House of Delegates

Board of Directors Report: Policy Recommendations for the May 2023 Virtual House of Delegates

COUNCIL ON PHARMACY MANAGEMENT POLICY RECOMMENDATIONS

The Council on Pharmacy Management is concerned with ASHP professional policies related to the leadership and management of pharmacy practice. Within the Council's purview are (1) development and deployment of resources, (2) fostering cost-effective use of medicines, (3) payment for services and products, (4) applications of technology in the medication-use process, (5) efficiency and safety of medication-use systems, (6) continuity of care, and (7) related matters.

Leigh Briscoe-Dwyer, *Board Liaison*

1. Payer-Directed Drug Distribution Models

To advocate that insurers and pharmacy benefit managers be prohibited from mandating drug distribution models that introduce patient safety and supply chain risks or limit patient choice.

Note: This policy would supersede ASHP policy 2248.

Rationale

Hospitals and health systems have a responsibility to confirm drug product integrity and pedigree to ensure safe and appropriate administration of drug products. Drug products supplied to a hospital or health system without an institution's direct oversight raise questions about the product's proper storage and pedigree. These drug products include patients' home drug products, including clinician-administered pharmaceuticals (i.e., brown bagging) brought in by the patient or caregiver, and clinician-administered pharmaceuticals shipped from an external pharmacy directly to the location where they are being administered (i.e., white bagging).

Due to patient safety and supply chain risks, hospitals and health systems should advocate for action from boards of pharmacy to directly address payer-mandated drug distribution models and encourage state policymakers to prohibit insurers and PBMs from mandating white and brown bagging, including prohibiting insurers and PBMs from steering

patients away from hospitals and health systems that refuse to accept potentially dangerous white-bagged or brown-bagged drug products.

Background

The Council reviewed ASHP policy 2248, Health-System Use of Drug Products Provided by Outside Sources, at the request of the ASHP Board of Directors to discuss policy-related member concerns expressed during the 2022 House of Delegates meetings, and voted to recommend amending it as follows (~~strikethrough~~ indicates deletions):

> ~~To support care models in which drug products are procured and/or prepared for administration by the pharmacy and are obtained from a licensed, verified source to ensure drug product and patient safety and continuity of care; further,~~
>
> ~~To encourage hospitals and health systems not to permit administration of drug products supplied to the hospital, clinic, or other healthcare setting by the patient, caregiver, or pharmacy contracted by a healthcare insurance payer or pharmacy benefit manager; further,~~
>
> ~~To advocate adequate reimbursement for preparation, order review, and other costs associated with the safe provision and administration of drug products; further,~~
>
> To advocate that insurers and pharmacy benefit managers be prohibited from mandating drug-distribution models that introduce patient safety and supply chain risks or limit patient choice.

The Council discussed some ASHP member concerns voiced during the 2022 House of Delegate meetings, such as preservation of the clear bagging process; allowing some flexibility for sites to use white bagging as part of a formulary management strategy; and the impression that patient's own medications might be singled out. While feedback from the Executive Committee of the ASHP Section of Specialty Pharmacy Practitioners was considered, the Council desired alignment with ASHP's advocacy position to adequately address the disruptions in patient care and risks to patient safety associated with white and brown bagging of clinician-administered medications.

2. Use of Social Determinants of Health Data in Pharmacy Practice

To encourage the use of patient and community social determinants of health (SDoH) data in pharmacy practice to optimize patient care services, reduce healthcare disparities, and improve healthcare access and equity; further,

To educate the pharmacy workforce and learners about SDoH domains, including their impact on patient care delivery and health outcomes; further,

To encourage research to identify methods, use, and evaluation of SDoH data to positively influence key quality measures and patient outcomes.

Note: This policy would supersede ASHP policy 2249.

Rationale

Social determinants of health (SDoH) are defined by the Centers for Disease Control and Prevention (CDC) as the "conditions in the environments where people are born, live, learn, work, play, worship and age." These conditions can have a significant impact on healthcare outcomes, health equity, and the quality of life for individuals and communities. SDoH have been found to account for 80-90% of modifiable contributors to health outcomes. From a third-party payer perspective, the recent shift of many organizations from fee-for-service to value-based reimbursement models places more emphasis on SDoH, screening, and evidence-based decision-making to prioritize long-term health outcomes. Healthy People 2030, a national program developed by the Office of Disease Prevention and Health Promotion within the U.S. Department of Health and Human Services, includes 355 measurable, data-driven, national objectives to improve the health and well-being of the American public by the year 2030. Health People 2030 recognizes five distinct SDoH domains: Economic Stability, Education Access and Quality, Healthcare Access and Quality, Neighborhood and Built Environment, and Social and Community Context. Patient screenings and data collection from multiple data sources to ascertain SDoH would be optimized through the use of standardized codes (e.g., ICD-10-CM Z codes, SNOMED-CT value sets) that are consistent, discrete data elements that are reportable and can be shared with other technologies, leading to actionable intelligence to enhance quality improvement initiatives. To support this goal, there is a need for broader implementation of SDoH health information technology (IT) tools into general practice and development of policies for how to appropriately use SDoH in clinical decision-making. The Office of the National Coordinator for Health Information Technology has identified four priority areas for advancing interoperability and use of SDoH data: standards and data, infrastructure, policy, and implementation. Many health IT and electronic health record (EHR) vendors have invested significant resources in development of SDoH tools and products. Among these products are screening tools, population health metrics, referral and care transition tools, and analytic and reporting tools. Health systems must have access to appropriate technology-based platforms to exchange SDoH data and make referrals for patients at discharge or transfer

to another institution. Lack of standardization of data and reporting across health systems makes sharing of best practices and metric goal-setting difficult.

Efforts to address SDoH through pharmacy practice have varied. A 2018 survey of postgraduate pharmacy residents and their program directors found that only 1% of residents and 4% of residency program directors stated they had received education and training on Healthy People 2020. (Chandra RN. Pharmacists' knowledge of social determinants of health in post-graduate pharmacy residency programs. Wright State University; Dayton, OH; 2018.) The pharmacy workforce has opportunities to advance the use of SDoH in pharmacy practice (e.g., consults, medication reconciliation, patient assistance programs) to improve health outcomes.

