

# House of Delegates

## Board of Directors Report: Policy Recommendations for the May 2021 Virtual House of Delegates

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# COUNCIL ON THERAPEUTICS

## POLICY RECOMMENDATIONS

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*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.*

Paul C. Walker, *Board Liaison*

### **Council Members**

Christi Jen, *Chair* (Arizona)  
Rena A. Gosser, *Vice Chair* (Washington)  
Sarah L. Anderson (Colorado)  
Amy Boblitt (Illinois)  
Kelly Bobo (Tennessee)  
Calvin Ice (Michigan)  
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Andrew Mays (Mississippi)  
Carolyn Oxencis (Wisconsin)  
Erin Warren, *Student* (South Carolina)  
Vicki Basalyga, *Secretary*

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### **1. Pharmacogenomics**

- 1 To advocate that pharmacists take a leadership role in pharmacogenomics-related
- 2 patient testing, based on current or anticipated medication therapy; further,
  
- 3 To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy
- 4 records in a format that clearly states the implications of the results for drug therapy
- 5 and facilitates availability of the genetic information throughout the continuum of care
- 6 and over a patient's lifetime; further,
  
- 7 To encourage health systems to support an interprofessional effort to implement
- 8 appropriate pharmacogenomics services and to determine appropriate dissemination of
- 9 actionable genetic information to appropriate healthcare providers for review; further,
  
- 10 To encourage pharmacists to educate prescribers and patients about the use of
- 11 pharmacogenomic tests and their appropriate application to drug therapy
- 12 management; further,
  
- 13 To advocate that all health insurance policies provide coverage for pharmacogenomic
- 14 testing to optimize patient care; further,

- 15 To encourage pharmacy workforce education on the use of pharmacogenomics and its  
16 application to therapeutic decision-making.

*Note: This policy would supersede ASHP policy 1104.*

### **Rationale**

Clinical pharmacogenomics is the practice of using genetic information to guide optimal drug selection and drug dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity. Currently, pharmacogenomic testing is used for specific drug-gene pairs in patients currently taking a medication associated with gene or prior to initiating therapy. Pharmacists are especially prepared to take a leadership role in selecting appropriate tests as they have an understanding of pharmacokinetic and pharmacodynamics properties of drugs in specific diseases and patient populations.

Over the past 10 years, the Clinical Pharmacogenetics Implementation Consortium (CPIC) has published over 23 guidelines that cover 19 genes and 46 drugs across several therapeutic areas as well as resources to facilitate the implementation of pharmacogenomics into routine clinical practice and the electronic health record. These guidelines include indications for which drugs and genes are most likely to be clinically useful based on current evidence. However, barriers such as prioritizing testing, interpretation for actionable results, incorporation of genomic data into the electronic health record, and reimbursement remain. Furthermore, there is also the challenge of how to ensure that the results of pharmacogenomic tests stay with the patient throughout their health journey. Implementation of pharmacogenomic testing has the potential to improve patient care by decreasing failed treatment attempts due to medication ineffectiveness or adverse effects and by increasing effectiveness of improperly dosed medications.

With the advent of widely available pharmacogenomic tests, many are also marketed to the public, which introduces another layer of complexity. The Food and Drug Administration (FDA) has alerted patients and healthcare providers that claims for many genetic tests to predict a patient's response to specific medications have not been reviewed by the FDA and may not have the scientific or clinical evidence to support their use. Changing drug treatment based on the results from such a test could lead to inappropriate treatment decisions and potentially serious health consequences for the patient.

Another barrier that many providers and patients encounter is insurance coverage of pharmacogenomic testing. A 2019 *JAPhA* article found that coverage and payments of pharmacogenomics varied by the company and gene-drug pairs and remain suboptimal. The article found that, of gene-drug indication group (GDIG), 50% were mentioned in policies but were covered less than 20% of the time. When mentioned in a policy, 7 GDIGs were uniformly covered, and 11 GDIGs were uniformly not covered. Overall, insurance companies covered approximately 40% of GDIGs mentioned in their policies.

Furthermore, the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics states that pharmacogenomics has an essential place in pharmacy education because pharmacists should be educated to be able to recommend pharmacogenomic testing for drug and dosage selection; design patient-specific drug and dose regimens based on the patient's pharmacogenomic profile and other pertinent information;

educate patients, pharmacists, and other healthcare professionals about pharmacogenomic principles and appropriate indications for clinical pharmacogenomic testing; and communicate pharmacogenomic-specific drug therapy recommendations to the healthcare team.

### **Background**

The Council reviewed ASHP policy 1104, Pharmacogenomics, as part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

To advocate that pharmacists take a leadership role in pharmacogenomics-related patient testing, based on current or anticipated medication therapy ~~the therapeutic applications of pharmacogenomics, which is essential to individualized drug therapy;~~ further,

~~To support research to validate and standardize genetic markers and genetic testing for drug therapy and to support research and other efforts that guide and accelerate the application of pharmacogenomics to clinical practice; further,~~

To advocate for the inclusion of pharmacogenomic test results in medical and pharmacy records in a format that clearly states the implications of the results for drug therapy and facilitates availability of the genetic information throughout the continuum of care and over a patient's lifetime; further,

To encourage health systems to support an interprofessional effort to implement appropriate pharmacogenomics services and to determine appropriate dissemination of actionable genetic information to appropriate healthcare providers for review; further,

To encourage pharmacists to educate prescribers and patients about the use of pharmacogenomic tests and their appropriate application to drug therapy management; further,

To advocate that all health insurance policies provide coverage for pharmacogenomic testing to optimize patient care; further,

To encourage ~~pharmacist~~ pharmacy workforce education on the use of pharmacogenomics ~~and advocate for the inclusion of pharmacogenomics and its application to therapeutic decision-making in college of pharmacy curricula.~~

## 2. FDA Requirement for Dose-Response Information

- 1 To advocate that the Food and Drug Administration require drug product
- 2 manufacturers to (1) identify average dose-response curves for desirable and
- 3 undesirable effects, and make this information available to healthcare providers; and (2)
- 4 publish dose-response information, to the extent possible, on factors that lead to
- 5 differences in pharmacokinetics and pharmacodynamics among individuals; further,
- 6 To encourage drug product manufacturers to conduct studies on and publicly report
- 7 minimum effective dose data.

*Note: This policy would supersede ASHP policy 0602.*

### **Rationale**

Knowledge of the relationships among dose, drug concentration in blood, and clinical response (effectiveness and undesirable effects) is important for the safe and effective use of drugs. This information can help identify an appropriate starting dose, titration of dosing, and identification of doses that would produce unacceptable side effects or be unlikely to provide added benefit. Important to this understanding is the analysis of the dose–response relationship, particularly with drug levels above the ED50, the dose that provides approximately 50% of the maximum possible drug effect, as efficacy increases only slightly, while adverse effects increase.

Manufacturer dose-finding studies sometimes provide a dose estimate and the range of a drug’s population ED50, but this information appears to have little bearing on prescribing. Many are either not aware of this measurement or do not consult the information after the drug is marketed with recommended dosage guidelines. Often overlooked is the variation in individual ED50 depending on body size, pharmacokinetics, and pharmacodynamics. This variation in ED50 may cause the effective dose to be lower in many patients compared with participants in clinical trials. It is important to note that the ED50 also can alert a clinician to the likely useful and safe dose range and should be more widely available. ED50 should be an important variable in drug approval, marketing, and, most importantly, prescribing. Furthermore, numerous observational studies have shown that providers often prescribe increasingly higher levels of treatment, often without clear clinical indication for such high doses. As such, the FDA recommends that dose-response assessment should be an integral part of drug development, including minimum effective doses.

