



House of Delegates

Supplemental Board of Directors Report: Policy Recommendations for the June 2019 House of Delegates

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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.

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2. Compounded Sterile Preparation Verification

- 1 To advocate that health systems adopt automation and information technology to
- 2 facilitate in-process and final verification of compounded sterile preparations (CSPs) to
- 3 ensure CSP quality; further,

- 4 To advocate that, until such time as automation or technology can be implemented,
- 5 independent in-process and final verification of CSPs be performed; further,

- 6 To oppose the use of the syringe pull-back method or other proxy methods of CSP
- 7 verification.

(*Note: This policy would supersede ASHP policy 1617.*)

Rationale

Adoption of automation and information technology for preparing and dispensing compounded sterile preparations (CSPs) is increasing but not evenly distributed among healthcare organizations. A 2017 ASHP survey showed that 64% of hospitals did not use any technology for sterile product preparation activities. Only 26.9% of health systems surveyed employed barcode verification in their IV medication preparation and verification process. The survey

found that 12.8% of all health systems surveyed used drug workflow software to manage IV drug preparation, verification, and dispensing. There are many reasons for these disparate rates of adoption. Each institution has a different break-even point of investment versus return, and challenges of implementation can be daunting. Some organizations have implemented automated compounding technology only to withdraw it later. These technologies may slow the preparation and verification process; however, the enhanced safety outweighs losses in operational efficiency.

Information technology and automation, including robotics, can be used to improve the safety of CSP compounding. Although IV workflow technologies continue to be developed and improved, the majority of pharmacy departments continue to compound manually without the assistance of barcode or other technologies. Health systems have been slow to adopt IV workflow technology, with only 27% of respondents to the 2017 survey indicating their departments use barcode scanning to verify the ingredients in CSPs. If automated procedures are not employed, there are only two methods of in-process or final verification: real-time, direct, and independent visualization, or retroactive, proxy verification (e.g., the syringe pull-back method). The dangers of the syringe pull-back method have been well demonstrated, and the 2016 Institute for Safe Medication Practices (ISMP) [Guidelines for Safe Preparation of Compounded Sterile Preparations](#) discourage its use.

Background

The Council reviewed ASHP policy 1617, Automated Preparation and Dispensing Technology for Sterile Preparations, in light of USP Chapter 800 and the recently approved ASHP Guidelines on Handling Hazardous Drugs. After reviewing and accepting suggested edits from the Board of Directors, the Council voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate that health systems adopt automation and information technology to facilitate in-process and final verification of compounded sterile preparations (CSPs) to ensure CSP quality for preparing and dispensing compounded sterile preparations when such adoption is (1) planned, implemented, and managed with pharmacists' involvement; (2) implemented with adequate resources to promote successful development and maintenance; and (3) supported by policies and procedures that ensure the safety, effectiveness, and efficiency of the medication use process; further,

To advocate that, until such time as automation or technology can be implemented, independent in-process and final verification of CSPs be performed; further,

To oppose the use of the syringe pull-back method or other proxy methods of CSP verification.

~~To educate patient safety advocacy groups and regulatory agencies on the capabilities and benefits of automation and technology for preparing and dispensing compounded sterile preparations, and to encourage them to establish expectation of adoption by health systems; further,~~

~~To foster further research, development, and publication of best practices regarding automation and information technology for preparing and dispensing sterile preparations.~~

The Council noted that the text deleted from the first clause was redundant with ASHP policy 1020, Role of Pharmacists in Safe Technology Implementation, which states that pharmacists have an essential role "in the evaluation, implementation, and ongoing assessment of all technology intended to ensure safety, effectiveness, and efficiency of the medication-use process." The Council further noted that patient safety advocacy groups, such as ISMP, have been made aware of the benefits of automation and technology for preparing and dispensing CSPs, and that research, development, and publication of best practices regarding automation and information technology in preparing and dispensing CSPs is ongoing. The Council recognized the barriers to adoption of such technology and recommended that ASHP take a stand in opposition to the syringe pull-back method of CSP verification and in favor of real-time, direct, and independent visualization.

COUNCIL ON PUBLIC POLICY

POLICY RECOMMENDATIONS

The Council on Public Policy is concerned with ASHP professional policies related to laws and regulations that have a bearing on pharmacy practice. Within the Council's purview are (1) federal laws and regulations, (2) state laws and regulations, (3) analysis of public policy proposals that are designed to address important health issues, (4) professional liability as defined by the courts, and (5) related matters.