Tools available within some EHR platforms include those measuring quality of life, suicidal ideation rating, community service referral capabilities, and use of secondary survey data in conjunction with the CDC/ATSDR social vulnerability index to further evaluate population health at a community level. SDoH tools can be categorized as either single domain, such as the Hunger Vital Sign tool to evaluate food insecurity, or multiple domain, such as the WE CARE survey to evaluate education, employment/income, food insecurity, and housing/utility domains. The validity of each tool should be considered before implementing into practice, and more research is needed to determine the utility of specific tools in pharmacy practice. The Pharmacy Quality Alliance (PQA) has developed a Medication Access Framework for Quality Measurement and is evaluating a pharmacy measure concept to address the social determinants of health that hinder patient medication access and contribute to poor health outcomes.

Background

The Council reviewed ASHP policy 2249, Screening for Social Determinants of Health, at the request of the ASHP Board of Directors to address policy-related member concerns expressed during the 2022 House of Delegates meetings, and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

> ~~To encourage social determinants of health (SDoH) screening and data collection using standardized codes during the provision of pharmacy patient care services; further,~~
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> ~~To promote the integration of SDoH data into the design and delivery of clinical pharmacy services, including the creation of targeted interventions and leveraging the use of clinical decision support to improve patient outcomes; further,~~
>
> ~~To encourage the use of SDoH data in reporting and evaluating the effectiveness of pharmacist patient care; further,~~
>
> ~~To encourage the use of SDoH data to identify opportunities to reduce healthcare disparities and improve healthcare access and equity; further,~~
>
> To encourage the use of patient and community social determinants of health (SDoH) data in pharmacy practice to optimize patient care services, reduce healthcare

disparities, and improve healthcare access and equity; further,

To educate the pharmacy workforce and learners about SDoH domains ~~principles~~, including their impact on patient care delivery and health outcomes; further,

~~To advocate for the funding of community resources related to improving patient access to medications, and the integration of these resources into health-system care delivery models; further,~~

To encourage research to identify methods, use, and evaluation of SDoH data to positively influence key quality measures and patient outcomes.

The Council discussed ASHP delegate concerns voiced during the 2022 House of Delegates that ASHP policy 2249, Screening for Social Determinants of Health, was wordy and covered several concepts. The Council found opportunities to streamline the policy recommendation while ensuring its focus remains on advancing the use of SDoH data in clinical and community patient care settings. The most important aspect discussed was the importance of informing meaningful data collection from multiple sources, including the patient, to drive outcomes. Appropriate handling of this sensitive data must be considered, and the Council encouraged ASHP to weave this factor into educational offerings or additional policy. Although there was some discussion of whether this policy recommendation should fall under the purview of another council, Council members found it appropriate to stay rooted with the Council on Pharmacy Management.

3. Pharmacy Accreditations, Certifications, and Licenses

To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidence-based principles of patient safety and quality of care; further,

To advocate that health-system administrators allocate the resources required to support medication-use compliance and regulatory demands.

Note: This policy would supersede ASHP policy 1810.

Rationale

Pharmacy leaders have years of experience managing the demands and challenges of ensuring that pharmacy services meet the standards of accreditation organizations. In the past, this responsibility was predominantly achieved through accreditation by The Joint Commission (TJC) and compliance with state laws and Board of Pharmacy regulations, as well as with federal requirements (e.g., those of the Drug Enforcement Administration). The number of

accreditation standards pharmacy leaders needed to be knowledgeable about was limited. Healthcare organizations with ambulatory care services (e.g., home infusion, specialty pharmacy) have had to manage the additional accreditation process for these business units. Recent changes in healthcare have increased this challenge for pharmacy leaders: (1) TJC is no longer the only accreditor for hospitals and health systems; (2) healthcare organizations are developing or acquiring new business units that have their own accreditation processes that need to be integrated into existing ones; and (3) new accreditation, certification, or licensure processes have been created for services and businesses that fall under the responsibility of pharmacy leaders.

The expansion of healthcare organizations and the growth of the pharmacy enterprise are creating a new environment with multiple accreditors and regulators, presenting pharmacy leaders with the growing challenge of compliance with overlapping accreditation, certification, and regulatory standards. Examples include the Michigan Board of Pharmacy requirement to obtain certification to conduct compounding and the California Board of Pharmacy requirement that each IV hood have its own pharmacy license. In addition, community pharmacy accreditation processes and standards are being implemented that pharmacy leaders need to consider as well.

ASHP recognizes the difference between certifications that are the sole responsibility of and have a direct impact on a pharmacy and certifications of a healthcare organization's service line (e.g., stroke or transplant services) that are the responsibility of the organization but have medication management components that need to be addressed by the pharmacy. Pharmacists and pharmacy departments are being challenged by a growing number of required accreditations, certifications, and licensures, which result in increased need for pharmacist-in-charge designations, workforce fatigue, and direct and indirect costs. Health-system administrators need to recognize this changing environment and allocate the resources required to support medication-use compliance and regulatory demands.

Background

The Council reviewed ASHP policy 1810, Pharmacy Accreditations, Certifications, and Licenses, as part of sunset review and voted to recommend amending it as follows (~~strikethrough~~ indicates deletions):

> ~~To advocate that healthcare accreditation, certification, and licensing organizations include providers and patients in their accreditation and standards development processes; further,~~
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> To advocate that healthcare accreditation, certification, and licensing organizations adopt consistent standards for the medication-use process, based on established evidence-based principles of patient safety and quality of care; further,
>
> ~~To encourage hospitals and health systems to include pharmacy practice leaders in decisions about seeking recognition by specific accreditation, certification, and licensing organizations; further,~~

To advocate that health-system administrators~~, including compliance officers and risk managers,~~ allocate the resources required to support medication-use compliance and regulatory demands.

The Council noted that the ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive adequately covers aspects of the policy clauses suggested for deletion.

4. ASHP Statement on Leadership as a Professional Obligation

To approve the ASHP Statement on Leadership as a Professional Obligation (Appendix A).

Note: This statement would supersede the ASHP Statement on Leadership as a Professional Obligation dated June 12, 2011.