### **Background**

The Council reviewed ASHP policy 0602, Minimum Effective Doses, as part of sunset review and voted to recommend amending it as follows (underline indicates new text; ~~strikethrough~~ indicates deletions):

To advocate that the Food and Drug Administration require drug product manufacturers to (1) identify ~~minimum effective doses for medications~~ average dose-response curves

for desirable and undesirable effects, and make this information available to healthcare providers; and (2) publish dose-response information, to the extent possible, on factors that lead to differences in pharmacokinetics and pharmacodynamics among individuals; further,

To encourage drug product manufacturers to conduct studies on and publicly report minimum effective dose data.

### 3. Medical Cannabis

- 1 To recognize that there is limited evidence to support safe and effective use of medical  
2 cannabis; further,
- 3 To encourage research that quantifies the therapeutically active components and  
4 defines the effectiveness, safety, and clinical uses of medical cannabis; further,
- 5 To recognize that there is not a standardized product subject to the same regulations as  
6 a prescription drug product, and to advocate for the development of processes that  
7 would ensure standardized formulations that would ensure consistent potency and  
8 quality of medical cannabis; further,
- 9 To advocate for the alignment of federal and state laws to eliminate barriers to research  
10 on and therapeutic use of medical cannabis, including review of medical cannabis's  
11 status as a Schedule I controlled substance, and its potential for reclassification; further,
- 12 To encourage healthcare organizations to develop policies and procedures regarding  
13 the handling of medical cannabis consistent with applicable laws, regulations, and  
14 accreditation standards; further,
- 15 To promote the documentation of medical cannabis use and indication in the electronic  
16 health record; further,
- 17 To encourage education that prepares pharmacists as part of an interprofessional team  
18 to educate patients, caregivers, healthcare providers, and healthcare administrators  
19 about therapeutic and legal aspects of medical cannabis use

*Note: This policy would supersede ASHP policy 1101.*

#### **Rationale**

To date, 33 states and the District of Columbia, Guam, and Puerto Rico have enacted workable medical cannabis laws that provide, or will provide, meaningful access to medical cannabis for

qualifying patients. Healthcare providers in those jurisdictions, including pharmacists, are grappling with the challenges presented by medical use of medical cannabis (defined for purposes of this policy as whole or parts of the natural marijuana plant and therapeutic products derived therefrom). ASHP recognizes that there is some evidence supporting the effectiveness of medical cannabis to treat or ameliorate symptoms of disease. The extent and quality of this evidence is limited, however, and even less is known about the safety of medical cannabis, especially related to its long-term use. Well-designed research is necessary to further define the therapeutic uses of medical cannabis, including determination of its therapeutically active components; clinical indications and contraindications; precautions; dosing; routes of administration; adverse effects; drug-drug, drug-disease, and drug-laboratory interactions; and effectiveness compared to existing therapies.

Current inconsistencies in product formulation, potency, and quality are also a hindrance to developing a strong evidence base. Standardizing these factors, to the extent possible, will help ensure the quality and reliability of research results. ASHP encourages efforts by the United States Pharmacopeia to develop quality standards for medical cannabis. Federal legislation and regulation, including marijuana's classification as a Schedule I substance under the Controlled Substances Act, remains a barrier to the necessary research, and ASHP advocates that federal and state laws and regulations be aligned to remove or minimize these barriers.

Conflicting federal and state laws also create confusion about research on and use of medical cannabis, as federal law precludes procurement, storage, preparation, or distribution of medical cannabis by pharmacies or healthcare facilities registered with the Drug Enforcement Administration. Given the complexity of the issues involved, ASHP encourages healthcare organizations to develop policies and procedures regarding medical cannabis to conduct research and provide patient care that is consistent with applicable laws, regulations, and accreditation standards. Recreational or medical use of cannabis should be documented in the patient medical record. ASHP recognizes the need for pharmacists and other healthcare providers to provide education about the unique therapeutic and legal issues created by research on and use of medical cannabis

### **Background**

The Council reviewed ASHP policy 1101, Medical Marijuana, as a part of sunset review and voted to recommend amending it as follows (underscore indicates new text; ~~strikethrough~~ indicates deletions):

~~To oppose state legislation that authorizes the use of medical marijuana until there is sufficient evidence to support its safety and effectiveness and a standardized product that would be subject to the same regulations as a prescription drug product; further,~~

To recognize that there is limited evidence to support safe and effective use of medical cannabis; further,

To encourage research to define that quantifies the therapeutically active components and defines the effectiveness, safety, and clinical uses of medical marijuana cannabis; further,

To recognize that there is not a standardized product subject to the same regulations as a prescription drug product, and to advocate for the development of processes that would ensure standardized formulations; that would ensure consistent potency; and quality of medical cannabis-marijuana products to facilitate research; further,

~~To encourage the Drug Enforcement Administration~~ advocate for the alignment of federal and state laws to eliminate barriers to medical marijuana research on and therapeutic use of medical cannabis, including review of medical marijuana's cannabis's status as a Schedule I controlled substance, and its potential for reclassification, ~~if necessary to facilitate research;~~ further,

~~To oppose the procurement, storage, preparation, or distribution of medical marijuana by licensed pharmacies or health care facilities for purposes other than research;~~ further,

~~To oppose the smoking of marijuana in settings where smoking is prohibited;~~ further,

To encourage healthcare organizations to develop policies and procedures regarding the handling of medical cannabis consistent with applicable laws, regulations, and accreditation standards; further,

To promote the documentation of medical cannabis use and indication in the electronic health record; further,

To encourage ~~continuing~~ education that prepares pharmacists as part of an interprofessional team to educate patients, caregivers, health care providers, and healthcare administrators about therapeutic and legal aspects of medical cannabis use ~~to respond to patient and clinician questions about the therapeutic and legal issues surrounding medical marijuana use.~~

The Council recommended that the term “medical marijuana” be replaced with the term “medical cannabis,” which has become the customary form in medical and scientific publications. The Council also suggested that ASHP not oppose medical cannabis legislation as an issue of patient autonomy, given the demonstrated (albeit limited) therapeutic effectiveness of medical cannabis. The Council discussed initial efforts by the United States Pharmacopeia to develop standards for medical cannabis products as well as those promulgated in Canada. The Council could envision that in the not-too-distant future, a standardized medical cannabis product could stimulate research and therapeutic use, and concluded that ASHP should take a forward-thinking stance to prepare pharmacists to address those challenges.

The Council noted the many issues confronting pharmacies and healthcare organization that are struggling to address medical cannabis programs approved in their state or jurisdiction. Given the significant differences among these programs, the Council concluded that the best policy would be to encourage those institutions to proactively develop policies and procedures



to address medical cannabis (e.g., procurement, storage, preparation, distribution, and administration) in light of their unique circumstances (e.g., patient populations, services, laws, regulations, and accreditation standards). The Council noted that ASHP policy 1522, Disposition of Illicit Substances, addresses patient possession of illicit substances, and concluded that the issue did not need to be addressed in this policy. The Council discussed documentation of medical and recreational use of cannabis, and concluded that no general recommendation could be made about the appropriate place for it in the patient medical record (e.g., social history if recreational, medicine list if clinical), but suggested that a best practice may develop. The Council noted that the Institute of Medicine has concluded that smoking marijuana is an unsafe delivery system and deleted the sixth clause, fearing that it could be interpreted as encouraging smoking of marijuana in areas where smoking of tobacco is not prohibited.

The Council agreed that there is need for research on best practices regarding management and use of medical cannabis, and suggested that ASHP could draw on member experience to offer education and guidance on the topic. The Council specifically recognized the potential importance of the medical cannabis model adopted by Connecticut, in which only pharmacists may dispense medical cannabis.