Todd A. Karpinski, *Board Liaison*

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5. 340B Drug Pricing Program Sustainability

- 1 To affirm the intent of the federal drug pricing program (the “340B program”) to stretch
2 scarce federal resources as far as possible, reaching more eligible patients and providing
3 more comprehensive services; further,
- 4 To advocate legislation or regulation to ensure continued access to the 340B program in
5 accordance with the intent of the program; further,
- 6 To advocate that reimbursement and contracting policies promote 340B program
7 stability and to oppose reimbursement and savings reductions to covered entities;
8 further,
- 9 To advocate for clarification and simplification of the 340B program and any future
10 federal discount drug pricing programs with respect to program definitions, eligibility,
11 and compliance measures to ensure the integrity of the program; further,
- 12 To encourage 340B participants to provide appropriate stewardship of the 340B
13 program; further,

- 14 To educate pharmacy leaders and health-system administrators about the internal
15 partnerships and accountabilities and the patient-care benefits of program participation;
16 further,
- 17 To educate health-system administrators, risk managers, and pharmacists about the
18 resources required to support 340B program compliance and documentation; further,
- 19 To encourage communication and education concerning the value of the 340B program;
20 further,
- 21 To advocate that the Health Resources & Services Administration Office of Pharmacy
22 Affairs have sufficient regulatory authority to enforce compliance with the 340B
23 program.

(Note: This policy would supersede ASHP policy 1817.)

Rationale

Statutory and other policy changes to the federal drug pricing (“340B”) program over the years have spurred an increase in the number of hospitals and other eligible entities that participate. Since the program’s inception, the number of 340B-eligible and participating hospitals has continued to grow. In response, policymakers and other stakeholders have raised questions over how the discounts are used by covered entities and what value the program brings to their respective communities. Congress has held hearings, and bills have been introduced to reform the program. Among the items Congress is considering are transparency, increasing authority of the Health Resources & Services Administration (HRSA) to oversee the program, reimbursement cuts imposed under Medicare Part B on 340B drugs, and examining policy that passes the discount along to the patient.

Expansion of Medicaid eligibility in 2014 (through provisions in the Affordable Care Act) allowed additional hospitals to participate in the program, further driving scrutiny and questions from policymakers and stakeholders. In response to policymaker and stakeholder concerns, ASHP recognizes the important intent and role of the 340B program and stresses the need for its continued sustainability. These developments demonstrate the need for pharmacy leaders to engage in a strategic response to this compliance environment.

The original intent of the 340B program was to “to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (H.R. Rept. 102-384, pt. 2, at 12 [1992]). ASHP emphasizes the need for clarification and simplification (to the extent possible) of the program in order to enable compliance and maintain program integrity. Further, there is a need for communication and collaboration with public and private payers to ensure optimization of benefits from the 340B program and related contract and reimbursement policies.

Background

At its September 2018 meeting, the Council recommended amending ASHP policy 1817, 340B Drug Pricing Program Sustainability, and the Board approved the recommendation. At its February 2019 meeting, the Council recommended further amending the policy recommendation to address recent actions by payers to impose different terms and conditions on 340B pharmacies than on other pharmacies, in effect clawing back to the payer savings provided by the 340B program to covered entities. The amendments to policy 1817 recommended by the Council at its September and February meetings are as follows (underline indicates new text; ~~strike through~~ indicates deleted text):

To affirm the intent of the federal drug pricing program (the “340B program”) to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; further,

To advocate legislation or regulation that would ~~optimize~~ ensure continued access to the 340B program in accordance with the intent of the program; further,

To advocate ~~with state Medicaid programs to ensure~~ that reimbursement and contracting policies promote 340B program stability and to oppose reimbursement and savings reductions to contracted entities; further,

To advocate for clarification and simplification of the 340B program and any future federal discount drug pricing programs with respect to program definitions, eligibility, and compliance measures to ensure the integrity of the program; further,

To encourage 340B participants ~~pharmacy and health-system leaders~~ to provide appropriate stewardship of the 340B program ~~by documenting the expanded services and access created by the program~~; further,

To educate pharmacy leaders and health-system administrators about the internal partnerships and accountabilities and the patient-care benefits of program participation; further,

To educate health-system administrators, risk managers, and pharmacists about the resources required to support 340B program compliance and documentation; further,

To encourage communication and education concerning the value of the 340B program ~~expanded services and access provided by 340B participants to patients in fulfillment of its mission~~; further,

To advocate that the Health Resources & Services Administration Office of Pharmacy Affairs have sufficient regulatory authority to enforce compliance with the 340B program.