COUNCIL ON PHARMACY PRACTICE POLICY RECOMMENDATION

The Council on Pharmacy Practice is concerned with ASHP professional policies related to the responsibilities of pharmacy practitioners. Within the Council's purview are (1) practitioner care for individual patients, (2) practitioner activities in public health, (3) pharmacy practice standards and quality, (4) professional ethics, (5) interprofessional and public relations, and (6) related matters.

1. Reducing Healthcare Sector Carbon Emissions to Promote Public Health

To promote reducing carbon emissions from the healthcare sector through collaboration with other stakeholders; further,

To encourage members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities.

Rationale

ASHP acknowledges the scientific consensus on the adverse impact of carbon emissions on human health and the environment and recognizes the need to reduce carbon emissions, including from the healthcare sector. Climate change negatively impacts human health and increases strain on the healthcare system. Health-related consequences of climate change that lead to increased morbidity and mortality include but are not limited to heat-related illnesses, respiratory illnesses, and vector-borne diseases. The 2015 Lancet Commission on Health and Climate Change concluded that addressing climate change is the greatest public health opportunity of the 21st century and that failure to adequately address climate change could undo most of the past century's progress in global health.

Carbon emissions are a target for addressing climate change. It has been estimated that the healthcare sector is responsible for 8.5% of carbon emissions in the U.S. Sources of healthcare carbon emissions rank as follows: healthcare facility operations (estimated to

account for 7% of healthcare sector emissions); purchased sources of energy, heating, and cooling (11%); and healthcare sector procurements or supply chain for services and goods (>80%).

Healthcare organizations have been called upon to reduce their carbon footprint ("decarbonize") as a measure to promote patient and public health. The federal government has goals to decrease carbon emissions by 50% by 2030 and to achieve net-zero levels by 2050. Many healthcare-related organizations have made climate change and decarbonization pledges, including the members of the Medical Society Consortium on Climate & Health and organizations engaged in the National Academy of Medicine (NAM) Action Collaborative on Climate Change and as. In the fall of 2021, NAM launched the Action Collaborative on Decarbonizing the U.S. Health Sector (the "Climate Collaborative"), mobilizing four work groups: healthcare supply chain and infrastructure; healthcare delivery; health professional education and communication; and policy, financing, and metrics.

The pharmacy workforce has an important role in reducing carbon emissions from healthcare-related sources (Beechinor RJ et al. Climate change is here: what will the profession of pharmacy do about it? *Am J Health-Syst Pharm.* 2022; 79:1393-6). ASHP encourages collaboration with stakeholders that share a commitment to reducing carbon emissions from the healthcare sector and encourages members of the pharmacy workforce to seek out opportunities to engage in efforts to reduce carbon emissions in their workplaces and communities. To fill their roles in reducing carbon emissions, the pharmacy workforce will require education, training, and resources on emissions-reduction strategies. The development of evidence-based strategies will require research and dissemination of information on ways to reduce carbon emissions.

Background

The Council examined this topic in response to suggestions from ASHP members and staff. The Biden-Harris Administration and the Health and Human Services have called on healthcare stakeholders to (1) reduce their organization's emissions by 50 percent by 2030 and achieve net zero by 2050; (2) publicly report on their progress; (3) complete an inventory of Scope 3 (value chain) emissions; and (4) develop climate resilience plans for their facilities and communities. Since then, over 650 hospitals, health systems, suppliers, pharmaceutical and medical device companies, and other industry stakeholders submitted pledges to the White House with their commitments. Providence Health, Kaiser Permanente, The Joint Commission, the American College of Physicians, and NAM are among those organizations.

The Council noted that although many healthcare-related organizations have made climate change and decarbonization pledges, there is a notable absence of pharmacy organizations, which offers ASHP an opportunity provide leadership in these important efforts. The Council suggested that ASHP express support for the NAM initiative as well as other collaborative efforts to reduce the healthcare sector's carbon footprint and pledge to foster education, training, and the development and dissemination of resources to support the pharmacy workforce in reducing carbon emissions. Further, the Council suggested that the Board of Directors consider developing an ASHP commitment statement on reducing healthcare carbon emissions, similar to the ASHP Commitment Statement on Diversity, Equity, and Inclusion.

COUNCIL ON THERAPEUTICS
POLICY RECOMMENDATION

The Council on Therapeutics is concerned with ASHP professional policies related to medication therapy. Within the Council's purview are (1) the benefits and risks of drug products, (2) evidence-based use of medicines, (3) the application of drug information in practice, and (4) related matters.

Pamela K. Phelps, *Board Liaison*

1. ASHP Statement on Criteria for an Intermediate Category of Drugs

To discontinue the ASHP Statement on Criteria for an Intermediate Category of Drugs (Appendix B).

Background

The Council discussed the ASHP Statement on Criteria for an Intermediate Category of Drugs as part of sunset review. The Council recommended discontinuing the statement as ASHP's position has moved away from the strategy of seeking certain drugs and drug classes in an intermediate drug category and toward pharmacist prescribing authority. The Council reviewed all other ASHP policies that include this intermediate category classification (see policy recommendations that follow) and amended them to reflect this change in ASHP position.

SECTION OF PHARMACY EDUCATORS POLICY RECOMMENDATION

The mission of the ASHP Section of Pharmacy Educators is to support pharmacy educators in preparing, engaging, and advancing the pharmacy workforce to optimize health.

Melanie A. Dodd, *Board Liaison*

1. ASHP Statement on Precepting as a Professional Obligation

To approve the ASHP Statement on Precepting as a Professional Obligation (Appendix C).

Appendix A:

ASHP Statement on Leadership as a Professional Obligation

Position

The American Society of Health-System Pharmacists (ASHP) believes that the pharmacy workforce has a professional obligation to serve as leaders in the safe and effective use of medications. These leaders have an obligation to encourage pharmacy practitioners, administrators, faculty members, preceptors, technicians, and learners to advance patient care and strengthen the pharmacy profession by embracing the responsibility to exert leadership within their practices and across their organizations. ASHP urges the pharmacy workforce to accept this responsibility, actively seek the development of leadership skills, and exercise leadership when working with others within and outside of the profession.

