APhA
AMERICAN PHARMACISTS ASSOCIATION

2019 House of Delegates
Report of the Policy Committee

- ❖ Consolidation within Health Care
- ❖ Pharmacists' Role in Mental Health and Emotional Well-Being
- ❖ Referral System for the Pharmacy Profession

Committee Members

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2018–19 APhA Policy Committee Report

Consolidation within Health Care

The Committee recommends that the Association adopt the following statements:

1. APhA advocates that health care mergers and acquisitions must preserve the pharmacist–patient relationship.
   [Refer to Summary of Discussion Items 8,9,10,11,12.]

2. APhA supports optimizing the role of pharmacists in the provision of team-based care following health care mergers and acquisitions in order to:
   - enhance patient experience and safety,
   - improve population health,
   - reduce health care costs, and
   - improve the work life of health care providers.
   [Refer to Summary of Discussion Items 12 and 13.]

3. APhA asserts that the scope of review by federal agencies regarding the impact of health care mergers and acquisitions on patients and the provision of care is inadequate. Therefore, APhA calls for:
   - Reform of the review process for health care mergers and acquisitions;
   - Creation of an ongoing post-health care mergers and acquisitions evaluation process; and
   - Open and continuing dialogue among stakeholders regarding strategies to assure patient access to care.
   [Refer to Summary of Discussion Items 14,15,16,17,18.]

Summary of Discussion

1. The Committee discussed the original focus of this policy topic around vertical integration and broadened the issue to address integration in any health care setting, be it considered a vertical or horizontal type of integration. (all statements)

2. The Committee considered the original title language and modified it to "consolidation within health care" to be inclusive of vertical integration while also applying to other types of integration. Additionally, the language of "mergers and acquisitions" are used throughout these policy statements as it is the terminology familiar to a business environment and federal agencies who review these types of business deals. (all statements)

3. The Committee discussed the topic of payment and reimbursement for pharmacists within integrated health care models and determined that existing policy from APhA **2017 Pharmacy Performance Networks** (statement 2) and **2017 Pharmacists' Role within Value-based Payment Models** (statement 3) sufficiently covers the issues of payment and reimbursement. (all statements)

4. The Committee reviewed APhA **2013 Ensuring Access to Pharmacists' Services** as it relates to recognition by payers and the integration of outcomes and claims data between providers and determined no additional statements were needed on technology or payment. (all statements)

5. The Committee reviewed APhA **2004,1990 Freedom to Choose** and believed that this existing policy covers the topic of patient choice and did not feel an additional policy statement was needed. (all statements)

6. The Committee considered the use of the phrase "health care integration" instead of the phrase "mergers and acquisitions" to be broader; however, it was noted that health care integration typically refers to the integration of health care information technology (HIT) so this term was not used. The Committee believed the terminology of "mergers and acquisitions" is more accurate when calling for reform of the process as this is what the FTC and other federal agencies review. (all statements)

7. The Committee decided to keep the policy statements focused on the pharmacist–patient relationship versus specific mergers and acquisitions so that the statement would have broader application. (all statements)

8. The Committee considered potentially focusing on business practices as a whole and not only looking at vertical integration as there may be other controversial business practices that may occur in the future that would not be covered by a policy specifically focused on vertical integration. They also discussed the existing APhA policy that applies to business practices and felt no additional statements were needed at this time. (Statement 1)

9. The Committee decided that these policy statements are meant to include both a patient's access to medications and pharmacist patient care services. (statement 1)

10. The Committee specifically chose the term "preserve," in statement 1, to ensure that when a pharmacist–patient relationship exists, any merger or acquisition would maintain this relationship. The Committee noted that there may be some health care mergers and acquisitions that don't involve pharmacists and chose not to use the term "ensure" in place of "preserve." (statement 1)

11. The Committee developed statement 1 with the intent for consumer protection and preserving the patient's relationship with the pharmacist. (statement 1)

12. The Committee discussed the potential positive and negative aspects of vertical and horizontal integration and emphasized the importance of addressing issues and opportunities that might impact patient's access to care post-mergers and acquisitions. (Statement 1,2)

13. The Committee reviewed the Institute for Healthcare Improvement (IHI) Triple and Quadruple Aim and believed it was important to incorporate these concepts into the policy statement to emphasize. (statement 2)

14. The Committee noted that the current oversight of the Federal Trade Commission (FTC) includes the "quality of goods or services," but the review of this subject as it relates to a health care setting may not be comprehensive or transparent and could be limiting a patient's access to care. The Committee referenced the following charges of the FTC regarding merger review: https://www.ftc.gov/enforcement/merger-review.   (statement 3)

15. The Committee referenced a statement from the American Medical Association (AMA) that discussed how the FTC is not considering the effect of mergers and acquisitions on patient care. While this may not currently be within the FTCs purview, the Committee felt that it should be. The Committee crafted the proposed statement to be similar with the AMA statement, aiming to raise awareness by policy makers of the impact of these mergers and acquisitions on patient care. (statement 3)

16. The Committee recognized the current involvement of the FTC and DOJ in the review and approval process of mergers and acquisitions and decided to broaden the statement scope to include engagement of other federal agencies, such as the Department of Health and Human Services (HHS) or others. (statement 3)

17. The Committee reviewed the American Medical Association's analysis and response to the CVS–Aetna merger that urged the DOJ and state antitrust enforcers to monitor the post-merger effects of this merger. (statement 3)

18. The Committee discussed the importance of an ongoing post-merger review process by federal agencies to evaluate the impact a merger or acquisition has on quality of care over time, similar to how FDA conducts post-market surveillance for a newly approved medication. (statement 3)

Consolidation within Health Care

Background Paper Prepared for the 2018-2019 APhA Policy Committee (not yet copyedited)

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Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2018-2019 Policy Committee to recommend policy to the APhA House of Delegates related to vertical integration in healthcare and its impact on access to pharmacist-provided patient care. The Board's guidance on this topic included -but was not limited to- vertical integration's impact (positive and negative) on (1) system, provider, and patient incentives, (2) the competitive process, (3) restriction on product supply, (4) patients' right to choose providers, and (5) patient access to care.

Background

In 2015, David Szotsak (Assistant General Counsel at Blue Cross and Blue Shield) described the U.S. health care system as "hopelessly fragmented" [1]. In the DePaul Journal of Health Care Law [1] he wrote:

Health care providers offer services to patients in distinct venues – hospitals, out-patient surgery centers, physicians' offices, drugstores, and may other places. In a wholly separate industry, health insurance companies finance this care. This dysfunctional system arose over many decades, due to the combination of historical accident and government policy. Not surprisingly, nobody knows what anything really costs – or should cost, at least, based on market value – and financial incentives encourage all kinds of counterproductive behavior … Imposing change across so many separate entities and industries, each with its own economic interests and motivations, is increasingly difficult, and progress remains sclerotic. The necessary and inevitable solution is for a major player in the health care industry to undertake dramatic, all-encompassing vertical integration.

According to a report published by the Healthcare Financial Management Association [2], healthcare organizations are facing pressure to "reduce the cost of care, improve the coordination of care delivery, and assume financial risk for the health outcomes of patient populations." In addition, health care service providers need to monitor and measure quality and costs in ways that are being imposed upon them by payers and government agencies. All of this adds to the costs of transacting in the new systems of health care. To meet these pressures organizations are "seeking partners who can help them add new capabilities, achieve economies of scale, enrich data on clinical outcomes, or widen access to services" [2].

Such organizational behaviors are not new. In 1997, during the era of managed care expansion, Robert Pitofsky, then chair of the Federal Trade Commission (FTC) suggested that "as pressures to control healthcare costs and assure quality continue, there is an increasing recognition of the efficiencies that can come about through cooperation and collaboration" [2,3]. More recent examples of vertical

integration include pharmacy partnerships and mergers with insurance companies, wholesalers, and pharmacy benefit managers. Another example is vertical integration between pharmaceutical manufacturers and integrated delivery networks for distribution of specialty pharmaceuticals.

As background, two organizational behavior frameworks are instructive: (1) Transaction Cost Economics and (2) Collaboration Theory. Transaction Cost Economics reveals how vertical integration can control certain costs. Collaboration Theory reveals how vertical integration can improve some processes of patient care. Each will be described next.

Transaction Cost Economics

In channels of distribution for goods and services, firms will internalize activities that they are able to perform at lower cost and will rely on other firms for activities in which other channel members have an efficiency or effectiveness advantage [4]. The "transaction cost economics" framework proposes that members of the channel of distribution for a service are assumed to (1) be opportunistic (having a tendency to take competitive advantage of other parties) if given the chance, (2) have imperfect or asymmetric information, and (3) have bounded rationality (i.e. rationality that is limited by available information, cognitive limitations, and finite amount of time for decision making) [4]. These market forces work to bring about an "efficient sort" for transactions and channel governance structures so that exchange relationships can be understood in terms of "transaction cost economizing" [5].