#### 4. Nonprescription Availability of Oseltamivir

1 To support expanded access to oseltamivir through a proposed intermediate category  
2 of drug products, as described by ASHP policy, that would be available from all  
3 pharmacists and licensed healthcare professionals (including pharmacists) who are  
4 authorized to prescribe medications, rather than nonprescription designation; further,

5 To support diagnosis and tracking of influenza through pharmacist-driven influenza  
6 point-of-care testing and reporting to the appropriate public health agencies prior to  
7 oseltamivir dispensing; further,

8 To support intraoperative documentation of oseltamivir dispensing and associated  
9 testing to all members of the healthcare team in outpatient and inpatient settings;  
10 further,

11 To advocate that specific and structured criteria be established for prescribing, dosing,  
12 and dispensing of oseltamivir for treatment and prophylaxis by pharmacists; further,

13 To advocate that pharmacist-provided counseling for oseltamivir and patient education  
14 on influenza be required for dispensing; further,

15 To continue to promote influenza vaccination by pharmacists, despite oseltamivir  
16 availability; further,

- 17 To advocate that the proposed reclassification of oseltamivir be accompanied by  
18 coverage changes by third-party payers to ensure that patient access is not  
19 compromised and that pharmacists are reimbursed for the clinical services provided.

### **Rationale**

Oseltamivir (Tamiflu) is a neuraminidase inhibitor used for the treatment and chemoprophylaxis of influenza. In July 2019, manufacturer Sanofi signed a deal with Roche Pharmaceuticals to obtain exclusive nonprescription rights to Tamiflu. ASHP would support the availability of oseltamivir as an intermediate category of drug products, as described in the [ASHP Statement on Criteria for an Intermediate Category of Drug Products](#). This designation would facilitate appropriate use of oseltamivir after patient assessment and professional consultation by a pharmacist or other licensed healthcare professional who is authorized to prescribe medications.

There are several perceived advantages and disadvantages of the nonprescription designation for oseltamivir. Potential benefits include quicker and improved oseltamivir access for patients, public health value by reducing exposure of sick individuals at provider visits, unlikely development of oseltamivir resistance based on currently available data, and experience with oseltamivir as a nonprescription medication in New Zealand since 2007. Potential concerns include stockpiling, shortages, questionable efficacy (an approximate reduction in symptom duration of one day), adverse effects (e.g., nausea, vomiting, headache, neuropsychiatric effects), reduction of influenza vaccination rates because of oseltamivir availability, dosing considerations (e.g., renal function, pediatric weight-based dosing), costs, reimbursement for clinical services provided by pharmacists (e.g., point-of-care influenza testing, questionnaire screening tool for oseltamivir dispensing), blunting of other more severe underlying conditions without a provider visit, and overextension of pharmacist responsibilities and duties. Furthermore, public health considerations must also be a part of this expanded access. With availability over or behind the counter, patients may bypass visiting their primary care providers to obtain oseltamivir, and pharmacists will therefore need to assume an active role in promoting public health by reporting positive cases to local health departments, should rapid testing and reporting be a requirement of dispensing.

Given the intent to expand patient access to oseltamivir, ASHP advocates that the proposed reclassification should not result in increased costs to patients and pharmacies. Modifications to national, regional, and local drug coverage decisions are needed to ensure that payer policies do not unintentionally restrict or prevent access. In addition, the reclassification will likely result in an increased workload and potential liability associated with pharmacist provision of this care, which includes patient screening (and point-of-care testing, if applicable), patient education, oseltamivir dosing, counseling, and documentation of the care provided in the pharmacy and medical record. Pharmacists should be compensated for these clinical and patient care services.

### **Background**

The Council discussed several issues surrounding the clinical and public health implications of

the nonprescription status of oseltamivir. From a clinical perspective, the Council explored considerations for treatment versus prophylaxis, reporting to health departments as a part of the reporting data collection and public health, access to patient information when considering dose adjustments, age restrictions for dispensing, the requirement for testing prior to dispensing, tracking potential resistance, and temporal dispensing restrictions (e.g., only available during flu season). Other topics the Council discussed included the cost of therapy due to loss of insurance coverage that has been seen with other drugs moving from prescription to nonprescription, inappropriate use and dispensing due to lack of patient education (e.g., patient presents with “stomach flu” and wants oseltamivir), concerns of stockpiling and shortages, impact on pharmacist workload due to the recommended reported and testing requirements, pharmacist reimbursement, and the availability of rapid testing.

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# COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT POLICY RECOMMENDATION

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*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.*

Julie A. Groppi, *Board Liaison*

## **Council Members**

Garrett Schramm, *Chair* (Minnesota)  
Christopher Edwards, *Vice Chair* (Arizona)  
Joseph Barone (New Jersey)  
Angela Bingham (Pennsylvania)  
Lauren Busch, *Student* (Missouri)  
Carol Heunisch (Illinois)  
Jesse Hogue (Michigan)  
Amy Holmes (North Carolina)  
Norman Hooten (Florida)  
Denise Kelley (Texas)  
Ann Lloyd (Oklahoma)  
Tiffani Neubel-Johnson (Texas)  
Jennifer Sternbach (New Jersey)  
Erika Thomas, *Secretary*

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## **1. Education and Training in Telehealth**

- 1 To acknowledge that telehealth is a growing modality that supports the pharmacy
- 2 workforce in providing direct patient care; further,
  
- 3 To support training and education for the pharmacy workforce in innovative models
- 4 that support telehealth services; further,
  
- 5 To promote the incorporation of students and residents into virtual modalities of care
- 6 and interdisciplinary collaboration; further,
  
- 7 To foster documentation and dissemination of best practices and outcomes achieved by
- 8 the pharmacy workforce as a result of telehealth services.

### **Rationale**

Continuous development of information technology is rapidly redefining the provision of healthcare. The expansion of telehealth services creates opportunity to improve access to telepharmacy and telemedicine for patients unable to access health services in traditional



modalities. Lack of access to healthcare remains critical for many individuals for a variety of reasons including geographic issues (i.e. rural communities), lack of transportation, physical or fiscal challenges. The provision of medical care using telehealth allows patients to have access when they need it at the time they need it.

To ensure that telepharmacy becomes a strong component of telehealth, training and education must be developed that supports the pharmacy workforce in their delivery of optimal patient care. Expanded access for the pharmacy workforce as well as interoperability and information integrity between organizations where patients may receive care is crucial. Additionally, student learners must have appropriate access levels with oversight to the electronic health record to ensure development of the skills needed for this type of care. Research supporting improved outcomes while maintaining security for patients' health information is needed to foster continued development.

### ***Background***

The Council discussed the differing definitions organizations have developed for telehealth, telemedicine, and telepharmacy. Telehealth, telemedicine, and telepharmacy have numerous documented potential benefits and are especially beneficial in rural and remote areas that lack sufficient healthcare services, including specialty care. The range and use of telehealth services have expanded over the past decades, along with the role of technology in improving and coordinating care that brings the pharmacy workforce closer to our patients. However, during the COVID-19 pandemic, multiple legislative changes quickly expanded telehealth as a method of providing healthcare while most of the nation was on lockdown.

Given the recent rapid expansion of telehealth, the Council addressed this topic to determine the need for an ASHP policy to advocate for telehealth training and education for the pharmacy workforce. Members recognized that the ASHP Statement on Telepharmacy is under sunset review, but could take up to two years for the statement to be updated and finalized. Members were in agreement that there is an immediate need for professional policy and are crafting a new ASHP policy to review and vote to recommend at a fall 2020 Council meeting. Council members also commended ASHP for the launch of a new online telehealth resource center.