ASHP encourages colleges of pharmacy, pharmacy technician training programs, and employers to grow the pipeline for developing a diverse group of future leaders by extending beyond management coursework and integrating education on leadership as a practice philosophy throughout the training and curriculum. The pharmacy workforce shares the responsibility to mentor pharmacy students, pharmacy residents, pharmacists, pharmacy technicians, and non-pharmacist support staff. Pharmacy workforce members in formal leadership roles have a specific responsibility to: 1) foster the development of leadership skills among others within the workforce; 2) facilitate the development of practice models that provide regular opportunities to exercise leadership; 3) encourage others to exercise leadership in practice; and 4) build relationships across the organization to serve as the voice of pharmacy and safe medication use. ASHP also encourages hospital and health-system executives to support the development of leadership skills of all healthcare professionals.

Leadership in practice

The ASHP Statement on Professionalism includes leadership ("influenc[ing] others with unquestionable integrity") as a professional responsibility shared by individuals and the institutions where they work.[1] The ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive explains the formal leadership roles of the pharmacy executive, including the responsibility to successfully build and manage relationships with diverse groups to ensure pharmacy is involved with strategic planning and decision making processes.[2] As both of those statements highlight, the pharmacy workforce also has the professional obligation to serve as leaders in the safe and effective use of medications.

Definitions of leadership commonly focus on working toward goals and exerting influence.[3] For example, Nahata[4] stated that leadership "is about a vision, direction, strategies, motivating, and inspiring." The focus on goals and influence guides understanding of the inherent requirement for leadership in pharmacy. The success of current pharmacy practice models and the successful implementation of future models rest on the ability of members of the profession to influence others. In the complex and evolving healthcare environment, leadership from the pharmacy workforce is required to promote and advance the profession and our care for patients. Thus, leadership is not an option—it is a professional obligation.

The most successful organizations facilitate the inclusive development of routine leadership roles and encourage participation in those roles. The frontline pharmacy workforce must exhibit themselves as leaders each time they step into the workplace. The practice of effectively influencing the behavior of physicians, pharmacists, nurses, pharmacy technicians, learners, support staff, and

other healthcare team members to optimize medication safety and patient outcomes constitutes successful leadership. Such leadership often requires pharmacy team members to work across interprofessional teams to optimize patient safety and medication use. Innovative practice models can support the development of both clinical and leadership skills. ASHP encourages development and implementation of these types of practice models.

Each pharmacy workforce member's personal and professional experiences affect how they approach the patients and decisions that come before them. The diversity of their perspectives and lived experiences fosters decision-making that better reflects the whole population, resulting in better, richer analyses as clinicians and healthcare leaders. When pharmacy leadership includes all voices and perspectives, practicing members of the team and members of the public are more likely to trust theirs will be heard. The ASHP Task Force on Racial Diversity, Equity, and Inclusion has put forth recommendations to promote this aspect of leadership.[5]

The obligation to develop a pharmacy workforce prepared for professional leadership requires colleges of pharmacy, pharmacy technician training programs, and employers to adopt the training of leadership and its values. Currently, leadership training is inconsistently present in both academic and practice settings. White's survey[6] as well as the report of the American Association of Colleges of Pharmacy Argus Commission[7] support the need for formalized training programs to cultivate the required leadership training among learners. To cultivate high-quality candidates to fill the pharmacy leadership gap, the report also recommends expansion of didactic leadership training, distance learning programs, the use of social media for networking and mentorship, and an increased focus on the full spectrum of leadership. All members of the pharmacy workforce should take personal responsibility for leadership of the medication-use process and for mentorship of learners, pharmacy technicians, and other colleagues. Although it is not the exclusive responsibility of formal pharmacy leaders such as pharmacy directors and managers, formal leaders must foster and support diverse leadership among the members of a pharmacy team.

The pharmacy workforce also has an obligation to exert leadership and participate in shaping the future of the profession.[8] Participation in professional societies such as ASHP and ASHP state affiliates provides opportunities to shape the future of the profession and affords excellent opportunities for the development of leadership skills. Professional organizations such as ASHP and ASHP state affiliates also have an obligation to encourage the development of leadership skills and support their development among their memberships.

Conclusion

Leadership is a professional obligation of all members of the pharmacy workforce and not the exclusive responsibility of those who hold formal leadership roles or titles. All members of the pharmacy workforce should accept the obligation to develop and exert leadership skills to ensure the safe and effective use of medications. Colleges of pharmacy, pharmacy technician training schools, professional organizations, and employers should encourage the development of these skills among learners and practitioners and should provide both formal training and opportunities for all team members to develop leadership capability and capacity.

References

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8. ASHP Practice Advancement Initiative 2030: New recommendations for advancing pharmacy practice in health systems. *Am J Health-Syst Pharm*. 2020; 77:113-121.

Additional Resources

American Society of Health-System Pharmacists. ASHP statement on advocacy as a professional obligation. *Am J Health-Syst Pharm.* 2019; 76:251–4.
American Society of Health-System Pharmacists. Section of Pharmacy Practice Leaders. https://www.ashp.org/pharmacy-practice-leadership
American Society of Health-System Pharmacists. Leadership Resource Center. https://www.ashp.org/pharmacy-practice/resource-centers/leadership
ASHP Foundation Pharmacy Leadership Academy.® https://www.ashpfoundation.org/leadership-development/pharmacy-leadership-academy
American Society of Health-System Pharmacists. Pharmacy Leadership Certificate: Management Basics. https://elearning.ashp.org/products/10194/pharmacy-leadership-management-basics-certificate
ASHP Practitioner Recognition Program. https://www.ashp.org/about-ashp/awards/board-of-directors-awards/ashp-fellows

The American Society of Health-System Pharmacists accredits pharmacy residency training programs in the following topic areas:

- Community-Based Pharmacy Administration and Leadership
- Corporate Pharmacy Administration and Leadership
- Health System Pharmacy Administration and Leadership
- Pharmacy Administration and Leadership with Masters (Community; Health-System; Specialty)
- Specialty Pharmacy Administration and Leadership

Additional information

Developed through the ASHP Council on Pharmacy Management and approved by the ASHP Board of Directors on February 28, 2023, and by the ASHP House of Delegates on MONTH XX, 2023. This statement supersedes the ASHP Statement on Leadership as a Professional Obligation dated June 12, 2011.