When it comes to organizations within a channel of distribution, the decision to "make" (i.e. provide the service or function themselves) or "buy" (i.e. outsource the service or function to another channel partner) depends upon the (1) specificity of the service or function, (2) level of uncertainty about the future of the relationship between channel members, (3) complexity of the interaction, and (4) frequency of trade. For these four factors, higher levels of each are associated with a more integrated channel of distribution.

We propose that healthcare provision is becoming more integrated, orchestrated, and harmonized through vertical integration in order to minimize the costs of transacting for firms engaged in such strategies. We believe that there will be success and failure for organizations as channel members "compete for market power, efficiencies, and chances to be opportunistic in order to be profitable in both the short and long term" [6]. We suggest that healthcare provision is in a highly competitive period in which both healthcare providers and payers need to minimize costs of transacting.

Collaboration Theory

Collaboration Theory [7-11] provides guidance for "how joint decision-making among autonomous, key stakeholders of an inter-organizational domain can be used to resolve planning problems of the domain and/or manage issues related to the planning and development of the domain" [11]. Working together enables the participating organizations to create and capture mutual advantages that translate into positive return on investment and more efficient management. Collaboration Theory consists of five features:
1.   Collaborative performance system
2.   Information sharing
3.   Decision synchronization
4.   Incentive alignment
5.   Integrated processes

The practical application of collaboration theory has been realized in the past by product supply chains [7] and by the travel sector [11] through which multiple organizations worked together to fill gaps, achieve efficiencies, and create extra value that could be shared amongst organizations. In the current health care environment, similar approaches could be successful in the health care domain.

Collaborative Performance System
A collaborative performance system devises and implements performance metrics that guide the collaborating organizations to improve overall performance [7]. This process resolves the related issues of (1) who should be involved in determining the mutual objective and (2) what performance objectives should be specified with respect to the mutual objective. This process is assumed to enhance each participating organization's profit, return-on-investment, and cash flow. For example, current and future quality care indicators could be used to assess the performance of a collaborative system, which could affect the costs of care and payments to the providers involved. Since many health care performance metrics are associated with medication use, collaboration between pharmacists and other health care team members is essential.

Information Sharing
Information sharing denotes access to private data in all partners' systems enabling the monitoring of the progress of service provision as customers pass through each process in the overall system [7]. This includes data acquisition, processing, representation, storage, dissemination, status metrics, cost data, and performance data. Such access to information enables the participating organizations to elicit the bigger picture of the situation that takes into account important factors for making effective decisions. For example, health information exchanges can be created to serve as a vital platform for providing coordinated care and for collecting information essential to continuous quality improvement initiatives to enhance outcomes of care.

Decision Synchronization
Decision synchronization can be defined as the extent to which the participating organizations are able to orchestrate critical decisions for optimizing overall performance. This includes re-allocating decision rights in order to synchronize planning and execution that seeks to match capacity for service provision with demand for services [7]. The way to judge effective decision synchronization is based on its effects on (1) response towards fulfilling customer demands (logistical benefits) and (2) profitability and efficiency for participating organizations (commercial benefits). For example, often community pharmacists identify information that is important to the success of medication therapy after the medication has been prescribed. Closer synchronization of drug selection and regimen overview is likely to improve medication management and outcome. One way this could be accomplished is to have the pharmacist select the most appropriate medication to fit the patient's health and financial situation within a collaborative practice agreement.

Incentive Alignment
Incentive alignment refers to the process of sharing costs, risks, and benefits among the participating organizations. This motivates entities to act in a manner consistent with their mutual strategic objectives, including making decisions that are optimal for the overall domain and revealing truthful private information [7]. It covers estimating costs, risks and benefits as well as formulating incentive schemes such as pay-for-performance and pay-for-effort [7]. The assumption is that the actions of individual organizations are based on the expectation the act will result in mutual benefit and will result in benefit to the individual organizations. For example, a collaborative system including hospitals, clinics,

and community pharmacies could have payments linked to the quality and costs of care they jointly provide for a panel of patients.

Integrated Processes
Integrated processes refer to the extent to which participating organizations design efficient processes that deliver services to customers in a timely manner at lower costs [7]. Explicit description of these processes allows organizations to synchronize the entire sequence of integrated work activities required to deliver services that fulfill customer needs. Flexibility is needed in order to respond to the variety of customer requirements at minimum costs with respect to supply capacity. To create flexibility, participating organizations can redesign the distribution system, service offerings, production processes, and management systems to be cost effective and flexible to match supply with different conditions of customer demand. An example of this would be closer coordination across provider types when patients are hospitalized and then discharged. Sharing complete information and designing full integration during transitions of care would enhance care decisions, benefiting providers and patients.

Based on the background just presented, it is not surprising that vertical integration is taking place in the U.S. health care system. Reducing the costs of transacting and improving coordination of care delivery will help organizations assume financial risk for the health outcomes of patient populations.

Benefits of Vertical Integration in Healthcare

As explained by Transaction Cost Economics [4-6] and Collaboration Theory [7-11], there are potential benefits that can be gained from vertical integration in healthcare. These include:

1. Streamlining care delivery to reduce costs [2, 12]
2. Providing a seamless care experience [2, 12]
3. Integrating/coordinating clinical operations [2, 12]
4. Potentially increasing medical quality [2, 12]
5. Spurring innovation [2, 12]
6. Altering financial incentives to overuse care [13]

Some argue that these goals are consistent with recent health care reforms that have created powerful incentives for health care organizations to form vertically integrated systems to shift away from fee-for-service to new payment models based on value [13].

Detriments of Vertical Integration in Healthcare

There has been relatively little vertical integration antitrust enforcement in the United States [14] because vertical arrangements are viewed as procompetitive inasmuch as such integration is necessary to innovate, lower costs, or managed clinical and financial risk [12]. However, concerns can arise if a "network's power in one market in which it operates enables it to limit competition in another market" [12,15,16]. **That is, does the vertical integration create market power for the network to limit competition in the sales of any other services?**

There is evidence that vertical integration carries potential downside risks to competition and consumer welfare through (1) exercise of market power, (2) unnecessary increases in referrals and reimbursement rates, and (3) reductions in consumer choice [13]. Increases in market power may lead to tying/bundling of services that restrict competition and access to care [13]. It may also lead to "foreclosure" which

occurs when actual and potential competitors are disadvantaged through boycotts, restriction of supply, restrictive contracts, refusals to deal, raising barriers to entry, elimination of a potential entrant, facilitation of collusion, evasion of rate regulation as a result of post-merger opacity of transfer prices, or other strategies that inhibit rivals from competing [2,12,13,15,17,18]. Another anticompetitive effect of vertical integration is that merged entities may increase health spending from greater utilization and patient volume by increasing referrals and reimbursement rates within the bounds of health self-referral laws [13]. Finally, reductions in consumer choice may arise because patients are forced into decisions that are at odds with their interests but would instead maximize the integrated network's profits [13].

Contemporary Examples from 2018

Thomas Greaney and colleagues [19,20] prepared an assessment of the 2018 proposed mergers of CVS/Aetna and Express Scripts/Cigna as examples of vertical mergers that combine payment and the provision of healthcare items and services. Their assessment showed these integrations could signal a major change in how pharmaceuticals are purchased and used, and these mergers might enable insurers to restructure health benefits altogether. The detriments of such mergers relate to the risk of "foreclosure" in which the merged entities would cut off rival's access and, thus impair competition in the pharmacy and PBM markets. There is also the risk that such a high level of market concentration would lead to higher prices [19,20].

The benefits of such mergers could mean that pharmaceutical benefits would no longer be considered in isolation from medical and hospital benefits [19,20]. When pharmaceutical benefits are separate, they are viewed as costs. However, if integrated they would be viewed as products that could offset substantial costs elsewhere. Such a shift could mean that decisions related to formulary tiers and maximization of drug rebates would now be based on holistic assessments of the costs and benefits from their use in patient care (rather than on profits from rebates).

Policy recommendations from their analysis included:
1. The need for vigorous antitrust enforcement to assure that the "pro-competitive benefits of financial and clinical integration are not thwarted by excessive concentration, collusion, or abuse of dominant positions" [19].
2. Unbundling of Monopolized Services [20]
3. Challenging Anticompetitive Terms in Insurer-Provider Contracts [20]
4. Promotion of Provider and Insurer Entry [20]
5. Advocacy in Scope of Practice Laws [20]
6. Price and Quality Transparency [20]
7. Pro-Competitive Policies at CMS [20]

The American Medical Association also conducted an analysis and prepared a position paper for the CVS/Aetna merger. Their assessment was that such mergers "substantially lessen competition in many health care markets, to the detriment of patients" [21].