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# COUNCIL ON PHARMACY MANAGEMENT

## POLICY RECOMMENDATION

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*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.*

Jamie S. Sinclair, *Board Liaison*

### **Council Members**

Staci Hermann, *Chair* (New Hampshire)  
Arpit Mehta, *Vice Chair* (Pennsylvania)  
Jennifer Belavic (Pennsylvania)  
Daniel Dong (California)  
Monica Dziuba (Louisiana)  
Kaitlyn Grieves, *Student* (Kentucky)  
Amanda Hays (Missouri)  
Jessica Hill (New Jersey)  
Rondell Jagers (Georgia)  
Trinh Le (North Carolina)  
Bonnie Levin (Maryland)  
Christopher Scott (Indiana)  
Eric Maroyka, *Secretary*

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### **1. Supply Chain Resilience During Disasters and Public Health Emergencies**

- 1 To support building an enhanced and resilient hospital and health-system supply chain
- 2 that is lean and economical during normal operations yet nimble enough to support
- 3 patient care needs during large surges in demand for pharmaceuticals and medical
- 4 supplies; further,
  
- 5 To advocate for ongoing federal evaluation of a national hazard vulnerability
- 6 assessment to determine how pandemics and disasters present risks to healthcare and
- 7 public health critical infrastructure; further,
  
- 8 To advocate for the development of critical pharmaceutical and medical supply
- 9 requirement listings based on a national hazard vulnerability assessment to guide the
- 10 composition of government and distributor-managed emergency stockpiles; further,
  
- 11 To urge Congress and state legislatures to direct medical supply and pharmaceutical
- 12 distributors to manage both "private sector-owned" medical materiel (just-in-time for
- 13 normal operations) and government-owned/distributor-managed emergency stockpiles
- 14 (just-in-case for emergencies) that can flow into the private sector supply chain when
- 15 release of government-owned materiel during public health emergencies, disasters, or
- 16 contingencies is authorized.

**Rationale**

Hospitals and health systems experience supply chain challenges for patient care during routine operations, and these challenges can be exacerbated by public health emergencies and disasters. Aspects of the novel coronavirus disease 2019 (COVID-19) pandemic that have required nimbleness in thinking and action are the transformation of organizational governance and the need for speed in decision-making. The COVID-19 pandemic has dramatically changed inventory management and supply chain practices.

Many pre-existing factors contributed to the supply chain crises triggered by COVID-19, including but not limited to overextended supply lines, lean manufacturing, and outsourcing, which have been especially unfavorable for hospitals and health systems running just-in-time (JIT) inventory replenishment. Designed to use capital more efficiently, JIT replenishment relies on highly accurate demand forecasting and tight coordination with suppliers. When there is a sudden increase in demand, from a larger number of buyers trying to purchase the same products at the same time or from the typical number of buyers trying to make larger purchases, the thin supply chains that support JIT inventories can't respond quickly enough, creating long-term backorders at the local, regional, and national levels. An alternative just-in-case (JIC) inventory strategy would maintain extensive inventories to reduce backorder risks in the face of supply and demand uncertainties, but at the cost of forcing organizations to tie up capital in inventory.

During the COVID-19 pandemic, hospital and health-system governance structures had to quickly pivot to accommodate shifts in unexpected operational, clinical, and financial challenges. Organizations quickly embraced the "new normal" of supply chain management conundrums (e.g., shortages of personal protective equipment and critical drug, minimizing drug waste), controversial drug therapy considerations for pharmacy and therapeutics committees, and provisioning planning for alternate care sites (e.g., field hospitals). To prepare the healthcare system to endure the stresses on critical infrastructure caused by future public health emergencies or disasters, a shift toward a hybrid supply chain model needs serious consideration, to reap the benefits of both models and build resiliency into supply chains. Such a system would use information from a national hazard vulnerability assessment to guide the composition of emergency stockpiles of critical pharmaceuticals and medical supplies and require private-sector distributors of those products to manage the supply chains for those stockpiles when they are released during public health emergencies or disasters in addition to their normal operations.

**Background**

The Joint Council and Commission Meeting on Pandemic Preparedness and Response helped inform discussion of this policy topic, which centered on the resiliency of the supply chain of medical supplies and pharmaceutical during the COVID-19 pandemic.

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# COUNCIL ON PHARMACY PRACTICE

## POLICY RECOMMENDATION

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*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.*

Kristina L. Butler, *Board Liaison*

### **Council Members**

Andrew Stivers, *Chair* (Georgia)  
Amanda Hansen, *Vice Chair* (Ohio)  
Michael Dickens (Idaho)  
Karl Gumper (Massachusetts)  
Barbara Hintzen (Minnesota)  
Molly Leber (Connecticut)  
Karen McConnell (Colorado)  
Alex Mersch (Iowa)  
Christopher Pack (Oklahoma)  
Kuldip Patel (North Carolina)  
Brittany Riley (West Virginia)  
Jamielynn Sebaaly (North Carolina)  
Kenny (Jon) Wilson, *Student* (Alabama)  
Anna Legreid Dopp, *Secretary*

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### **1. ASHP Statement on the Pharmacist's Role in Public Health**

<sup>1</sup> To approve the ASHP Statement on the Pharmacist's Role in Public Health (Appendix A).



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## SECTION OF CLINICAL SPECIALISTS AND SCIENTISTS POLICY RECOMMENDATION

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*The Section of Clinical Specialists and Scientists represents clinical experts and advocates for practice advancement and improvement in patient care by creating and translating scientific advances into practice.*

Jamie S. Sinclair, *Board Liaison*

### **Executive Committee**

Joel C. Marrs, *Chair* (Colorado)  
Megan E. Musselman (Missouri)  
Douglas Slain (West Virginia)  
Aaron L. Steffenhagen (Wisconsin)  
Jodi L. Taylor (Tennessee)  
Stephanie L. Weightman (Texas)  
Vicki Basalyga, *Director*

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### **1. ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics**

- 1 To approve the ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics
- 2 (Appendix B).



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## ASHP Statement on the Pharmacist’s Role in Public Health

1 **Position**

2 Pharmacists play a vital role in maintaining and promoting public health. All pharmacists have a  
3 responsibility to participate in global, national, state, regional, and institutional efforts to  
4 promote public health and to integrate the goals of those initiatives into their practices.  
5 Furthermore, pharmacists have a responsibility to work with public health planners to ensure  
6 their involvement in public health policy decision-making and in the planning, development,  
7 and implementation of public health efforts.

8 The primary objectives of this statement are to (1) increase awareness of pharmacists’  
9 contributions to public health, (2) educate pharmacists about public health and their role in  
10 promoting public health, (3) describe the role of pharmacists in public health planning and  
11 promotion, and (4) identify new opportunities for pharmacists’ involvement in future public  
12 health initiatives. This statement does not provide an exhaustive review of pharmacists’ public  
13 health activities. Its intent is to stimulate dialogue about the role that pharmacists can play in  
14 improving public health in the U.S. The statement is also meant to draw attention to and  
15 highlight the significance of enhanced and proactive communication between the public health  
16 sector and the pharmacy profession’s leaders and stakeholders representing national and state

17 affiliates, colleges of pharmacy, and health systems to advocate the pharmacist's role in public  
18 health.

19

## 20 **Background**

21 Public health is a science-based field designed to "protect and improve the health of people and  
22 their communities."<sup>1</sup> In contrast to clinical medicine, public health concentrates on whole  
23 populations and communities, working to improve the places where they "live, learn, work and  
24 play,"<sup>2</sup> through health promoting policies, prevention, interventions and education.

25 These goals are accomplished through an upstream approach, or what could be considered  
26 "upstream healthcare." Public health recognizes four levels of prevention: primordial, primary,  
27 secondary and tertiary.<sup>3</sup> Primordial prevention is prevention of risk factors for disease, illness,  
28 injury, or poor health outcomes from ever developing; primary prevention is the prevention of  
29 disease, illness, injury, or poor health outcomes from occurring; secondary prevention focuses  
30 on reducing the impact of disease, illness, injury, or poor health outcomes; and tertiary  
31 prevention focuses on minimizing the long-term impact of disease, illness, injury, and poor  
32 health outcomes.<sup>3</sup> While all four levels of prevention are recognized and used in public health,  
33 primordial and primary prevention are considered largely upstream, whereas secondary and  
34 tertiary prevention are considered more downstream. Public health focuses heavily on  
35 upstream efforts while also working closely with the medical community and others to  
36 positively impact downstream work. Examples of the different types of prevention can be  
37 found in Table 1.