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ASHP Statement on Criteria for an Intermediate Category of Drug Products

Position

The American Society of Health-System Pharmacists (ASHP) supports the establishment of an intermediate category of drug products that would not require a prescription but would be available from a pharmacist after appropriate patient assessment and professional consultation.[1] These drug products would continue to be available by prescription from licensed health care professionals who are authorized to prescribe medications. Drug products appropriate for this intermediate category should have proven public health benefits and be identified by processes that include the input and advice of experts, such as pharmacists, physicians, and other licensed health care professionals. Identification of drug products for inclusion in the intermediate category should be based on the medical condition to be treated and potential adverse effects of the drug. Concerns that patients may not be able to fulfill a substantial self-care role associated with these drug products will be alleviated by taking into consideration the benefits of pharmacist oversight of these drug regimens. Data from postmarketing surveillance, epidemiologic studies, and adverse-drug-reaction reports should be collected and analyzed to evaluate the ongoing safety and effectiveness of drug products placed in this category. This information would be used to determine whether the product would remain in the intermediate category, return to prescription-only status, or move to nonprescription status.

Background

Rationale for Establishing an Intermediate Drug Category. Reclassification of prescription drug products to nonprescription status (e.g., antifungal products used for the treatment of vaginitis, nonsedating antihistamines) has been associated with improvements in patient autonomy, health care knowledge, and self-care behavior.[2-4] However, proposals to reclassify some prescription drug products to nonprescription status have been denied because of concerns about safety and whether patients would be capable of determining if they were suitable candidates for treatment. In 2008, for example, the Food and Drug Administration (FDA) ruled a third time against making lovastatin, a hydroxymethylglutaryl-coenzyme A reductase inhibitor (or statin), available without a prescription,[5] although the predicted public health benefit of increasing the availability of statins was estimated to range between 23,000 and 33,000 coronary heart disease events prevented per 1 million treated for 10 years.[6] ASHP supports inclusion of statins in an intermediate category of drug products that provides the benefit of pharmacist oversight.[7] Other drug products that should be considered for the intermediate category include injectable epinephrine to treat anaphylaxis; inhaled corticosteroids, leukotriene modifiers, and inhaled ß-agonists used in the treatment of asthma; select therapies for osteoporosis and hypertension; and vaccines.

ASHP and other pharmacy organizations have long proposed the creation of an intermediate category of drug products that would bridge the large gap between prescription and nonprescription status.[1,8,9] An intermediate drug category could improve patient access to medications that offer substantial public health benefit but present challenges for safety or effectiveness if used under existing models for nonprescription drug dispensing. Two concerns regarding the use of existing models are that (1) a product's labeling information may be beyond most consumers' capacity to understand (or may be subject to misinterpretation) and (2) monitoring procedures are not readily accessible to patients. Pharmacists' expertise, licensure, and education, which includes instruction on physiology, pharmacology, disease management, and physical assessment, make pharmacists well qualified to help patients make appropriate therapeutic decisions about the use of these drug products.

The terms "behind-the-counter (BTC) drugs" and "pharmacist-only drugs" have also been used to describe the proposed intermediate category of drug products. While an FDA-established BTC category does not currently exist, the term BTC has been used to refer to drug products such as pseudoephedrine and levonorgestrel (marketed as Plan B) that are available for purchase only at the pharmacy counter.[10,11] Implementation of that restriction has largely been a policing action (e.g., to restrict the amount of drug a patient can obtain or to confirm the patient's age). In some instances, these functions are completed by pharmacy support staff under the supervision of a pharmacist. ASHP recommends the use of the terminology intermediate category of drugs to describe drug products appropriate for this category that would be used by patients in conjunction with clinical assessment and consultation provided by pharmacists. Distribution of the aforementioned nonprescription products via an intermediate category model of dispensing could improve appropriate use of those products.

The purpose of this statement is to describe the criteria that should be used to identify drug products for inclusion in an intermediate category. While the practice implications of an intermediate drug category are briefly described, that discussion is beyond the scope of this statement. Pharmacoeconomic analyses should be conducted to assess the overall impact and costs of an intermediate category of drug products on patients, health systems, and health insurers, and new models of reimbursement for pharmacists' services should be developed. It should be noted that a few studies have demonstrated that overall costs to the health system decrease when the cost of these medications is not transferred solely to the patient.[12,13] Alternative reimbursement models, such as insurance coverage for these products, would be necessary to optimize the use of the intermediate category of drug products.

Criteria for an Intermediate Category of Drug Products

Appropriate identification of drug products for inclusion in the intermediate category should address the concerns associated with a substantial self-care role for patients by

providing the benefits of pharmacist oversight of these drug therapy regimens (e.g., assessing for appropriate indications, contraindications, precautions, adverse drug events, drug interactions, and therapeutic response). ASHP believes drug products proposed for inclusion in the intermediate category should

- Meet many of the criteria currently used to reclassify prescription drugs to nonprescription status (e.g., the drug product has a well-established benefit:risk ratio and a wide safety margin).
- Have been marketed as a prescription product for a length of time and been used by a number of patients deemed sufficient by FDA to detect serious adverse effects. Likewise, a product could be marketed as a nonprescription product but would benefit from pharmacist oversight because safety and effectiveness concerns have arisen with its nonprescription use.
- Have evidence of effectiveness and safety for the dosage and regimen recommended for the formulation intended for intermediate classification.
- Be used to prevent or treat a disease, symptom, or condition that can be readily detected by the patient or identified by the pharmacist or other health care provider.

Further, if the drug is used for a condition that requires laboratory or other medical monitoring, the pharmacy should be able to offer testing or have access to the results of that monitoring. Signs and symptoms of deterioration in health and the need for medical attention should be identifiable by the pharmacist or patient, as should signs demonstrating the effectiveness of the drug therapy. If the drug has the potential to rarely cause serious toxicity that can result in death or serious harm, there should be reliable early warning signs that can be readily detected and interpreted by the pharmacist or patient.

Antiinfective agents (systemic or other formulations) for which the emergence of resistance is a concern would not be appropriate for the intermediate category.

In applying these criteria, an independent decision should be made about each individual chemical entity, dosage form, and drug product because differences among various members of a drug class and dosage forms prevent using therapeutic class as a basis for classifying groups of related drug products.