Policy Issues for Pharmacy

Does vertical integration in healthcare impact access to pharmacist-provided patient care? The answer to that question is 'yes', but the impact can be a double-edged sword with not only the potential to create collaborative care opportunities for pharmacists but also the potential to lead to unfair market power that restricts access to providers and restrains patient choice [13].

Based on the findings presented in this paper, we recommend the following topics for consideration by the 2018-2019 APhA Policy Committee:

1. The need for vigorous antitrust enforcement to assure that the "pro-competitive benefits of financial and clinical integration are not thwarted by excessive concentration, collusion, or abuse of dominant positions."

2. Unbundling of Monopolized Services that would Restrict Pharmacist-Provided Patient Care Provision (ACCESS)

3. Challenging Anticompetitive Terms in Insurer-Provider Contracts

4. Promotion of Provider and Insurer Entry

5. Advocacy in Scope of Practice Laws for Pharmacist-Provided Patient Care in Integrated Systems

6. Price and Quality Transparency (TRANSPARENCY)

7. Pro-Competitive Policies at CMS

8. Advocacy for Patients' Right-to-Choose Providers for Pharmacist-Provided Patient Care (CHOICE)

As a starting point, we recommend three topics for discussion by the policy committee: (1) <u>Access</u> to Care (#2 above), (2) <u>Transparency</u> in price and quality monitoring (#6 above), and (3) <u>Choice</u> for patients (# 8 above). As these discussions take place, it would be important to keep in mind some of the unique characteristics of the health care system:

- The payer of care is not present when care is provided.
- Patients are not sure how to assess "quality" of the care provided.
- Incentives in the healthcare system are not aligned among payers, providers, and patients.

These unique aspects of healthcare make policy discussions difficult. For further reading that is specific to vertical integration in the pharmacy and pharmaceutical domains, we refer you to references 19-21 in this report.

<u>Related APhA Policy</u>

2004, 1990 **Freedom to Choose**
1. APhA supports the patient's freedom to choose a provider of health care services and a provider's right to be offered participation in governmental or other third-party programs under equal terms and conditions.
2. APhA opposes government or other third-party programs that impose financial disincentives or penalties that inhibit the patient's freedom to choose a provider or health care services.
3. APhA supports that patients who must rely upon governmentally-financed or administered programs are entitled to the same high quality of pharmaceutical services as are provided to the population as a whole.
(Am Pharm NS30(6):45 June 1990) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2010) (Reviewed 2015)(Reviewed 2018)

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Pharmacists' Role in Mental Health and Emotional Well-Being

The Committee recommends that the Association adopt the following statements:

1. APhA encourages all health care personnel to receive training and provide
    services to identify, assist, and refer people at risk for or currently
    experiencing a mental health crisis.
    [Refer to Summary of Discussion Items 8,9,10,11,12,13.]

2. APhA encourages employers and policy makers to provide the support,
    resources, culture, and authority necessary for pharmacists and student
    pharmacists to engage and assist individuals regarding mental health and
    emotional well-being.
    [Refer to Summary of Discussion Items 14,15,16,17,18,19.]

3. APhA supports integration of a mental health assessment as a vital
    component of pharmacist-provided patient care services.
    [Refer to Summary of Discussion Item 20.]

Summary of Discussion

1. The Committee discussed existing APhA **1979 Dispensing and/or Administration of Legend Drugs in Emergency Situations** and referenced the applicability of the existing statement on Good Samaritan Acts and new policy was not needed in this area. (all statement)

2. The Committee determined payment should not be specifically included as it may be misinterpreted that pharmacists are asking for payment for helping an individual in a mental health crisis. However, this idea may be covered with the reference to "resources" and previous APhA policy calls for compensation for pharmacists provided patient care services. (all statements)

3. The Committee discussed the importance of knowing where to refer patients for mental health care and how pharmacists have the opportunity to fill a recognized gap in primary care coverage for mental health services. (all statements)

4. The Committee referenced NAMI's *Navigating a Mental Health Crisis* when discussing activities to respond to a mental health crisis: https://www.nami.org/About-NAMI/Publications-Reports/Guides/Navigating-a-Mental-Health-Crisis/Navigating-A-Mental-Health-Crisis.pdf?utm_source=website&utm_medium=cta&utm_campaign=crisisguide. (all statements)

5. The Committee decided to consider the terms of "emergency" and "crisis" as meaning the same thing and used "crisis" throughout this policy item. NAMI references both terms interchangeably as do other organizations. (all statements)

6. The Committee referenced a statement from the Surgeon General that uses the phrase "mental and emotional well-being," https://www.surgeongeneral.gov/priorities/prevention/strategy/mental-and-emotional-well-being.html. The Committee decided that "mental health" should be used in these policy statements as we are trying to fight the stigma associated with mental health disorders and should not be afraid to use this term to encompass a wide variety of symptoms that may not necessarily qualify someone for a diagnosed mental illness. In addition, it was felt emotional well-being encompasses a wider range of symptoms that may not be included in mental health. (all statements)

7. The Committee agreed that the term mental health crisis could be defined as a situation where a patient has suicidal/homicidal ideation or extreme emotional disturbances as described by Mental Health First Aid USA and the National Alliance of Mental Illness (NAMI). The Committee also emphasized that substance use or addiction can be a part of a crisis but was not the focus of these policy statements. (all statements)

8. The Committee defined "health care personnel" by using the following definition from the Centers for Disease Control and Prevention (CDC): all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. (statement 1)

9. The Committee recognized the importance of training that includes what to do when patient needs are identified and the importance of resources for patient referral being available. The Committee reviewed APhA **2018 Efforts to Reduce the Stigma Associated with Mental Health Disorders or Diseases** and believed that the proposed policy statement expands on the 2018 policy by including information on referral of identified people needing assistance. (statement 1)

10. The Committee discussed focusing these policy statements on only the pharmacy profession, but felt it was important to include all health care personnel to address the issue of mental health crisis management across the patient care continuum. Health care personnel includes pharmacy staff members, medical and nursing providers, and other individuals serving patients across the health care spectrum. (statement 1)

11. The Committee utilized the analogy of individuals being CPR certified in preparation for potential need to administer the service to a patient in cardiac arrest. The likelihood of a health care personnel interacting with individuals at risk for or currently experiencing a mental health crisis is greater and therefore makes the case for training and engagement of individuals throughout the health care system. (statement 1)

12. The Committee discussed whether the training of health care personnel should be mandatory or voluntary and decided to encourage everyone to receive training but felt a mandate for this training was not necessary. (statement 1)

13. The Committee emphasized the importance of identifying people who are at risk as opposed to only focusing on those who are currently experiencing a mental health crisis. It is important to recognize pre-event signs and intervene where appropriate. (statement 1)

14. The Committee discussed the application of current Good Samaritans laws and the implementation of mental health screening into pharmacist workflow. The Committee felt that employers/company policies and policy makers needed to ensure that pharmacists had the support and resources necessary to appropriately implement the identified interventions. (statement 2)

15. When the Committee referred to "policy makers," this is meant to include federal and state legislators, regulatory agencies, and staff members at hospitals, health systems, or employers who develop internal company policies. (statement 2)

16. The Committee referenced APhA **2004,1965 Mental Health Programs** and determined existing policy is focused on pharmacist involvement and does not advocate for support or resources from employers to advance the pharmacist's role in this area. (statement 2)

17. The Committee discussed that individuals may not have a diagnosis of a mental health condition prior to being identified as being at risk or experiencing a mental health crisis. Therefore, the Committee utilized the term individual to describe the targeted population of these services as being potentially beyond current patients. (statement 2)

18. In reviewing the scope of this topic, the Committee acknowledged the numerous approaches it could take, in addition to existing APhA policy. The Committee decided to

keep the proposed policies focused on the patient/individual versus issues related to the individual practitioner, as they would be encompassed under the "individual" descriptor. (statement 2)

19. The Committee discussed that states have Qualified Mental Health Professionals lists that do not include pharmacists and additional work is needed to expand this throughout the states. (statement 2)

20. The Committee emphasizes the importance of inclusion of mental health and emotional well-being assessment as part of the JCPP Pharmacist's Patient Care Process (PPCP) and the value of identifying individuals at risk before a mental health crisis occurs. PPCP incorporates assessment of "health and functional status" or "other aspects of care" within its process and therefore could encompass assessment of mental health status as part of the process. The Committee also considered how mental health status is not disease specific and crosses many conditions and should be included as part of PPCP. The Committee acknowledged numerous places within PPCP for pharmacists to assess, identify, and act upon a patient's mental health needs. (statement 3)

Pharmacist's Role in Mental Health and Emotional Well Being

Background Paper Prepared for the 2018-2019 APhA Policy Committee (not yet copyedited)

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Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2018-2019 Policy Committee to recommend policy to the APhA House of Delegates related to a pharmacist's role in a mental health crisis. The Board's guidance on this topic included -but was not limited to- review of the impact of mental illness, pharmacist training in and provision of mental health first aid services, barriers to patient's seeking care for mental illness, and the impact of mental health stigma on patients obtaining care.