38 There are many factors that contribute to the overall health of a community or population.

39 To understand how best to prevent the risk factors of disease, illness, injury, and poor health  
40 outcomes from ever developing, one must first understand the many factors that contribute to  
41 overall health, referred to as “determinants of health.” While there are many determinants of  
42 health, most can be grouped into five primary categories: social factors, referred to as “social  
43 determinants of health”; policy; health services; individual behavioral choices; and biology and  
44 genetics<sup>4</sup>:

- 45 • **Social determinants of health** include but are not limited to socioeconomic  
46 status, employment status, educational attainment, cultural and physical  
47 environment, family influence, intimate partners, social groups, and religious  
48 groups.
- 49 • **Policy** includes but is not limited to economic policies, political policies, justice  
50 policies, educational policies, health policies, work policies, and neighborhood  
51 and zoning policies.
- 52 • **Health services** include but are not limited to access to services, quality of  
53 services, cost of services, insurance coverage, language access, health programs,  
54 and time and means of access.
- 55 • **Individual behavioral choices** include but are not limited to diet; physical  
56 activity; alcohol, drug, or tobacco use; handwashing; sexual activity; stress  
57 management; sleep; and therapy adherence issues.
- 58 • **Biology and genetics** include but are not limited to age; gender; sex; biological  
59 response to stimuli, stress, or medications; and genetic predispositions.

60 The combination of these factors heavily influences the overall health of individuals,

61 communities, and populations, making healthy living either easier or more difficult.<sup>2</sup> These  
62 factors are closely intertwined, with no single determinant independent of the others. One  
63 study ranked the relative contributions of determinants of health to overall health as follows:  
64 behavior, 40%; genetics, 30%; social factors 15%; healthcare, 10%; and environmental factors,  
65 5%.<sup>5</sup> As Shermock points out, “[e]ven if we get the part that healthcare practitioners typically  
66 focus on *completely right*, that still leaves 90% of what determines health unaccounted for.”<sup>6</sup>

67         Public health seeks to understand the determinants of health and their influence on risk  
68 factors, disease, illness, injury, and negative health outcomes through research. That  
69 knowledge is then used to improve the determinants of health and remove the barriers to  
70 healthy living, making the healthy choice the easier one.

71

## 72 **Public Health Activities of Pharmacists**

73 In 2006, the American Public Health Association (APHA) outlined the public health role of the  
74 pharmacist in a statement<sup>7</sup> building on two previous APHA publications.<sup>8,9</sup> In 2013, the  
75 American Association of Colleges of Pharmacy recognized the important role pharmacists can  
76 play in public health by including population-based care and reducing health disparities and  
77 inequalities in its Center for Advancement in Pharmaceutical Education (CAPE) Educational  
78 Outcomes.<sup>10</sup> These outcomes also emphasized the pharmacist’s role in the public health  
79 components of “design[ing] prevention, intervention, and educational strategies for  
80 individuals and communities to manage chronic disease and improve health and wellness.”<sup>10</sup>

81         The public health duties that an individual pharmacist performs will vary, based on the  
82 individual’s experience, abilities, training, and work setting. All pharmacists, working alone or in

83 collaboration with healthcare colleagues and administrators, can contribute to the promotion  
84 of public health. ASHP has described roles pharmacists have in specific public-health-related  
85 activities, including antimicrobial stewardship and infection control<sup>11</sup>; substance abuse  
86 prevention, education, and treatment<sup>12</sup>; prevention of controlled substances diversion<sup>13</sup>;  
87 managing drug product shortages<sup>14</sup>; immunization<sup>15</sup>; tobacco cessation<sup>16</sup>; and emergency  
88 preparedness and response.<sup>17</sup>

89 The following are examples of other activities that pharmacists can engage in to promote  
90 public health:

- 91 ● Promoting population health.
- 92 ● Developing disease prevention and control programs (including chronic disease or  
93 disease treatment programs).
- 94 ● Promoting medication safety efforts in their institutions and communities.
- 95 ● Engaging in opioid stewardship efforts, including prevention, intervention, and  
96 treatment.
- 97 ● Developing health-education policies and programs within their institutions that address  
98 the needs of patients, other healthcare professionals, community leaders, and the  
99 public, individually and as members of committees with purview over public health-  
100 related activities; and participating as members of public health organizations and  
101 chapters in pharmacy organizations.
- 102 ● Advocating for sound legislation, regulations, and public policy regarding disease  
103 prevention and management.
- 104 ● Engaging in public health-related research and education programs, initiating campaigns

105 to disseminate new knowledge, and providing training programs that include basic  
106 population health tools such as statistical analysis, epidemiology, disease surveillance  
107 techniques, risk reduction strategies, insights into methodology.<sup>18</sup>

108 **Population health.** Although pharmacists have a role in both, it is important to distinguish  
109 population health from community health. Community health “encompasses population groups  
110 and the locus (e.g., place, venue, or other unit) of programs, interventions, and other  
111 actions,”<sup>19</sup> typically implying a geographic basis. In contrast, population health focuses on  
112 groups of individuals defined by specific characteristics other than geography, such as a health  
113 determinant or disease state. For example, Kindig and Stoddart defined population health as  
114 “the health outcomes of a group of individuals, including the distribution of such outcomes  
115 within the group.”<sup>20</sup> They proposed that the field of population health includes policies and  
116 interventions that link health outcomes and patterns of health determinants. Evans, Barer, and  
117 Marmor<sup>21</sup> described factors in the social environment, external to the healthcare system, that  
118 exert a major and potentially modifiable influence on the health of populations.

119 Efforts to improve population health have been defined in different ways. The Institute  
120 for Healthcare Improvement Triple Aim Initiative uses the term “population health  
121 management” to describe “the work by healthcare organizations to improve outcomes for  
122 individual patients to maximize population health,” whereas the National Academy of Medicine  
123 prefers the term “population health improvement” to describe “work to identify and improve  
124 aspects of or contributors to population health, expanding the focus beyond traditional  
125 healthcare delivery systems.”<sup>22</sup> Homsted et al.<sup>23</sup> provide a process-based definition of  
126 population health management:

127           The active process of strategically utilizing health determinant data for a defined cohort  
128           to design, coordinate, and deliver high-quality, cost-effective, patient-centered care  
129           across the continuum, through optimizing communication, collaboration, and utilization  
130           of available resources with the goal of creating and sustaining health.

131   Population health management, a subset of population health, focuses on the comprehensive  
132   care of a specific population to implement needed services and interventions to improve the  
133   population's health.<sup>24</sup> Pharmacists can participate in population health management by being  
134   able to identify the needs of a population and implement necessary changes by, for example,  
135   performing medication reviews (especially of risky or costly medications) and working with  
136   other healthcare providers to develop care paths and chronic disease state management  
137   programs.<sup>26</sup> Given the importance of behavior as a determinant of health, pharmacists can  
138   improve population health through concerted actions to improve adherence to medication,  
139   diet, and exercise regimens, and through efforts to discourage harmful behaviors such as  
140   tobacco use, substance abuse, and high-risk sexual activity. Pharmacists practicing in  
141   ambulatory care and primary care settings are particularly well positioned to help ensure  
142   patients have received appropriate preventive care, such as well care visits, immunizations, and  
143   screenings (e.g., mammograms, colonoscopies). Those pharmacists also have a role in  
144   population health management by contributing to team-based monitoring and education of  
145   patients about healthy lifestyle choices and screening for social determinants of health.<sup>26</sup>

146           Medication therapy management (MTM) programs provide one example of a role  
147   pharmacists can have in population health management. MTM broadly encompasses a  
148   range of healthcare services provided by pharmacists that optimize patient outcomes.