The purpose of this policy is to clarify ASHP's stance on the 340B program in light of reform efforts by Congress and federal agencies. The Council was charged with examining existing ASHP policy on the 340B program and determining whether new policy is needed. The Council reviewed ASHP policy 1817, 340B Drug Pricing Program Sustainability, and recommended several changes to the policy. First, the Council removed any wording that could be interpreted to suggest ASHP is pursuing program expansion. ASHP previously supported expanding the 340B discount to cover inpatient care, but noting how the program and the increase in number of covered entities have been depicted by critics, the Council suggested backing away from advocating program expansion, as increased scrutiny has made expansion highly unlikely. Second, the Council discussed issues such as program transparency and the recent release of [340B stewardship resources](#) by the American Hospital Association. The Council observed that current policy calls for stewardship of the 340B program and encourages communication about the value of the program to the public. The Council noted that the policy language very broadly supports concepts such as program transparency and concluded that no additional language was needed. The Council further concluded that program transparency should also include communicating the value of the program to the public at large, emphasizing that the program actually saves the government and taxpayers money, as it is not publicly funded.

The Council made two additions to the policy. The first is the recognition that HRSA's Office of Pharmacy Affairs is the proper regulatory body to oversee the program. The statutory authority rests with HRSA. However, HRSA has been limited in its ability to issue regulations enforcing the program's requirements. A recent letter from Senator Orrin Hatch (R-Utah) to the Secretary of Health and Human Services suggested that CMS could assume authority to regulate the 340B program. The Council believes that HRSA is the appropriate body to regulate the program. Second, the Council included specific language that opposing cuts under Medicare Part B and state Medicaid programs that reduce reimbursement for drugs purchased under the program that could deter participation in the 340B program. Finally, the Council added language advocating that savings under the program be retained by the covered entity and not clawed back by payers, in accordance with the program's intent to stretch scarce federal resources as far as possible in caring for patients rather than as a source of revenue for payers.

6. Pharmacist Authority to Provide Medication-Assisted Treatment

- 1 To advocate for the role of the pharmacist in medication-assisted treatment (MAT) for
- 2 opioid use disorder, including patient assessment, education, and prescribing of
- 3 pharmacologic therapies; further,
- 4 To pursue the development of federal and state laws and regulations that recognize
- 5 pharmacists as providers of MAT for opioid use disorder.

Rationale

An estimated 2.5 million Americans suffer from opioid use disorder. In 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that the U.S.

increase screenings and treatment for opioid use disorder. Many pharmacists have the skills to provide direct care to patients with opioid addiction or assist other healthcare providers in caring for these patients. Although some states allow pharmacists to prescribe controlled substances under collaborative practice agreements, pharmacists are not eligible to obtain a waiver under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine or other drugs for opioid use disorder. Having such prescribing authority would allow pharmacists to fully exercise their expertise and expand the pool of MAT providers.

Background

The Council considered this topic in response to concerns expressed by members and state affiliates that pharmacists are not eligible to obtain a waiver under the Drug Addiction Treatment Act of 2000 to prescribe buprenorphine and other drugs for opioid-use disorder, which limits their role in providing MAT for opioid use disorder.

COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATION

The Council on Education and Workforce Development is concerned with ASHP professional policies, related to the quality and quantity of pharmacy practitioners. Within the Council's purview are (1) student education, (2) postgraduate education and training, (3) specialization, (4) assessment and maintenance of competence, (5) credentialing, (6) balance between workforce supply and demand, (7) development of technicians, and (8) related matters.

Stephen F. Eckel, *Board Liaison*

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(Maryland)
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2. Pharmacy Technician Training and Certification

- 1 To advocate that the completion of a pharmacy technician education and training
- 2 program accredited by ASHP and the Accreditation Council for Pharmacy Education
- 3 (ACPE) be required for all new pharmacy technicians by the year 2022; further,

- 4 To advocate that all pharmacy technicians be required to obtain and maintain
- 5 Pharmacy Technician Certification Board certification; further,

- 6 To foster expansion of ASHP/ACPE-accredited pharmacy technician education and
- 7 training programs.

(Note: This policy would supersede ASHP policy 1609.)