Background

Mental health can be thought of along a continuum evaluating the severity and presence of symptoms (Figure 1).[1]
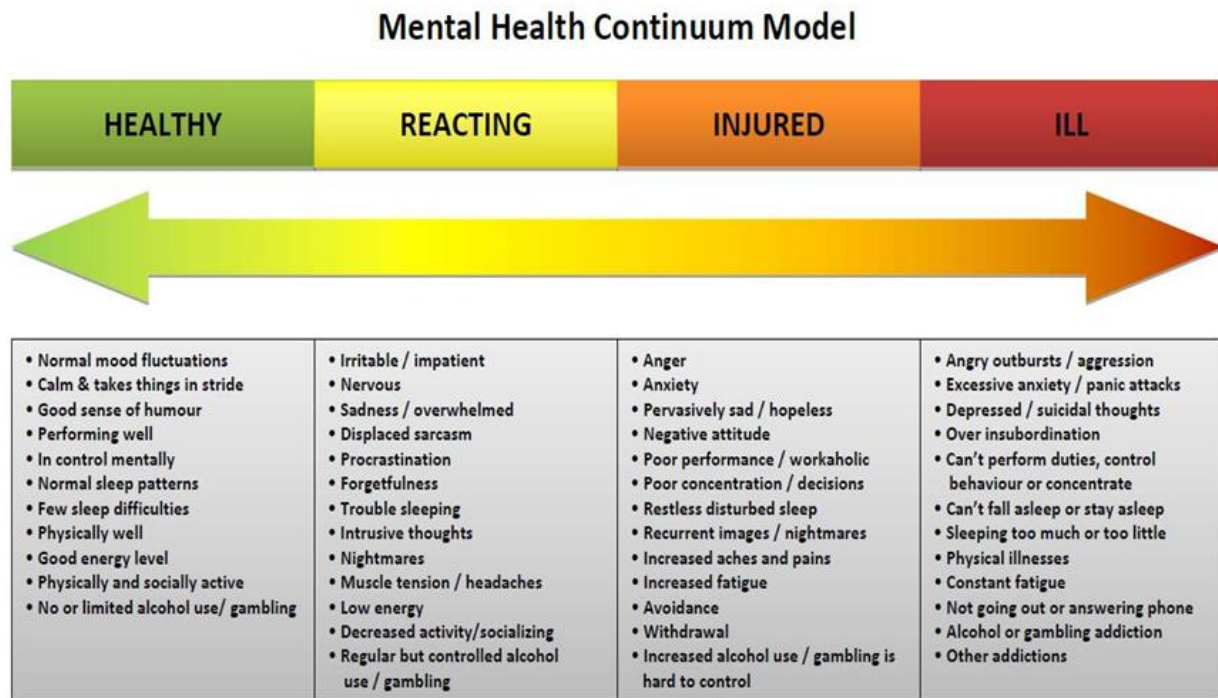

Mental Health Continuum Model

HEALTHY	REACTING	INJURED	ILL
• Normal mood fluctuations	• Irritable / impatient	• Anger	• Angry outbursts / aggression
• Calm & takes things in stride	• Nervous	• Anxiety	• Excessive anxiety / panic attacks
• Good sense of humour	• Sadness / overwhelmed	• Pervasively sad / hopeless	• Depressed / suicidal thoughts
• Performing well	• Displaced sarcasm	• Negative attitude	• Over insubordination
• In control mentally	• Procrastination	• Poor performance / workaholic	• Can't perform duties, control behaviour or concentrate
• Normal sleep patterns	• Forgetfulness	• Poor concentration / decisions	
• Few sleep difficulties	• Trouble sleeping	• Restless disturbed sleep	• Can't fall asleep or stay asleep
• Physically well	• Intrusive thoughts	• Recurrent images / nightmares	• Sleeping too much or too little
• Good energy level	• Nightmares	• Increased aches and pains	• Physical illnesses
• Physically and socially active	• Muscle tension / headaches	• Increased fatigue	• Constant fatigue
• No or limited alcohol use/ gambling	• Low energy	• Avoidance	• Not going out or answering phone
	• Decreased activity/socializing	• Withdrawal	• Alcohol or gambling addiction
	• Regular but controlled alcohol use / gambling	• Increased alcohol use / gambling is hard to control	• Other addictions

Figure 1 adapted from: Mental Health Commission of Canada. Home | Mental Health Commission of Canada. https://www.mentalhealthcommission.ca/

Patients presenting at different stages within the continuum are in need of different levels of care. Thus, the continuum acts as a useful resource to clarify the severity of impairment of those suffering from mental illness, and what resources these patients will benefit from.[1]

The continuum also illustrates the distinction between mental health and mental illness. Mental health represents our psychological and social well–being. It encompasses how we feel about ourselves and subsequently interact with others. While poor mental health can lead to poor physical health and mental illness, it is possible to have poor mental health with no comorbid mental illness.[2] For example, a person going through a hard life experience may have poor mental health during this time period without necessarily having a mental illness. Thus, feeling miserable or isolated may be red flags that your mental health requires attention and improvement. In these cases, it is important to utilize support from friends/families/other groups, focus on healthy lifestyle habits such as eating regularly and appropriate sleep hygiene, and even seeking support from a therapist can be beneficial.

At the one end of the continuum of mental illness, there are at least 43.8 million individuals afflicted in the US by mental illness every year.[3] There are several more millions of individuals who likely fall under the reacting and injured aspects of the continuum. These are often those undertreated, who should be diagnosed and properly treated for mental illness, or that need brief and temporary support to help them return to the healthy end of the continuum. While 1 in 5 adults in the US are afflicted by mental health conditions in a given year, only 41% of those adults receive mental health services. Among adults with a diagnosed serious mental illness, 62.9% received mental health services in the past.[3] Additionally, just over half (50.6%) of children with a mental health condition aged 8-15 received mental health services in the previous year.[3] In addition, we recognize that there are numerous other individuals that do not meet criteria for a diagnosis of mental illness or require treatment but experience episodes where they are unable to optimally cope or manage their temporary thoughts, feelings, and behaviors.

There are clear individual and societal consequences to inadequate identification and management of mental health symptoms. Individuals are at greater risk for poor psychological, social, occupational, and physical functioning that affects their quality of life, morbidity, and mortality.[3] Suicide is also the 10th leading cause of death in the U.S., the 3rd leading cause of death for people aged 10–14, and the 2nd leading cause of death for people aged 15–24.[3] Inadequately treated mental illness has also contributed to $193.2 billion in lost earnings per year.[3]

For a variety of reasons, whether it be those already diagnosed with mental illness, those who need to be diagnosed and/or treated, or those with more transient/temporary mental health symptoms, these groups of individuals face significant challenges obtaining resources to help them initiate and/or remain consistently engaged with a support system that can provide the needed support to help them resolve their temporary or long-term difficulties. Needed support might include the identification of strategies to manage and monitor symptoms, connecting with formal (i.e., therapists, prescribers, etc.) and informal support systems (i.e., peers, family, and religious groups), identification of treatment approaches including psychotherapy and/or medications, the use of available specific community programs and resources. Key reasons why these groups of individuals struggle to initially reach out for support or consistently engage in support include (1) the stigma experienced by all these groups that are afflicted with different levels of mental health challenges, and (2) the lack of convenient access to individuals trained to provide temporary supportive management of specific mental health challenges and know when and what types of additional support is needed for such individuals. The stigma associated with mental illness reflects the general societal belief that those with mental health concerns are often

dangerous, unstable, and incompetent because they are not fully able to function in their communities and communicate.[4] Even insurance companies have been shown to offer greater coverage for physical illness over mental illness.[5]

The National Alliance on Mental Illness (NAMI) and many other mental health advocacy groups and organizations have promoted anti-stigma campaigns to target the first reason for the lack of initiation or continued engagement to seek support services by those with ongoing and new mental health needs. Clearly, there is still much work to do to make individuals with a variety of mental health symptoms feel more comfortable reaching out and having someone help them through their symptoms. Mental health organizations continue to focus on facilitating cultures at work places, health care environments, and other areas of the community that avoid judgement and distance away from the individual suffering from ongoing or temporary mental health symptoms. Rather, the focus of this anti-stigma work is to help bring the affected individual together with a community resource and together support the individual towards improved mental health management.[6]