149 Pharmacists can expand their roles by leveraging provider status to improve public health  
150 through MTM.<sup>27</sup> MTM can be used to identify and resolve drug therapy problems. Pharmacists  
151 can develop comprehensive individual care plans, identify and meet vaccination needs, and  
152 improve health outcomes through adherence and management of chronic diseases. MTM has  
153 the potential to go beyond the treatment and management of diseases and provide  
154 pharmacists an opportunity to identify social determinants of health during patient care  
155 conversations (e.g., identifying social determinants of health such as food insecurities may  
156 shed light on why a patient skips meals and insulin, leading to uncontrolled diabetes) and help  
157 address them. Identifying social determinants of health that are impacting patient outcomes  
158 and advocating for these patients is an important aspect of MTM, and the future of pharmacy  
159 must incorporate social determinants of health principles if the profession is to treat the  
160 whole patient and meet the needs of an integrated and multi-professional healthcare system.

161         Some of the leading health initiatives of Healthy People 2030 include smoking cessation,  
162 fall risk assessment, vaccinations, and medical product safety,<sup>28</sup> which can all be addressed  
163 during MTM services provided by pharmacists. Motivational interviewing should be utilized for  
164 those who are actively smoking, and benefits of quitting discussed during MTM sessions. This  
165 activity, along with identifying needed vaccines and potential fall risks, could improve public  
166 health and patient outcomes.

167         The outcomes from the 2013 Center for the Advancement of Pharmacy Education  
168 (CAPE) emphasize the importance of this ability for future pharmacists to be trained in  
169 identifying and critically analyzing information that may impact patient-centered and  
170 population-based care.<sup>10</sup> As the volume of population and patient data grows, along with the

171 ability to analyze that data using tools such as machine learning, human language processing,  
172 and harvesting of data from health apps and social media, well-trained pharmacists will be able  
173 to harness the power of big data to care for populations more efficiently and effectively.

174 ***Disease prevention and control.*** Pharmacists can be involved in disease prevention and  
175 control in many ways. For example, they can help develop institutional screening programs to  
176 check immunization status and identify undiagnosed medical conditions (e.g., hypertension,  
177 diabetes, hyperlipidemia, depression, substance abuse, behavioral health issues). Pharmacists  
178 have gained authority in many parts of the U. S. to administer immunizations, sometimes with a  
179 prescription from a physician, but often just at the request of the patient, and are making it a  
180 routine part of offered services. The goals for disease prevention in Healthy People 2020 was  
181 focused on the diseases and conditions listed above.<sup>29</sup> Healthy People 2020 also introduced  
182 Leading Health Indicators,<sup>30</sup> which included social determinants of health.

183 In Healthy People 2030, more attention is focused on preventing disease through  
184 attention to upstream influences on health, such as social determinants.<sup>28</sup> Healthy People  
185 2030 continues to emphasize helping people prevent conditions that have a high impact on  
186 costs and quality of life, such as chronic disease, behavioral health and equity, or the equal  
187 opportunity to be the healthiest a person can be. Pharmacists can encourage and model  
188 behaviors to mitigate threats that are high risk to public health such as anthrax, botulism,  
189 plague, smallpox, as well as currently emerging diseases spread by viral and bacterial vectors  
190 such as Zika, HIV, influenza (e.g., H1N1), and coronaviruses. These behaviors include  
191 handwashing, social distancing, mask wearing, immunization, and not working when  
192 symptomatic.<sup>31</sup> Table 2 provides a list of ways to prepare for specific pharmacy public health

193 roles in epidemic or pandemic response.

194 All healthcare professionals, including pharmacists, have become increasingly  
195 concerned about the effect of stress on the overall health of people and interested in  
196 promoting ways to reduce stress (e.g., regular exercise, yoga, increasing time in nature,  
197 comfort animals). As Healthy People stakeholders, pharmacists can use and make their  
198 patients aware of available resources and services by providing website links, data, interactive  
199 tools, and reports as passive offerings in clinic and community pharmacies. Pharmacists can  
200 more actively manage disease prevention through collaborative care agreements, prescribing,  
201 therapeutic medication management, and counseling.

202 **Medication safety.** Medication safety is one of pharmacists' primary  
203 responsibilities.<sup>32,33</sup> Adverse medication events are estimated to cost the United States more  
204 than \$30 billion dollars a year and inflict incalculable loss and suffering on victims.<sup>34</sup> By  
205 providing focused and comprehensive medication instruction to individual patients and groups  
206 of patients, pharmacists can help reduce emergency room visits and hospital admissions by up  
207 to 30%.<sup>34</sup> The pharmacist's role in medication safety and preventable adverse events from  
208 medications align with the national public health goals outlined in Healthy People 2030,<sup>28</sup>  
209 which include reducing emergency department visits for overdoses from medications.  
210 Pharmacists are ideally suited to serve in leadership roles as an expert resource for medication  
211 safety by virtue of their education and training and their responsibility for ensuring medication  
212 safety through use of technologies such as barcoding, computerized provider order entry  
213 systems, infusion pumps, and clinical decision support. Pharmacists can improve medication-  
214 related processes and develop strong medication-safety practices utilizing Just Culture

215 principles<sup>35</sup> to facilitate high-reliability organizations<sup>36</sup> through engagement in facility-wide  
216 committees (e.g., medication safety or pharmacy and therapeutics committees).<sup>37,38</sup>  
217 Pharmacists can also promote adherence and effective medication use through initiatives in  
218 the community and local organizations. The 2013 CAPE outcomes include an increasing role  
219 for pharmacists in improving the safety of medications at each step in the medication-use  
220 system and in transitions of care.<sup>10</sup> Pharmacists are responsible for monitoring the  
221 medication-use system and reporting of medication-related adverse events because of their  
222 unique expertise in this area. Pharmacists are often an inherent part of transitions of care  
223 (e.g., through community pharmacies, managed-care facilities, long-term care), so they can  
224 play a significant role in ensuring medication safety by counseling patients, identifying  
225 potential medication-related adverse drug events, and putting in place strategies to prevent  
226 those events (e.g., notifying pharmacy colleagues in a setting that a patient is transferring to,  
227 or raising awareness of possible threats to medication safety for specific patients).  
228 Pharmacists' ability to problem-solve and decrease future medication-related adverse events  
229 is beneficial to public health at large.

230 ***Efforts to address the opioid epidemic.*** ASHP has described roles and responsibilities  
231 pharmacists have in substance abuse prevention, education, and assistance<sup>12</sup> and prevention  
232 of controlled substances diversion.<sup>13</sup> The scope and nature of the opioid epidemic warrant  
233 particular focus. Healthcare professionals have come to embrace what is termed "pain  
234 management and opioid stewardship," recognizing that "opioid stewardship is an integral...  
235 part of an overall pain management and stewardship strategy" and that behavioral and  
236 socioeconomic aspects of care should be "recognized as an overarching component that needs

237 to be addressed across the spectrum of patients.”<sup>39</sup> Pharmacists are well positioned in the  
238 healthcare and local communities to collaborate with other providers in the treatment of  
239 acute and chronic pain working to apply opioid-alternative therapies when possible. In  
240 addition, pharmacists should be engaged to recommend appropriate opioid dosage regimens  
241 that decrease overprescribing and reduce the risks of abuse and addiction when necessary.  
242 Pharmacists, as part of the interprofessional team, have roles in prevention, intervention, and  
243 treatment of opioid abuse and addiction that include but are not limited to the following.