Because drug information is continually evolving, drug products in the intermediate category may be reclassified as prescription or nonprescription medications as new effectiveness and safety information becomes available. Similarly, products could be permanently classified in the intermediate category if ongoing evidence documents the necessity of pharmacist intervention to ensure safe and effective use. The postmarketing surveillance of these medications through the collaboration of FDA and product manufacturers should be supported, in part, by information reported by pharmacists and patients to an established surveillance system, such as MedWatch, or similar reporting mechanisms.

Practice Implications

Implementation of the intermediate drug category would require that an ongoing relationship be established and maintained between the pharmacist and the patient and that documentation of the care provided be available to the patient's other health care providers, upon approval of the patient to provide such information. The exact nature and duration of the patient–pharmacist relationship would depend on the condition being treated and the drug therapy selected. A practice model that includes collaboration among the patient, the pharmacist, and the patient's physician (or other primary care provider) would enhance the use of these drug products and result in improved patient outcomes.

Increased pharmacist time for patient assessment, counseling, and documentation of services provided with these drug products would require reimbursement for these cognitive services. In addition, other conditions and procedures would be necessary to ensure the safety and effectiveness of these therapies, including the following:

- If the drug is to be used in conjunction with other therapies, such as diet and exercise, information about those adjunct therapies should be readily available to the patient from the pharmacist or through recommendation of the pharmacist or other health care provider.
- Patient care services provided by the pharmacist should be documented in the pharmacy record and available for sharing with other health care providers.
- Pharmacists and patients should provide information on actual or suspected adverse effects or drug interactions to programs such as MedWatch for the purposes of drug safety surveillance.
- Pharmacies should adopt standardized processes for the use of medications in the intermediate category that would guide patient triage, treatment, and referral to a physician when necessary. The expertise offered by clinical practice guidelines and professional associations should serve as the basis for these protocols, with appropriate modifications based on the unique characteristics of the patient population at the practice site.
- Pharmacies should adhere to quality measures that would be developed to assess the care provided (similar to those offered by the Pharmacy Quality Alliance) and engage in ongoing quality-improvement activities to assess and improve the quality of services provided.

A detailed discussion of these topics is addressed by other ASHP position and guidance documents, including the ASHP Statement on the Pharmacist's Role in Primary Care[14]; the ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling[15]; the ASHP Guidelines on the Pharmacist's Role in the Development, Implementation, and Assessment of Critical Pathways[16]; the ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records[17]; and the ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting.[18]

Conclusion

An intermediate category of drug products would increase patient access to and benefit from drug products that would otherwise be available only by prescription. The use of appropriate criteria for classifying drug products in an inter-

mediate drug category—in conjunction with pharmacist oversight of patient assessment, counseling, and monitoring—would improve public health without compromising patient safety.

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This statement was reviewed in 2017 by the Council on Therapeutics and by the Board of Directors and was found to still be appropriate.

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Appendix C:

ASHP Statement on Precepting as a Professional Obligation

Position

The American Society of Health-System Pharmacists (ASHP) believes that all pharmacists have a professional obligation to give back to the profession through involvement in the precepting process of students and postgraduate trainees. ASHP encourages pharmacy practice leaders, practitioners, postgraduate trainees, and faculty members to embrace the responsibility to be involved in the precepting process in an effort to advance pharmacy practice and improve patient care. To this end, ASHP urges all pharmacists and healthcare institutions to accept this responsibility and commit time and resources to the precepting process and the development of precepting skills.

ASHP encourages pharmacy practice leaders to create a culture of teaching and learning, integrate precepting as a practice philosophy, support an organizational commitment to well-being, and facilitate the integration of learners into patient care services and scholarly work. Pharmacy leaders and administrators, colleges of pharmacy, faculty, and current preceptors have a responsibility to foster and support the evidence-based development of the precepting skills of all pharmacy practitioners and postgraduate trainees, facilitate the development of practice models that provide regular opportunities to precept learners, encourage all pharmacists to be involved in the precepting process, and support the assessment of training programs' outcomes.

Background

Upon graduation, all pharmacists pledge to use their knowledge, skills, experiences, and values to train the next generation by taking the Oath of a Pharmacist.[1] The apprenticeship model of "see one, do one, teach one" is grounded in centuries of tradition across many healthcare disciplines. Current apprenticeship models, such as the Cognitive Apprenticeship Model, encourage the development of observable skills and critical thinking skills that are fundamental to contemporary practice.[2] The evolution of the current pharmacy education system and apprenticeship models requires preceptor supervision during experiential learning and postgraduate training.

Precepting consists of providing a learner with practical experiences in a practice setting in which they can develop and apply principles of pharmacy practice. The precepting process begins within the college of pharmacy curricula and co-curricula and extends through advanced pharmacy practice experiences (APPEs) and postgraduate trainee experiences. Throughout this prolonged process, preceptors serve vital roles by providing instruction, mentorship, coaching, facilitation, assessment, and feedback to learners. The precepting process teaches more than clinical skills by promoting skill development in professionalism, communication, teamwork, interprofessional collaboration, leadership, time management, and professional values as well as facilitating professional identity formation (PIF).[3] Involvement in the precepting process and experiential learning consists of more than serving as the primary preceptor on rotations and may extend to opportunities such as team precepting, shadowing experiences, speaking engagements, providing feedback to learners, facilitating topic discussions, learner mentoring, learner supervision, and more.