Role of the Pharmacist

As valued, trusted members of the community, pharmacists are at the frontlines of primary health care and thus regularly interact with individuals that have a diagnosed mental illness, not yet diagnosed mental illness, or less severe symptoms not meeting a diagnosis. While pharmacy school curriculums and continuing education programs typically cover the clinical management of diagnosed conditions, students and practicing pharmacists are often not exposed how to screen, provide brief supportive intervention, and/or offer referral to further management of mental health symptoms. If pharmacy staff were equipped with such knowledge and skills, they may be able to facilitate a significant population of individuals struggling with mental health symptoms to get needed attention to effectively manage their symptoms. The College of Psychiatric and Neurologic Pharmacy (CPNP) and National Alliance on Mental Illness (NAMI) collaborated on a 2012 national survey and assessed the opinions of 1,031 individuals with mental health concerns, or their caregivers, regarding their relationship with their pharmacist. 91% felt very comfortable going to their community pharmacy and 83% felt like the pharmacist respected them.[7] Studies show mixed findings with regards to pharmacists' comfort level and willingness to provide services to those with mental illness[4,7,8,9]. For example, several studies show pharmacists having greater discomfort with providing services to those with mental health conditions than those with physical illnesses such as asthma.[8] Further, a recent study reported that willingness/interest to provide services to those with mental illness was greater than comfort/confidence in doing so.[9] Such discomfort appears to be reflected in the finding that individuals with mental illness have been reported to receive less counseling, monitoring, and follow-up from pharmacists, compared with patients who have corporeal health conditions.[8] In the 2012 NAMI and CPNP survey presented previously, a little over half of the survey respondents reported having a strong professional relationship with the pharmacist, and 40% reported no relationship with their pharmacist. Furthermore, 75% reported not receiving effectiveness and/or safety monitoring assistance from the pharmacist.[7] These mixed findings about the collaboration between individuals with mental health needs and community pharmacists highlights, as noted earlier, there is a potential need for greater education and support for pharmacists to gain greater comfort and confidence in engaging patients with mental health needs.

Mental Health First Aid

Mental Health First Aid (MHFA) is a training program offered to the general public aiming to increase mental health literacy and impart the participant with the skills required to provide an immediate response to a person suffering from an acute mental health crisis. The program originated in Australia, and was designed by Betty Kitchener, a nurse specializing in health education, and Anthony Jorm, a mental health literacy professor, in 2001. The program runs eight hours, often split into two four-hour sessions. During this time, participants obtain the skill set necessary to not only intervene in a mental health crisis, but to identify those at risk and suffering from mental illness and direct them to the help they require. Many consider MHFA analogous to the CPR of mental illness.

The program focuses on depression and mood disorders, anxiety disorders, trauma, psychosis, and substance use disorders. Participants in the training learn the program's "Mental Health First Aid Action Plan," and are taught to apply the plan to many different scenarios – specifically guiding interactions with others experiencing suicidal thoughts or behaviors, panic attacks, nonsuicidal self-injury, overdose or withdrawal from substance use, and reaction to a traumatic event. The plan consists of five simple steps:
1. Assess for risk of suicide or harm
2. Listen non-judgmentally
3. Give reassurance and information
4. Encourage appropriate professional help
5. Encourage self-help and other support strategies

While no requirements exist for the training, it is available to anyone within the general public. The company providing the training strongly encourages professions whose daily interactions include frequent encounters with those at risk or experiencing mental illness/crisis to participate. Specific examples listed on the MHFA website include police officers, human resource workers, primary health care workers, schools, community faith organizations, friends and family of someone suffering from mental illness, and many more.[10]

Mental Health First Aid: Review of Existing Literature

With an apparent need to alter pharmacists' perceptions and increase knowledge base regarding mental health, a few pharmacies have adopted the use of MHFA training. With much talk regarding how to improve the outcomes of our patients with a mental illness, researchers have begun investigating the results and attitudes of those successfully completing MHFA.

One study took place in 8 rural Australian community pharmacies and entailed a survey assessing barriers to applying training as well as pharmacists' attitudes toward MHFA. Pharmacists identified and supported the need for MHFA and had low confidence in their ability to handle an acute mental health crisis without the additional training. The majority (72%) of pharmacists agreed that it is their role to provide MHFA, but less than half (48%) were comfortable in providing this support. All participants agreed that more training is required in MHFA and they further stated they would be prepared to undertake this training. 32% thought the training should be administered during their intern year, 24% thought training should be administered during their pharmacist years, and the majority (76%) preferred administration of training as a one-day course with an online component. The major barriers identified by pharmacists included time, geographic location, and resources.[11] This shows that pharmacists have both identified the need for

and are willing to undertake MHFA training in order to decrease the health disparities found in the mental health population.

A controlled trial was conducted assessing 60 third year pharmacy students at the University of Sydney who were randomly chosen to complete two 12-hour sessions of MHFA and complete a follow up survey. The survey (administered before and after the training) evaluated mental health literacy, the 7-item social distance scale, and 16 items related to self-reported behavior. Survey results showed that MHFA training reduced the student pharmacists' mental health stigma, improved recognition of mental disorders, and improved confidence in providing services to consumers with a mental illness in the pharmacy setting.[12] Another randomized controlled study of 262 members of the Australian public demonstrated that students (not just in pharmacy school) who participated in an online MHFA course responded better to measures of stigma reduction compared to those that used a written manual.[13] This indicates that completing a training program such as the MHFA is more valuable than just offering educational materials to the pharmacist.

A meta-analysis was performed estimating the effects of the MHFA program in participants of any occupation, both for adults and young people, based on results published up to March 2014. MHFA was found to be effective in increasing knowledge regarding mental health problems and effectively decreasing negative attitudes toward individuals suffering from mental health problems. The program was also shown to increase help-providing behavior.[14] Another publication reviewed 3 published trials and found improved concordance with health professionals about treatments, improved helping behavior, greater confidence in providing help to others, and decreased social distance from people with mental disorders.[15] This culmination of data goes to show that taking a course in MHFA significantly improves confidence, decreases stigma, and sets the participant up for a more successful interaction when reaching out to those with mental illnesses.

Important Considerations

Although studies have reported on the opinions of those taking the Mental Health First Aid program, little research has been done following patient outcomes. While one can certainly appreciate its impact on participants' attitudes and confidence regarding mental health and crisis situations, we don't have any data on how this relates back to the patient. This poses the question of whether these trainings really help prepare people to identify and communicate with those with mental health concerns or if participants are simply receiving a false sense of confidence. More research must be done exploring the outcomes of those receiving help from trained MHFA participants.

Mental Health First Aid is also designed for administration to the general public – it may be prudent to give healthcare professionals a more intensive program, tailored to their education and background, than the public receives. Pharmacists may also benefit from a focus on consultation, in addition to conversation, and how to incorporate both into their patient interactions.[16] One study, taking place at University of Sydney, evaluated the differences in confidence and attitudes of their student pharmacists towards suicidal crisis in three groups of students: the first group simply completed MHFA training, the second group completed MHFA training and observed a simulation of a patient and pharmacist interaction with a person undergoing suicidal crisis, and the third completed the MHFA training and participated in the live simulated interaction. Results displayed a clinically significant increase in confidence in all students who participated (due to the MHFA training) but showed greater increases in students participating in the

live interaction.[17] This could indicate that participating in a live simulation of a crisis situation may be a valuable addition to the MHFA curriculum for pharmacists.

In addition, MHFA is not the only program available to train participants on how to deal with mental health crisis and communicate effectively with those suffering. Other programs include options such as "Psychological First Aid (PFA)" and "Emotional CPR (eCPR)." PFA usually focuses more on protocol following a disaster, while MHFA is broader.[18] Thus, mental health first aid would likely be a more appropriate choice to administer as training since it has a more realistic and applicable scope. eCPR, however, is another training geared toward the general public to assist a person experiencing an emotional crisis using three components:

1. **C** = Connecting with Compassion and Concern to Communicate
2. **P** = emPowerment to experience Passion, Purpose and Planning
3. **R** = Revitalize through Re-establishing Relationships, Routines and Rhythms in the community[19]

No head to head studies exist comparing the different available trainings, so one cannot confidently say that MHFA is the best program offered in preparing pharmacists, or even the general public, for these interventions.

Additional Points for Policy Consideration

There are other areas beyond education and training for pharmacists and student pharmacists that may also need to be considered when developing policy. The role of other pharmacy staff members, professional liability, and integration of services into the pharmacy workflow are other topic areas that need to be considered.