244 *Prevention*

- 245 ● Collaborating with healthcare colleagues to take an interprofessional approach to pain  
246 management and opioid stewardship that incorporates evidence-based non-opioid  
247 therapies and reduces the risks of abuse, misuse, and addiction.
- 248 ● Adopting communication and educational approaches to explain dosing instructions to  
249 patients in ways that avoid or reduce common problems that stem from opioid misuse  
250 or overuse.
- 251 ● Leading efforts to prevent diversion of controlled substances.<sup>13</sup>
- 252 ● Working with other healthcare professionals, governmental agencies, and civic  
253 organizations to destigmatize opioid use disorder and foster development of treatment  
254 programs.
- 255 ● Using and advocating for the enhancement of state prescription drug monitoring  
256 programs.
- 257 ● Participating in public substance abuse education and prevention programs.

258 *Intervention*

- 259       ● Assisting in the identification of individuals, coworkers, and others who may be having  
260       problems related to opioid abuse.
- 261       ● Dispensing and administering naloxone, and training caregivers to administer and at-  
262       risk patients to self-administer naloxone.
- 263       ● Working with local school districts to provide programming and encourage peer  
264       interventions as well as opportunities for counseling with the pharmacist on options  
265       for treatment.

266    *Treatment*

- 267       ● Seeking out education and training in the use of medications used in medication-  
268       assisted treatment of opioid use disorder (e.g., methadone, buprenorphine,  
269       buprenorphine-naloxone, naltrexone).
- 270       ● Optimizing therapy outcomes by gathering vital clinical and health screening  
271       information about patients.

272    Laws regarding the prescribing, dispensing, and use of naloxone have changed dramatically in  
273    recent years. By 2019, every state in the U.S. had some form of immediate availability for  
274    naloxone in pharmacies.<sup>40</sup> Healthcare organizations have created training modules for  
275    pharmacists on how to use and administer the drug.

276        ***Health education.*** Another way pharmacists advance public health is by developing,  
277    promoting, and implementing education programs aimed across life's stages.<sup>41</sup> Pharmacists  
278    have acted as health educators on a variety of topics (Table 3).<sup>42-53</sup> In their role as health  
279    educators, pharmacists can assess and improve the health literacy of individuals and groups to  
280    improve adherence to medication, diet, and exercise regimens; reduce medication-related

281 adverse events; enhance the individual's role in their care and health; and build trust with  
282 pharmacists and the healthcare system. Pharmacists who serve as faculty in health professions  
283 schools and colleges have a stake in promoting Healthy People 2030. There is a responsibility  
284 on their part to integrate strategies on prevention into curricula and interprofessional  
285 experiences for the learner. Employing interactive techniques and tools such as games,  
286 simulations, and personal fitness devices encourages engagement and commitment by  
287 individuals to activities such as exercise and maintaining healthy diets.

288 **Public health policy.** Pharmacists should participate in public health policy development,  
289 from local boards of health to national programs.<sup>54</sup> By linking disease prevalence, medication  
290 utilization, and the determinants of disease, pharmacists can place prevention within a larger  
291 context. Medication use plays a central role in health and health policy, especially policy  
292 directed at chronic disease, which must be formulated with a broad understanding of the  
293 relationship between medication therapy and the many other factors that affect disease  
294 outcomes. Since medication use increases as patients age, pharmacists' unique perspective on  
295 healthcare policy will become more important as the average age of the U.S. population  
296 rises.<sup>55</sup>

297 As medication-use experts and experienced health-system administrators, pharmacists can  
298 and should contribute to the development of public-health related legislation and regulation  
299 and should be involved in public program oversight and administration. Legislators, regulators,  
300 and program managers at all levels of government should be educated to utilize this expertise.  
301 Pharmacists, as individuals and through their professional associations, state and local boards  
302 of health, and state boards of pharmacy, are encouraged to participate in legislative,

303 regulatory, and oversight processes.

304 Pharmacists will need knowledge of the policy and financial drivers of public health to  
305 engage in advocacy efforts to improve population outcomes.<sup>56</sup> To be most effective,  
306 pharmacists need to be trained to take leadership roles in public health policy. Postgraduate  
307 year 2 pharmacy residencies are now available in Population Health Management and Data  
308 Analytics Pharmacy, and dual Pharm.D./M.P.H. degrees are available, as are executive programs  
309 in public health practice.

310 **Research and training.** Pharmacists should be encouraged to pursue more advanced  
311 training and gather credentials that will give them added credibility in addressing broad public  
312 health initiatives. Pharmacists should strive to be proficient in research methodology,  
313 pharmacoepidemiology, and biostatistics, and how these areas apply to public health decision-  
314 making. Pharmacists should actively seek experience in the design, implementation, analysis,  
315 and interpretation of clinical studies (both observational and experimental), which can be  
316 achieved through both pharmacy curriculum and professional education.

317 Pharmacy curricula should be developed in such a way to include public health,  
318 biostatistics, and research design.<sup>57</sup> Inclusion of the content can help assure that future  
319 pharmacists have a strong working knowledge of public health principles as well as population  
320 health. It is essential that both experiential and didactic training for students, residents, and  
321 research fellows include exposure to research in public health policy, pharmacoepidemiology,  
322 pharmacoeconomics, health-related quality of life, and evidence-based medicine, with  
323 potential opportunities for publication and/or presentation of their work.

324 Professional education of practicing pharmacists may include refreshers on biostatistics,



325 research, and public health trends, with a focus on the application and analysis of research  
326 findings in the clinical setting. Mentoring and collaborative research projects across multi  
327 disciplines is encouraged. Pharmacists can play an important role in data monitoring  
328 committees. There are certificate and graduate education programs available for pharmacists  
329 to advance their knowledge and skills in the above-mentioned areas of practice.

330           Pharmacists should seek out opportunities to participate in collaborative research.<sup>58</sup>  
331 They are also well suited to serve on institutional review boards, medication safety committees,  
332 and pharmacy and therapeutics committees. It is recommended that pharmacists work directly  
333 with public health policymakers and other key stakeholders (e.g., leaders in professional  
334 organizations, medical centers, academic institutions, governmental agencies, and third-party  
335 payers) to learn about processes and to advance their knowledge in order to promote optimal  
336 pharmacotherapy.

337

### 338 **Future Roles**

339 Some of the future roles of pharmacists in public health will look very similar to their current  
340 roles. Safe dispensing of drugs will remain a core responsibility of the profession, but changes in  
341 laws regarding dispensing will allow pharmacists to proactively dispense knowledge about  
342 medications and increase their primary care responsibilities. Pharmacists will continue to  
343 provide easy access to vaccinations and partner with other care providers in grassroots public  
344 health campaigns, particularly for underserved populations. Pharmacists will remain key  
345 healthcare providers in tobacco cessation. As advances in technology make disease screening  
346 more accessible, pharmacists will play an increasingly important role in education and

347 screening for conditions such as obesity, hypertension, heart disease, substance abuse, sexually  
348 transmitted diseases, and others. With appropriate changes in law and regulation to confer  
349 provider status for pharmacists, interpretation of screening test results and referral to other  
350 healthcare providers will fall within the pharmacist's responsibilities. Recognition of  
351 pharmacists as healthcare providers and reimbursement for their services would also empower  
352 pharmacists to screen for food insecurity, physical or sexual abuse, human trafficking,  
353 substance use disorders, and mental health issues.

354           Advances in informatics will permit aggregation and application of population and  
355 patient-specific data in ways that will encourage development of population-specific, evidence-  
356 based screening and disease management programs. Pharmacists should gain awareness of  
357 how artificial intelligence can illuminate the relationships between risk factors, prevention,  
358 treatment, and patient outcomes to better predict successful interventions. The burgeoning  
359 field of pharmacogenomics has already demonstrated its value in patient-focused  
360 pharmacotherapy, as genotyping has enabled prescribers and pharmacists to reduce treatment  
361 failures and prevent adverse drug reactions in large groups of people. As pharmacogenomics  
362 and the rapidly expanding field of population genetics become even more important,  
363 pharmacists, as medication-use experts, will apply these new tools not simply to improve  
364 patient-specific pharmacotherapy but to advance public health through population health  
365 management.