Rationale

In January 2017, the Pharmacy Technician Certification Board (PTCB) suspended the condition that by 2020 the completion of an accredited technician education and training program is required to be eligible for the PTCB certification exam. There is no indication that PTCB will reinstate that requirement; however, ASHP supports completion of an education and training



program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) as well as PTCB certification for all pharmacy technicians. Although education requirements have been added by PTCB to take the certification exam starting in 2020, completion of an accredited education and training program is only one pathway for eligibility for the exam; PTCB also recognizes equivalent work experience. If an applicant has completed an unaccredited program, there is a required attestation for the content of that program.

In 2018, ASHP and ACPE developed revised national standards that serve as a guide for the development of ASHP/ACPE-accredited pharmacy technician education and training programs. These standards serve as the criteria for the evaluation of new and established pharmacy technician training programs and will help ensure that pharmacy technicians possess the knowledge, skills, and abilities necessary for their critical role on the healthcare team. A number of environmental factors, including changes in state laws allowing for expanded roles, responsibilities, and authority for pharmacy technicians, prompted the reassessment of the standards, which were last revised in 2015. ASHP supports more uniform state statutes and regulations regarding pharmacy technicians. The anticipated increase in demand for enrollment in ASHP/ACPE-accredited training programs will require an expansion of the number and distribution of such programs, including innovative education and training formats.

The target date of 2022 was included to provide a goal for requiring that all new pharmacy technicians in hospitals and health systems complete a pharmacy technician education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE). The date is in line with the initiatives and timeline of the Stakeholder Advisory Committee (the Committee). This Committee continues to advance the recommendations of the Pharmacy Technician Stakeholder Consensus Conference ([*Toward uniform standards for pharmacy technicians: Summary of the 2017 Pharmacy Technician Stakeholder Consensus Conference*](#)), the national consensus conference that engaged all sectors of pharmacy to define basic knowledge, skills, and abilities of pharmacy technicians, to promote and define advanced competencies, and to promote national definitions and regulation of pharmacy technicians. The Committee uses the recommendations and consensus statements to guide their work. Two of these statements are as follows:

- 2.1 The profession of pharmacy should move urgently towards the development and adoption of national standards for pharmacy technician education.
- 2.2 The profession of pharmacy should set a target for implementation of the national standard for pharmacy technician education at 3 to 5 years after adoption of the standard.

The accreditation standard for the education and training of pharmacy technicians was revised and approved by both the ASHP and ACPE Boards in June of 2018. Consistent with recommendation 2.2, 2022 is a reasonable target to require accredited training for new pharmacy technicians as it is four years from the time new standard was developed.

The Committee is currently working with the National Association of Boards of Pharmacy (NABP) to modify the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. NABP will consider commissioning a task force to evaluate the needs for a national licensure exam as well as educational and experiential prerequisites. Additionally, work is being done at the state level with individual boards of

pharmacy to evaluate requirements for accredited education and training for new pharmacy technicians. This activity follows the consensus statement below:

5.2 The level of urgency for achieving state-to-state consistency in regulation of pharmacy technicians' scope of practice, education, certification, and licensure or regulation is high.

Background

In September 2018, the Council reviewed ASHP policy 1609, Pharmacy Technician Training and Certification, as part of sunset review and voted to recommend amending it. In November 2018, PTCB made changes to the eligibility requirements for its certification exam. After considering the Council's policy recommendation in January 2019, the Board referred the recommendation to the Council for reconsideration to address PTCB's changes. The Council met in February 2019 and recommended amending ASHP policy 1609 as follows (underscore indicates new text; ~~strike through~~ indicates deletions):

To ~~support the position that by the year 2020,~~ advocate that the completion of a pharmacy technician education and training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE) be required ~~to obtain PTCB certification~~ for all new pharmacy technicians by the year 2022; further, [clause moved]

~~To advocate that Pharmacy Technician Certification Board (PTCB) certification be required for all pharmacy technicians; further,~~

To advocate that all pharmacy technicians be required to obtain and maintain Pharmacy Technician Certification Board ~~PTCB~~ certification; further,

To foster expansion of ASHP/ACPE-accredited pharmacy technician education and training programs.

COUNCIL ON PHARMACY MANAGEMENT

POLICY RECOMMENDATION

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.