Other pharmacy staff members such as a technician or clerk may have interactions with patients who have a mental illness and could prevent a mental health crisis if knowledgeable on appropriate procedures. Or, perhaps it is the responsibility of the pharmacy staff member to notify another individual who has training to intervene during a mental health crisis. Regardless of the situation, pharmacists and student pharmacists are not the only individuals in a pharmacy setting who may be able to have a positive impact on a patient's outcome should a mental health crisis situation develop.

Professional liability is another subject that needs to be considered. When identifying a patient who is having a mental health crisis or may be a danger to themselves or others, what is the responsibility of the pharmacist? Could the pharmacist be held liable if they do not refer the patient to an appropriate healthcare provider? What documentation within a medical record or the pharmacy record would be needed to ensure the pharmacist documents their interaction? Technology barriers prevent some pharmacists from being able to document directly into a patient's electronic health record (EHR) and APhA has existing policy that calls for this type of integration. What then would be the required documentation or the appropriate referral when a pharmacist does not have access to broader information or the ability to document their current interaction.

Conclusion

Although we do not have enough evidence suggesting that Mental Health First Aid improves patient outcomes, we do have overwhelming evidence that it decreases existing stigma regarding mental illness, which is one of the leading barriers to patients seeking care. It also increases pharmacists' confidence in approaching and interacting with a patient who is undergoing a mental health crisis, and aids pharmacists in identifying these patients. These are both huge steps in improving access to care for patients suffering from mental illness. However, with no head to head studies comparing Mental Health First Aid to other programs, we cannot confidently say this is the only program recommended for adequate training.

With the pharmacist being the most accessible and most frequently visited healthcare professional, community pharmacists are an incredibly underutilized tool in bridging the gap between those suffering from mental illness and the treatment and support they need to begin the healing process. In conclusion, pharmacists acknowledge the need to augment their knowledge regarding mental health crisis and can be an excellent tool in reaching out to patients suffering from mental illness. Training programs exist that may help to abolish stigma and increase confidence and awareness of pharmacists to encourage greater access to care for patients who need it but may not know how to ask for it.

Related APhA Policy

2018   Efforts to Reduce the Stigma Associated with Mental Health Disorders or Diseases
1. APhA encourages all stakeholders to develop and adopt evidence-based approaches to educate the public and all health care professionals to reduce the stigma associated with mental health diagnoses.
2. APhA supports the increased utilization of pharmacists and student pharmacists with appropriate training to actively participate in the care of patients with mental health diagnoses as members of interprofessional health care teams in all practice settings.
3. APhA supports the expansion of mental health education and training in the curriculum of all schools and colleges of pharmacy, postgraduate training, and within continuing professional development programs.
4. APhA supports the development of education and resources to address health care professional resiliency and burnout.

2016, 2003, 1987   Substance Use Disorder Education
APhA supports comprehensive substance use disorder education, prevention, treatment, and recovery programs.
(Am Pharm. NS27(6):424 June 1987) (JAPhA NS43(5): Suppl. 1:S58 September/October 2003) (Reviewed 2006)(Reviewed 2011) (JAPhA 56(4); 369 July/August 2016)

2011   The Role and Contributions of the Pharmacist in Public Health
In concert with the American Public Health Association's (APHA) 2006 policy statement, "The Role of the Pharmacist in Public Health," APhA encourages collaboration with APHA and other public health organizations to increase pharmacists' participation in initiatives designed to meet global, national, regional, state, local, and community health goals.
(JAPhA NS51(4) 482;July/August 2011)(Reviewed 2012)(Reviewed 2016)

2004, 1965 Mental Health Programs
APhA supports pharmacists' participation in the development and implementation of all aspects of mental health programs so that the special needs and problems of the mentally ill can be effectively met.
(JAPhA NS5:274 May 1965) (JAPhA NS44(5):551 September/October 2004)(Reviewed 2010)(Reviewed 2011)

2003   Drug Addiction/Chemical Dependency Education
APhA urges pharmacists and pharmacy students to become educated in the recognition and treatment of drug addiction and chemical dependency.
(JAPhA NS43(5):Suppl. 1:S57 September/October 2003) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

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2018–19 APhA Policy Committee Report

Referral System for the Pharmacy Profession

The Committee recommends that the Association adopt the following statements:

1. APhA supports referrals of patients to pharmacists, among pharmacists, or between pharmacists and other health care providers, to promote optimal patient outcomes.
   [Refer to Summary of Discussion Item 6.]

2. APhA supports referrals to and by pharmacists that ensure timely patient access to quality services and promote patient freedom of choice.
   [Refer to Summary of Discussion Items 6,7,8,9.]

3. APhA advocates for pharmacists' engagement in referral systems that are aligned with those of other health care providers and facilitate collaboration and information sharing to assure continuity of care.
   [Refer to Summary of Discussion Items 10 and 11.]

4. APhA supports attribution and equitable payment to pharmacists providing patient care services as a result of a referral.
   [Refer to Summary of Discussion Items 12,13,14.]

5. APhA promotes the pharmacist's professional responsibility to uphold ethical and legal standards of care in referral practices.
   [Refer to Summary of Discussion Item 15.]

6. APhA reaffirms its support of development, adoption, and use of policies and procedures by pharmacists to manage potential conflicts of interest in practice, including in referral systems.
   [Refer to Summary of Discussion Item 16.]

Summary of Discussion

1. The Committee reviewed APhA **2018 Pharmacists Electronic Referral Tracking** and noted this existing policy was focused on the process and procedures of a referral and intended for the new policy statements to be focused on the principles of a referral. (all statements)

2. The Committee avoided words such as "bidirectional" and wanted to avoid a focus on technology because these topics already exist in **2018 Pharmacists Electronic Referral Tracking** and **2015 Interoperability of Communications Among Health Care Providers to Improve Quality of Patient Care** policy statements. (all statements)

3. The Committee discussed varying types of referral processes and intends for these policy statements to apply to any type of referral process and intends for these policy statements to be broad to apply to any existing process or a process yet to be developed. (all statements)

4. The Committee reviewed multiple APhA policies that reference team-based care such as **2013 Ensuring Access to Pharmacists' Services**, **2011 Pharmacist's Role in health Care Reform**, and **2017 Pharmacists' Role within Value-based Payment Models**, which cover a broader context of what services pharmacist should be able to provide. (all statements)

5. The Committee discussed the important role pharmacists are having in providing primary care services and referenced APhA **2013 Pharmacists Providing Primary Care Services** in addition to the following article from Forbes: https://www.forbes.com/sites/sachinjain/2018/10/10/can-pharmacists-help-reinvent-primary-care-in-the-united-states/#1d45b1d2590b. (all statements)

6. The Committee emphasized that the original intent of (statement 1) is to get referrals and be a part of the system and the intent of (statement 2) is to get the right patients to the right providers. (statements 1 and 2)

7. The Committee believes that any pharmacist could be included in a referral system described in these policy statements as a referrer of patients and recipient of referrals if able to meet quality service expectations. (statement 2)

8. The Committee considered the phrases "needed," "medically necessary," or "essential pharmacist services" in place of "quality" but believed "quality" more accurately described a measurable outcome. The Committee discussed that "medically necessary" was more of a subjective term and "essential" implied that pharmacists may provide non-essential services and decided not to use these terms. (statement 2)

9. The Committee reviewed APhA **2004,1990 Freedom to Choose** and still felt it was necessary to call out the importance of a patient's freedom of choice regarding a referral system within statement 2. (statement 2)

10. The Committee considered including the "team-based care" in statement 3, but felt that the statement needed to be broader. The Committee believes that a referral system aligned with those of other health care providers encompasses "team-based care." (statement 3)

11. The Committee discussed using the phrase "referral systems for pharmacists" and changed it to "advocates for pharmacists' engagement in referral systems" to add clarity for the role of a pharmacist within an existing or new system versus something being created solely for pharmacists. (statement 3)

12. The Committee discussed using the phrase "patient care services" and determined that it encompasses the breadth of services that pharmacists provide and is the appropriate terminology for the policy statements. (statement 4)

13. The Committee discussed the pharmacist's liability when referring a patient or having a patient referred to her/him and believed these topics are covered in statement 4 through upholding ethical and legal standards of care in referral practices. (statement 4)

14. The Committee felt that the term "equitable" was necessary to ensure pharmacists received sufficient payment to cover patient care services provided by pharmacists similar to other health care providers. Additionally, the word "attribution" was included in order to ensure recognition of the pharmacist's role in the delivery and management of patient care services. (statement 4)

15. The Committee reviewed the Oath of a Pharmacist, APhA's Pharmacist Code of Ethics, and the AMA Referral Code of Ethics when developing these statements and decided that "ethical and legal standards of care" was all encompassing. (statement 5)

16. The Committee reviewed APhA **2011 Potential Conflict of Interest in Pharmacy Practice** and reaffirmed their support of a component of this existing policy while attributing the reaffirmed statement to referral practices. (statement 6)

Referral System for the Pharmacy Profession

Background Paper Prepared for the 2018-2019 APhA Policy Committee *(not yet copyedited)*

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Issue

The American Pharmacists Association (APhA) Board of Trustees has directed the 2018-2019 Policy Committee to recommend policy to the APhA House of Delegates related to a referral system for the pharmacy profession. The Board's guidance on this topic included -but was not limited to- two-way referral mechanisms, ability to refer patients to other pharmacists, health information technology needs to accommodate new referral methods, and ethical considerations when considering referrals.

