectives to consider for a strategic plan include (a) collaborate with other institutions using the same EHR software to develop a prioritized list of enhancements specifically for pharmacy and (b) institute a safe, technology-enabled, technician-operated distribution system with the goal of having at least 50% of pharmacist work-hours devoted to patient-care activities. (P 19, SR 2)