Jennifer M. Schultz, *Board Liaison*

Council Members

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4. Intimidating or Disruptive Behavior

- 1 To affirm the professional responsibility of the pharmacist to ensure patient and
- 2 workplace safety by communicating with other healthcare personnel to clarify and
- 3 improve medication management; further,

- 4 To advocate that hospitals and health systems adopt zero-tolerance policies for
- 5 intimidating or disruptive behaviors in their institutions; further,

- 6 To encourage hospitals and health systems to develop and implement education and
- 7 training programs for all healthcare personnel to encourage effective communication,
- 8 set expectations for standards of conduct, promote use of de-escalation techniques, and
- 9 discourage intimidating or disruptive behaviors; further,

- 10 To encourage colleges of pharmacy and residency training programs to incorporate
- 11 training in communications and managing intimidating or disruptive behaviors; further,

- 12 To collaborate with other organizations to advocate codes of conduct that minimize
- 13 intimidating or disruptive behavior in hospitals and health systems; further,

- 14 To encourage hospitals and health systems to adopt processes for identification and
15 reporting of intimidating or disruptive behaviors to evaluate and mitigate unacceptable
16 behaviors in a timely and effective manner.

(Note: This policy would supersede ASHP policy 0919.)

Rationale

Intimidating or disruptive behaviors can lead to medical errors, contribute to poor patient satisfaction, increase costs, and cause staff turnover. Such behaviors range from passive behaviors such as providers refusing to answer questions or return pages to use of condescending language to overt actions such as verbal outbursts or physical threats. The Institute for Safe Medication Practices conducted a national survey regarding intimidation in the workplace in 2003 and conducted a follow-up survey in 2013 for comparison. There has been no reduction between 2003 and 2013 in the percentage of respondents who were aware of a medication error during the year in which disrespectful behavior played a role.

In addition, healthcare workers face an increased risk of work-related assaults resulting primarily from intimidating or disruptive behavior of patients and their caregivers or family members. Disruptive behavior, including interference with treatment plans, vulgar language, and threatening statements, can impede a healthcare worker's ability to provide safe and effective care. While such behavior is often overlooked, underreported, or considered to be part of the job, it can also lead to more serious confrontations. Unfortunately, there is no clear way to identify patients or family members who will be disruptive to healthcare personnel, so every patient and family member must be treated with the same level of caution.

According to the Bureau of Labor Statistics and National Crime Victimization Survey, more assaults occur in the healthcare and social services industries than in any other industry. For healthcare workers, assaults comprise 10-11% of workplace injuries involving days away from work, compared with 3% of injuries of all private sector employees. Further, it has been identified that workplace violence can harm a person's intrinsic sense of self-worth and confidence, which can result in physical symptoms including headaches, anxiety, and depression. The American Nurses Association and the American Medical Association have taken positions concerning violence against healthcare workers and are actively promoting solutions to address the issue.

ASHP believes organizations should develop training programs to discourage disruptive behaviors and to train employees in handling disruptive situations, including de-escalation techniques, and colleges of pharmacy and residency training programs should also provide such training. These organizational efforts will help with compliance with The Joint Commission leadership standard on disruptive behavior (LD.03.01.01), which suggests that healthcare organizations should "educate all team members – both physicians and non-physician staff – on appropriate professional behavior defined by the organization's code of conduct. The code and education should emphasize respect. Include training in basic business etiquette (particularly phone skills) and people skills."

Background

The Council discussed ASHP policies 0810, Education, Prevention, and Enforcement Concerning Workplace Violence, and 0919, Intimidating and Disruptive Behaviors, to determine whether ASHP policy adequately addresses threatening or abusive behavior of patients and family members toward pharmacy staff. The Council voted to recommend amending policy 0919 to read as follows (underscore indicates new text; ~~striketrough~~ indicates deletions):

To affirm the professional responsibility of the pharmacist to ensure patient and workplace safety by communicating with other healthcare personnel to clarify and improve medication management; further,

To advocate that hospitals and health systems adopt zero-tolerance policies for intimidating or disruptive behaviors in their institutions; further,

To encourage hospitals and health systems to develop and implement education and training programs for all healthcare personnel to encourage effective communication, set expectations for standards of conduct, promote use of de-escalation techniques, and discourage intimidating or disruptive behaviors; further,

To encourage colleges of pharmacy and residency training programs to incorporate training in communications and managing intimidating or disruptive behaviors; further,

To collaborate with other organizations to advocate codes of conduct that minimize intimidating or disruptive behavior in hospitals and health systems; further,

To encourage hospitals and health systems to adopt processes for identification and reporting of intimidating or disruptive behaviors to evaluate and mitigate unacceptable behaviors in a timely and effective manner.

This policy was amended to expand its scope, including mention of disruptive or intimidating behavior by patients and family members and support for reporting mechanisms to maintain acceptable standards of conduct.