BACKGROUND

As the Centers for Medicare and Medicaid Services (CMS) and health insurance companies move in the direction of value-based models, the concept of team-based care becomes much more vital in delivery and optimization of health care. One direct influencer often discussed by health care providers is patient referrals. Patient referrals traditionally consist of a health care provider with potential limited resources (i.e., training, equipment, time, or scope of practice) seeking the assistance of a differently resourced or capable health care provider. An important mechanism physician practices can employ to greatly increase their capacity to meet patient demand is to use a coordinated, team-based, patient-centered approach to care and delegate appropriate clinical responsibilities to non-physician practitioners.[1] Due to the increased demand for primary care providers, pharmacists can help address health care needs in the management of specific disease states in which they have the training and authority to oversee. There are over 300,000 pharmacists in the U.S., many of whom are underutilized in their capacity to contribute to addressing these unmet health care needs.[2] In addition, CMS continues to encourage the collaborative treatment and management of patients within the health care team.

PHARMACISTS' TRAINING AND CERTIFICATION

Pharmacist education, training, credentialing, and professional practice models closely mirror those of physicians in the U.S. In parallel to the physicians' Doctor of Medicine (M.D.) degree, pharmacists complete a degree program at the Doctor of Pharmacy (Pharm.D.) level, both focused on the delivery of meaningful clinical services.[3] Beyond the entry level degree to practice as a pharmacist, most will continue further training. Post-graduate training includes continuing education, certificate training programs, Advanced Practice and on-the-job Training, Fellowships and specialty certification. Some state laws require additional training and/or recognition for the provision of patient care services and expanded scope of practice.

A Post-Graduate Year One (PGY-1) residency program is the baseline of residency training. It is a 12 month organized, directed, accredited program that builds upon knowledge, skills, attitudes and abilities gained from pharmacy school.[4] Further training is available through Post-Graduate Year Two (PGY-2)

residency program and is often referred to as a specialty residency as its focus is within a specific area of pharmacy practice, such as oncology, pediatrics, ambulatory care, or management. A PGY-2 residency increases the depth of knowledge related to medication therapy and clinical leadership in the specific area of focus.[5] Board certification through pharmacy-specific certifications, such as the Board of Pharmacy Specialties (BPS) is a credential sometimes required or preferred in advanced practice settings. Certification for pharmacists is in alignment with physician certification through the American Board of Medical Specialties.[6] Pharmacists are also able to attain additional certifications through multi-disciplinary certifications such as the Certified Diabetes Educator (CDE).

CURRENT REFERRAL PRACTICE WITHIN HEALTH CARE

Pharmacists to Other Health Care Providers

Rather than create a referral system that is independent of current practice in other health care settings, it is important to understand the current state of referrals within the field. Two segments of the health care community that have established referral practice models are physicians and dentists. Understanding the current referral systems, communication, provider databases, payment or other compensations, and ethical considerations for referrals helps build a platform for the discussion of pharmacist referral.

Generally, in the physician setting, primary care physicians typically provide the referral to a specialist based on the need for specific expertise, complexity of patient needs, or guideline recommendations of certain disease states. Variability in referral practice does exist based on the health insurance and compensation models for the health care provider. As patients are referred to specialists, issues/ obstacles are present with the continuity of care and proper communication of clinical decisions. Many referrals do not include a transfer of information, either to or from the specialist; and when they do, it often contains insufficient data for medical decision making.[7] Furthermore, the list of available providers is heavily based on practice-setting and relationship with the primary care provider. Concern also exists regarding the return of the referred patient to the referring practitioner.

Payment and compensation for referrals, whether through direct or self-referral, are heavily regulated and in many cases against the law. Under current law, if a health care provider sends a referral to another health care provider, the primary provider may not be compensated for the referral.[8] Furthermore, physicians are prohibited from referring patients to specific entities in which they have a vested interest.[9]

The ethical considerations and views of the referral system in the various health care settings are well defined by the corresponding code of ethics. The American Medical Association (AMA) Code of Medical Ethics states "[p]hysicians' fiduciary obligation to promote patients' best interests and welfare can include consulting other physicians for advice in the care of the patient or referring patients to other professionals to provide care."[10] AMA's code of ethics further outlines the specific consideration for the physician, when a physician seeks or provides consultation about a patient's care or refers a patient for health care services, including diagnostic laboratory services. Specifically, a physician should:

> a) *"Base the decision or recommendation on the patient's medical needs, as they would for any treatment recommendation, and consult or refer the patient to only health care*

professionals who have appropriate knowledge and skills and are licensed to provide the services needed.

b) *Share patients' health information in keeping with ethics guidance on confidentiality.*
c) *Assure the patient that he or she may seek a second opinion or choose someone else to provide a recommended consultation or service. Physicians should urge patients to familiarize themselves with any restrictions associated with their individual health plan that may bear on their decision, such as additional out-of-pocket costs to the patient for referrals or care outside a designated panel of providers.*
d) *Explain the rationale for the consultation, opinion, or findings and recommendations clearly to the patient.*
e) *Respect the terms of any contractual relationships they may have with health care organizations or payers that affect referrals and consultation."* [10]

Another topic that the AMA Code of Ethics considers is self-referrals. When physicians enter into arrangements that provide opportunities for self-referral they must:

a) *"Ensure that referrals are based on objective, medically relevant criteria.*
b) *Ensure that the arrangement:*
   1. *Is structured to enhance access to appropriate, high quality health care services or products.*
   2. *Is within the constraints of applicable law.*
   3. *Does not require physician-owners/investors to make referrals to the entity or otherwise generate revenues as a condition of participation.*
   4. *Does not prohibit physician-owners/investors from participating in or referring patients to competing facilities or services.*
   5. *Adheres to fair business practices vis-à-vis the medical professional community—for example, by ensuring that the arrangement does not prohibit investment by nonreferring physicians.*
c) *Take steps to mitigate conflicts of interest, including:*
   1. *Ensuring that financial benefit is not dependent on the physician-owner/investor's volume of referrals for services or sales of products*
   2. *Establishing mechanisms for utilization review to monitor referral practices*
   3. *Identifying or if possible making alternate arrangements for care of the patient when conflicts cannot be appropriately managed/mitigated*
d) *Disclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral."* [11]

The American Dental Association (ADA) published its own "General Guidelines For Referring Dental Patients," which states:

"[D]entists shall be obliged to seek consultation, if possible, whenever the welfare of patients will be safeguarded or advanced by utilizing those who have special skills, knowledge, and experience. When patients visit or are referred to specialists or consulting dentists for consultation:
1. *The specialists or consulting dentists upon completion of their care shall return the patient, unless the patient expressly reveals a different preference, to the referring dentist, or, if none, to the dentist of record for future care.*

2. *The specialists shall be obligated when there is no referring dentist and upon completion of their treatment to inform patients when there is a need for further dental care."*[12]

Currently there does not exist a formal process or mechanism for pharmacist referral to and by other health care professionals, nor a system for referrals between pharmacists.

DEVELOPING PHARMACISTS REFERRAL SYSTEMS

The development of a referral system for pharmacists consists of a multitude of factors to consider. A framework for pharmacist referral needs to be developed that guides the process across and within the healthcare system. Whether it be support for transitions of care or comprehensive medication management, access to pharmacists with advanced or specialized knowledge and skills can only improve care delivery and outcomes. Supporting the framework are access by pharmacists to necessary information within patient medical records utilizing technology and other communication vehicles. Under the *Health Insurance Portability and Accountability Act of 1996* (HIPAA), the Department of Health and Human Services (HHS) adopted standards for electronic transactions, including referral certification and authorization.[13] These standards outline that specific requests or responses between a health plan and health care provider follow HIPAA requirements.