Experiential learning is fundamental to the application of knowledge and skills gained during didactic curricula.[3,4] To determine if students are practice ready, colleges of pharmacy utilize entrustable professional activities (EPAs), which are workplace tasks or responsibilities students are entrusted to perform in the experiential setting with direct or distant supervision.[5] Evaluation of entrustability levels of EPAs requires input from preceptors to assign a degree of trust in student competence. While mastery of EPAs requires the learner to gain foundational knowledge, skills, and attitudes in didactic curricula, these activities cannot be adequately replicated in the classroom; therefore, they should be fully elucidated and evaluated in the experiential setting.[4] Likewise, postgraduate programs require qualified preceptors to provide appropriate training, supervision, and guidance to all postgraduate trainees as they progress toward competence using the postgraduate trainee program's defined assessment scale.[6]

Preceptors are necessary to ensure learners attain the desired level of competency for practice; however, a dearth of preceptors has been a long-standing problem. Experiential site and preceptor capacity are frequent concerns of experiential education directors.[7] There are several contributing factors to this persistent preceptor shortage. First, colleges of pharmacy must adhere to the Accreditation Council for Pharmacy Education (ACPE) accreditation standards, which require enough preceptors to deliver and evaluate students in the experiential setting.[8] Between 2000 to 2020, there was a greater than 70% increase in the number of colleges of pharmacy, and since 2013, there has been a 65% increase in postgraduate training programs.[9] Furthermore, preceptors of postgraduate trainees require advanced training and/or experience to meet postgraduate training standards.[6] These requirements and expansion of programs may limit the number of experiential sites or individuals available to precept at any given time, which may worsen if all pharmacists do not accept precepting as a professional responsibility.

Another contributing factor to these shortages may be pharmacist burnout. Burnout is increasingly associated with work-related stressors, resulting in decreased clinician job satisfaction, productivity, interprofessional teamwork, and mental health. Increasing concerns about the personal ability to effectively balance patient care, administrative, teaching, and other roles may negatively influence pharmacists' interest in precepting. The consequences of burnout to patient care reinforce the need of colleges of pharmacy and healthcare institutions to systematically commit to the well-being of all pharmacy practitioners, pharmacy technicians, and learners.

Within the challenges of our ever-evolving healthcare and educational systems, high-quality preceptors are needed now more than ever. Their contributions continue the rich tradition of pharmacists as one of the most trusted healthcare professionals and bring value to healthcare institutions, learners, and patients.

Value of precepting

The amount of literature demonstrating mutual benefit for learners, preceptors, healthcare institutions, and patients is vast.[3,10] Ultimately, a synergistic relationship among stakeholders can improve patient care by aligning the goals of colleges of pharmacy, learners, preceptors, and healthcare institutions and embracing precepting as a practice philosophy.[11] Additionally, when learners are used as pharmacist extenders, clinical productivity increases, personal and

professional growth ensues, and institutional metrics improve.[3,10]

Value to learners. Preceptors are often one of the most influential teachers learners encounter as part of their training. They significantly influence learners' PIF through instructing, modeling, coaching, and facilitating as learners internalize and demonstrate the values and behaviors of pharmacists in practice. Preceptors' provision of feedback on learners' performance and their intraprofessional and interprofessional interactions are instrumental in learners' professional socialization and identity development. Preceptors also significantly impact learners' career choices and trajectories, personal and professional development, involvement in professional advocacy, and participation in scholarly activities.[3] Learners also benefit from collaborating with various professionals in their interprofessional practice experiences.

Value to preceptors. There is tangible value for preceptors who incorporate students and postgraduate trainees into experiential learning opportunities. Incorporation of learners as pharmacist extenders helps preceptors expand their clinical services to patients and allows them to accommodate more learners, particularly when the Layered Learning Practice Model (LLPM) is used. The LLPM is the teaching approach in which seasoned clinical preceptors supervise learners' clinical and precepting experience and train postgraduate trainees to precept students.[12] Learners may also serve as productive members of the LLPM. In addition to gaining supervised autonomy, learners develop foundational precepting skills by participating in near-peer teaching as appropriate for their development. This model utilizes a team approach so that pharmacists, postgraduate trainees, students, and technicians within larger healthcare teams maximize and extend the reach of pharmacy services.

Incorporating learners also allows preceptors to increase scholarly activities. Preceptors have ample opportunities to collaborate with learners for presenting and publishing abstracts, posters, and manuscripts.[3] These partnerships can help advance preceptors' research goals while developing learners' scholarly skills. Preceptors can leverage journal clubs or presentations on upcoming literature or clinical topics to maintain an updated knowledge base. Precepting is a professionally rewarding opportunity to influence future pharmacy clinicians and leave an enduring legacy on the future of the profession.[3]

Value to healthcare institutions and patients. Abundant literature documents the benefits of learners to healthcare institutions. Utilization of learners at healthcare institutions improves institutional metrics by expanding pharmacy services and advancing research agendas and dissemination rates.[10,13] For example, literature has shown tangible benefits of learners when they participate in taking medication histories, optimizing transitions of care, performing discharge counseling, practicing medication therapy management, and administering vaccinations.[10] Involvement of learners in these activities has been associated with the prevention of errors, decreases in medication costs, increased patient interventions and encounters, and decreased pharmacist-to-patient ratios.[10,14] Finally, trainees often apply for positions within their training institution, creating a pipeline of future employees.

Responsibilities of stakeholders

Positively impacting patient care is the shared vision of learners, preceptors, healthcare institutions, colleges of pharmacy, and professional organizations, and preceptors are necessary

to achieve that vision.[11] Preceptors provide an invaluable aspect of pharmacy education as they empower learners to independently apply their knowledge and skills in real-world situations. Colleges of pharmacy uphold the responsibility to prepare APPE-ready students by adhering to ACPE standards regarding experiential learning, and postgraduate training programs uphold the responsibility to ensure postgraduate trainees are practice or advanced practice ready. Practitioners involved in the precepting process play an integral role in determining these outcomes for learners. When experiential learning is thoughtfully designed, students, postgraduate trainees, preceptors, healthcare institutions, and ultimately patients benefit.[3,15]

Preceptors have diverse learning needs and preferences, and healthcare institutions vary in development resources available to preceptors. Preceptor development is instrumental in supporting the design of experiential learning and preparing preceptors for teaching and mentoring within the precepting process. To improve preceptor efficiency and maximize learning, development regarding in-the-moment experiential teaching is crucial, and additional training and sharing best practices in leveraging learners to help meet institutional goals should be a priority. It is imperative that professional organizations, colleges of pharmacy, and healthcare institutions collaborate to provide evidence-based preceptor development resources in a variety of media and formats and promote an inclusive and equitable culture of teaching and learning. As such, the continual professional development of preceptors is a shared responsibility among these entities.