Besides an interdisciplinary referral system, a referral system within the profession of pharmacy may increase access to pharmacists with specialized skillsets and enhance collaboration within the profession of pharmacy. A challenge for many pharmacists is isolation in practice and the ability to consult with or refer patients for further work-up by a specialist might be a solution to this pharmacist well-being challenge. Currently, pharmacists with specialized skillsets may not be readily accessible to other pharmacists because of system processes, payment policies or other barriers.

As seen in other health care professions, referral systems need a searchable database of providers that the referring provider may access and directly communicate the request. Physicians, other providers, and even pharmacists need a reliable resource to identify board certified or credentialed pharmacists to refer patients with specific needs. Referring providers will also need the ability to verify each of the specialists listed in the database maintain their professional licenses and other credentials. In addition, a referral database must also possess the capacity to collect the necessary information on providers for payers, employers, and referring health care providers.

Individual practice settings may have specific needs based on their resource availability and pharmacist-provided patient care services offered. Traditionally, in the inpatient setting, physicians and other health care providers partner with pharmacists under collaborative practice agreements (CPAs) and standing orders to optimize medication management needs. The inpatient settings afford a pharmacist with access to patient protected health information (PHI), clinical lab data, and ability to document within the patient's electronic health record (EHR). Similarly, outpatient clinics have comparable PHI and access to primary care providers to coordinate patient care.

One example study shows the opportunity for community pharmacies to be an ideal point of contact for specific health care needs. Cognitive memory screening can be easily incorporated into clinical service offerings in community pharmacy practice and provides a valuable opportunity to identify patients at-risk and refer them to a physician for appropriate testing and diagnosis.[14] Consultant pharmacists have limited access to PHI and often need to request specific information from the referring provider. The study identified maintaining recommended minimum expected resource requirements for overall

pharmacist referrals practice are necessary; however, understanding specific pharmacy practice settings abilities and limitations helps address the issues currently being faced by the pharmacists in these settings.

As patient referrals are received by the pharmacist there is need for the interoperability of the EHR to ensure the proper documentation, recommendations, and implementation of clinical decisions. The decisions and notes made by both the primary care provider and each specialist need to be readily accessible throughout the continuum of care. In addition, as pharmacists receive referrals from the health care providers, the need for access to patient history and clinical data becomes important to provide team-based care. Pharmacists need this information to make well informed clinical-decisions based on the complete clinical state of the patient.

Access to the referring health care provider and other team members to coordinate care and provide important evaluation and treatment decisions is considered the norm within health care settings. A practice model [See, Figure 1] from Canada looks at how pharmacists may be integrated into the outpatient referral-consultation process.[15]
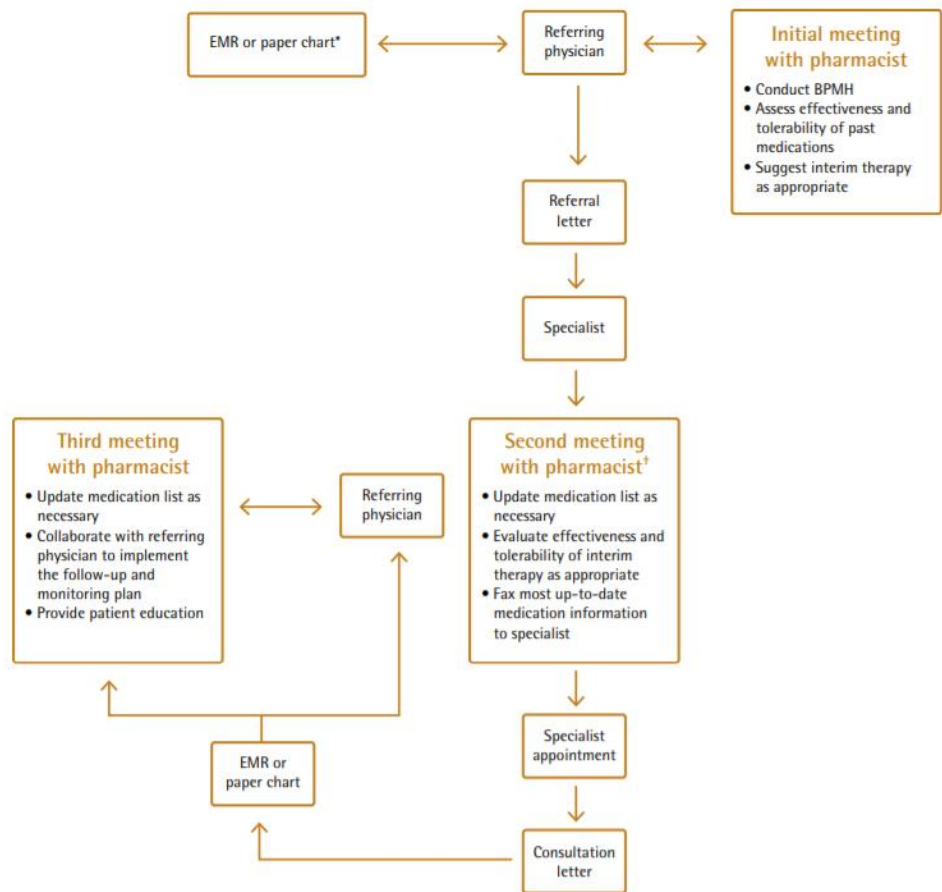
BPMH—best possible medication history, EMR—electronic medical record.
*Sources informing the medication information in the referral letters.
†Might not be needed if the wait time for the specialist visit is short (ie, < 3 mo).

Figure 1. Proposed model for involving pharmacists in the referral-consultation process[16]

Legal, financial and ethical considerations must also be taken into account when building a pharmacist referral system. For a pharmacist to be eligible to receive referrals from other health care providers and payment for the referrals, most health care plans require formal referrals be sent to other health care providers, or at minimum a CPA to exist. Notifying a referring provider of decisions made by the pharmacist and the patient is needed to ensure proper documentation and communication. Depending on the payer and state specific regulations, pharmacists may be viewed as health care providers under Medicaid[16], or by commercial payers[17]; however, pharmacists would need federal recognition to receive referrals as health care providers within Medicare.

In practice, the clinical decisions shall be independent of the business decisions for the pharmacist. However, compensation to the pharmacist for the medical referral also needs to be carefully addressed under any functioning patient referral system. Although physicians and pharmacists are not directly compensated under Medicare for referring to a particular specialist, pharmacists often provide services incident to physician services arrangements that are billed by physicians using evaluation and management (E/M) codes. It is important to note that if CMS finalizes a recently proposed rule that would collapse E/M codes for new and established office visits (Levels 2 through 5 (99202-99205)) into a single blended payment rate, the Agency projects decreased payments for certain specialties (geriatrics (-4%), rheumatology (-7%), neurology (-7%), hematology/oncology (-7%), and endocrinology (-10%)) that require additional time under more complex E/M codes, which would also impact potential compensation for participating pharmacists.[18]

A last point of ethical consideration comes with the patient's choice of where the prescription should be filled. The Pharmacist Code of Ethics addresses this through III. A pharmacist respects the autonomy and dignity of each patient.[19] As a health care provider, pharmacists must be cautious to direct patients towards the personalized care specific to the best clinical, financial, and outcomes focused decision. This includes the ability for patients to fill a prescription at their preferred location.

AUDIENCE

The concept of pharmacist referral is not a novel one. Pharmacists have been referring patients daily to other healthcare professional, as well as receiving referrals, without formal documentation and communication processes or compensation for those activities. As the landscape of patient-centered care further develops the accessibility and opportunities for pharmacist-delivered care becomes critical to the optimized delivery of quality healthcare. Payers, health care providers, health care agencies, pharmacists, and patients must all understand the challenges and benefits of incorporating pharmacists into existing referral systems, as well as the benefit of creating referral systems within and outside of the pharmacy profession. A collaborative approach is needed to develop and implement the process that might include the legislative, regulatory, and practice policy spheres to ensure the key role of pharmacist referrals in providing integrated care.

2018   **Pharmacists Electronic Referral Tracking**
1. APhA supports the development of electronic systems that enhance and simplify the ability of pharmacists in all practice settings to receive, send, and track referrals between all members of the health care team, including other pharmacists, irrespective of the health care system, model, or network in which the patient participates.
2. APhA supports the interoperability and integration of referral tracking systems with electronic health records so patients can receive the benefit of optimally coordinated care from all members of the health care team.

2004   **Freedom to Choose**
1. APhA supports the patient's freedom to choose a provider of health care services and a provider's right to be offered participation in governmental or other third-party programs under equal terms and conditions.
2. APhA opposes government or other third-party programs that impose financial disincentives or penalties that inhibit the patient's freedom to choose a provider or health care services.
3. APhA supports that patients who must rely upon governmentally-financed or administered programs are entitled to the same high quality of pharmaceutical services as are provided to the population as a whole.

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