Responsibilities of professional organizations

Professional organizations play a pivotal role in the development of precepting standards and preceptor development resources. ASHP and ACPE provide guidance on the standards and requirements for preceptor training and development.[6,8] Professional organizations should collaborate with preceptors, healthcare institutions, and colleges of pharmacy to provide practical and contemporary preceptor development resources and programming to meet the standards. These organizations are equipped to spotlight best teaching practices and practice models of their diverse members.[16] Professional organizations are also positioned to advocate for the importance of precepting and preceptor development to pharmacists and healthcare institutions.

Responsibilities of colleges of pharmacy and postgraduate training programs

In addition to providing preceptor development resources to meet individual and group preceptor development needs, colleges of pharmacy and postgraduate training programs can assist in the creation, research, and dissemination of best practices in precepting and innovative practice models to spur the development of others.[11] Colleges of pharmacy and postgraduate training programs also aid in the development of preceptors and healthcare institutions through sharing de-identified aggregate feedback from learners, quality assurance programs, and in the acknowledgement of quality precepting through recognition programs.[16]

Responsibilities of healthcare institutions

It is critical to the training of the next generation of pharmacists that healthcare institutions embrace the responsibility to support preceptor development and to develop precepting as a

practice philosophy within their institutions. Practice and research models that integrate learners and leverage them to extend pharmacy services should be encouraged and highlighted. Particular importance should be placed on the well-being of busy preceptors who are balancing clinical, professional, and precepting responsibilities. While preceptors continue to adapt to newer educational models that discourage long didactic sessions, preceptors need time for the precepting process. Protected time may be necessary for planning practice experiences, orienting learners, reviewing expectations, discussing learner background and goals, completing and delivering feedback and evaluations, reviewing learner's work, and providing teaching pearls from learning activities. Although this time may vary based on the specific site and infrastructure in place, leadership discussions with precepting teams can help determine what type of support is needed and foster collaborative solutions.

Additionally, this responsibility includes providing financial support to attend preceptor development offerings, protected time to be involved in the precepting process and attend training and development programs, access to development resources, and an organizational commitment to employee well-being. The expectation of precepting as a practice philosophy should be included in role descriptions, performance appraisals, and career ladders to encourage and recognize effective precepting. Examples of competency areas on performance appraisals include commitment to precepting, advocacy for the profession, communication and collaboration, qualities of the learning environment, use of teaching and learning strategies that develop clinical reasoning and other skills, feedback and assessment practices of learners, content expertise, contribution in the area precepted, and ongoing professional engagement.[6,17,18] These competencies may also serve as a framework for self- and peer assessment that are essential to professional development as well as guide preceptor development plans.[17,18, 19,20]

Responsibilities of preceptors

Preceptors should approach precepting with a commitment to lifelong learning and continual personal and professional growth. Strategies to implement this philosophy include continuing professional development (CPD) and the self-directed assessment seeking (SDAS) approaches. In CPD, learning needs are identified through self-assessment and reflection; specific, measurable, achievable, relevant, time-bound (SMART) goals are developed to meet learning needs; the effectiveness of the plan is assessed; and learning is applied to teaching practices.[19,20] Recognizing the limitations of self-assessment alone, the SDAS performance improvement process involves seeking feedback and assessment from external sources such as peers and learners, self-reflecting to identify areas of strength and growth, and developing a plan for improvement.[21] Development plans may include preceptor development offered through written, online, on-demand, live, and other resources. The Habits of Preceptors Rubric is an example of a criterion-referenced tool to support preceptors engaged in self-directed assessment to guide CPD.[22] Preceptors may also create a teaching or precepting philosophy to guide their work. Postgraduate trainees and students also have important roles in preceptor development through provision of constructive and professional feedback on learning experiences and precepting practices. Preceptors should create an environment and foster dialogue that encourages and welcomes feedback from learners throughout a rotation. In

addition, colleges of pharmacy and postgraduate trainee programs should train learners to provide constructive, meaningful feedback for learning experiences and preceptors.

Incorporating precepting into practice

Serving as a liaison between classroom education and practical application, preceptors are role models for the practice of pharmacy and share the art of the profession with learners. Preceptors are vital to modeling professionalism, communication, and application of skills and knowledge when they advise, mentor, and provide feedback during thoughtfully designed experiential learning. Additionally, throughout postgraduate training, it is imperative that trainees not only learn to precept effectively, but also to employ those skills by becoming preceptors themselves following completion of postgraduate training. All pharmacists with practice experience, including those with and without postgraduate training, have a responsibility to be involved in the precepting process.

Preceptors have a responsibility to be involved not only in training learners, but also in the continuous quality improvement process of the training. Both colleges of pharmacy and postgraduate trainee programs have set standards for continuous quality improvement. ACPE 2016 Standard 20 requires that colleges of pharmacy solicit preceptors for continuous quality improvement of educational programs, especially in experiential learning, and ASHP standards require that preceptors provide input related to continuous improvement and formal postgraduate trainee program evaluation.[6,8] These efforts ensure that experiential learning for both students and postgraduate trainees remain parallel with contemporary practice. Preceptors and learners are vital to these quality improvement processes to ensure patient care and outcomes and institutional metrics are optimized.

Finally, preceptors are encouraged to publish examples of the value of precepting as a practice philosophy, the value of learners as pharmacist extenders, and the impact of learners on patient outcomes through scholarly work. As precepting is incorporated into daily practice, this scholarly work reflects contemporary practice, documents value to other healthcare institutions, provides a framework for the development of effective precepting, and encourages other healthcare institutions to embrace precepting as a professional responsibility. Disseminating both positive and negative outcomes as scholarly work is vital to optimizing outcomes for all stakeholders, most importantly patients.

Conclusion

ASHP believes involvement in the precepting process of learners is the professional responsibility of all pharmacy practice leaders, pharmacists, postgraduate trainees, and faculty to advance pharmacy practice and improve patient outcomes. All pharmacy stakeholders play a vital role in embracing precepting as a practice philosophy and supporting a culture of teaching and learning in the experiential setting. Professional organizations, pharmacy leaders and administrators, colleges of pharmacy, and healthcare institutions should support pharmacists, postgraduate trainees, and pharmacy technicians in developing and utilizing precepting skills, provide resources for formal precepting training and development, and promote learner and preceptor well-being.

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