366

### 367 **Conclusion**

368 Pharmacists play a vital role in maintaining and promoting public health. Pharmacists can

369 improve public health by promoting population health; developing and implementing disease  
370 prevention and control programs; advancing medication safety practices; engaging in opioid  
371 stewardship; developing health-education policies and programs; advocating for relevant and  
372 impactful legislation, regulations, and public policy regarding public health; engaging in public  
373 health-related research and education programs; initiating campaigns to disseminate new  
374 knowledge; and providing training that includes basic population health tools. All pharmacists  
375 have a responsibility to participate in global, national, state, regional, and institutional efforts  
376 to promote public health. Pharmacists should integrate the public health practices outlined in  
377 this statement into their practices and be empowered by their employers and policymakers to  
378 contribute to and improve public health efforts. To more fully utilize their unique expertise,  
379 pharmacists should be involved in public health policy decision-making and in the planning,  
380 development, and implementation of public health efforts.

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### Other Resources

Pharmacists looking for further involvement in public health have many options. First, training and competence in public health disciplines are invaluable for understanding the field of public health and its applications to pharmacy practice. Accredited schools of public health offer traditional didactic classes, and some have courses or continuing education available online that will give the beginner a clearer understanding of the four traditional areas of public health practice: health administration and policy, health education, biostatistics, and epidemiology. Pharmacists who wish to pursue a degree in public health can also do so online at a growing number of schools of public health.

Pharmacists with an interest in federal public health initiatives can start with one of three main points of access. The first is the Centers for Disease Control and Prevention ([www.cdc.gov](http://www.cdc.gov)), the largest repository of documents, program descriptions, and contacts in the realm of prevention. Major efforts aimed at disease surveillance, infectious disease control, immunization, health education, chronic disease maintenance, and disease-related data management provide an ample and readily available source of information. The second major source of information is the Office of Disease Prevention and Health Promotion (<https://health.gov/>), which provides access to Healthy People and MyHealthfinder (a personalized screening tool) as well as information about food and nutrition, physical activity, health literacy, and healthcare quality. Finally, the Agency for Healthcare Research and Quality website ([www.ahrq.gov](http://www.ahrq.gov)) has a section on prevention (<https://www.ahrq.gov/prevention/index.html>) that provides information on a variety of

topics as well as access to information from the U.S. Preventive Services Task Force and the Guide to Clinical Preventive Services.

State government websites provide public health information for their respective states. State entities serve as the main policymaking entity for public health priorities and strategies, provide a conduit for federal public health dollars, and are the main repository of health information and data for the state. States often organize a range of advisory groups, task forces, and planning committees whose output shapes their public health agenda. These entities also provide input and direction for state legislative bodies to address, legislate, and fund.

On the local level, departments of health serve as the main government entities involved in public health. Aside from their usual routine of immunizations and restaurant inspections, these boards serve as the policymakers for disaster response and provision of primary care to underserved populations. They receive federal and state dollars that are used to fund public health efforts. They are closest to the general population both in their makeup and in their efforts at improving the public's health. Pharmacists interested in learning more about public health and the types of activities that community public health agencies are involved in can register for a free interactive tutorial at [www.nynj-phtc.org/orientation](http://www.nynj-phtc.org/orientation).

Below is a list of websites that provide information related to public health.

### ***Public Health Organizations***

- World Health Organization ([www.who.int](http://www.who.int))
- Pan American Health Organization ([www.paho.org](http://www.paho.org))
- American Public Health Association ([www.apha.org](http://www.apha.org))
- Association of State and Territorial Health Officials ([www.astho.org](http://www.astho.org))
- National Association of County and City Health Officials ([www.naccho.org](http://www.naccho.org))
- Public Health Foundation ([www.phf.org](http://www.phf.org))
- Association of Schools of Public Health ([www.asph.org](http://www.asph.org))
- Association for Prevention Teaching and Research ([www.aptrweb.org/](http://www.aptrweb.org/))

### ***Federal Health Agencies***

- U.S. Department of Health and Human Services ([www.dhhs.gov](http://www.dhhs.gov))
- Office of the Surgeon General, Public Health Reports  
(<https://www.hhs.gov/surgeongeneral/reports-and-publications/publichealthreports/index.html>)
- Centers for Disease Control and Prevention ([www.cdc.gov](http://www.cdc.gov))
- Food and Drug Administration ([www.fda.gov](http://www.fda.gov))
- Health Resources and Services Administration ([www.hrsa.gov](http://www.hrsa.gov))
- National Institutes of Health ([www.nih.gov](http://www.nih.gov))
- Agency for Healthcare Research and Quality ([www.ahrq.gov](http://www.ahrq.gov))
- Environmental Protection Agency ([www.epa.gov](http://www.epa.gov))



**Additional Information**

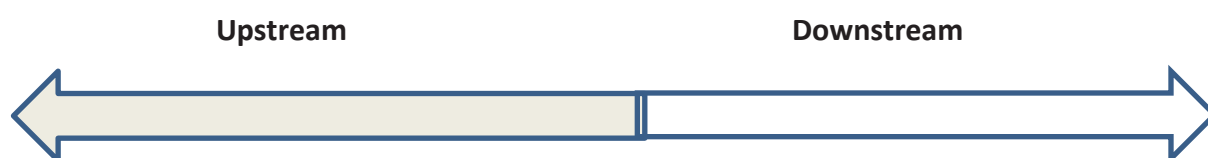
Developed through the ASHP Council on Pharmacy Practice and approved by the ASHP Board of Directors on March 26, 2021. This statement would supersede the ASHP Statement on the Role of Health-System Pharmacists in Public Health dated June 24, 2007.

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Table 1. Examples of prevention.



<b>Primordial Prevention (prevent risk factors)</b>	<b>Primary Prevention (prevent illness/injury)</b>	<b>Secondary Prevention (reduce impact)</b>	<b>Tertiary Prevention (chronic impact)</b>
Banning smoking in public areas, smoking education programs	Anti-smoking campaigns, taxes on cigarettes, smoking cessation programs, patches, gum	Treatment for smoking related illness, medical intervention, patient counseling	Disease management, respiratory treatment, therapies and screenings
Eliminating food deserts, nutrition education, healthy cooking classes, dietary guidelines	Increasing access to farmers’ markets, health screenings	Individual nutrition counseling, medical intervention for diet-related illness, vitamins	Disease management, health monitoring
Laws and regulations against human trafficking, education regarding human trafficking, establishment of safe internet practices	Establishment of human trafficking hotline, raising awareness among the public, establishment of sentinel reporting, education programs for healthcare providers as well as police officers and other public servants.	Screening for trafficking as part of all healthcare provider interactions, treatment of injuries and illnesses	Establishment of resources and safe havens for victims, mental health counseling
Opioid education programs, safe practices to avoid illness and injury	Improved opioid prescribing policies, opioid disposal locations and policies etc., patient education	Monitoring opioid use (both systemically and individually), early intervention	Medication-assisted therapy, access to treatment centers, monitoring

Table 2. Preparing for Specific Pharmacy Public Health Roles in Epidemic/Pandemic Response<sup>a</sup>

<b>Role in Communication and Information</b>		
<b>To prepare for</b>	<b>Cause</b>	<b>Issues</b>
Counseling visitors and family members	Concerned and anxious due to fear of unknown	<ul style="list-style-type: none"> <li>● Prepare for increased phone calls and directing of family members that come to the facility to visit</li> </ul>
Poor or confusing communication or information, misinformation	Health officials may update information frequently to adjust to evolving situation; different authorities may say conflicting or confusing things	<ul style="list-style-type: none"> <li>● Communicate and collaborate with institution, local, and/or state Incident Command Centers for coordinated and informed response</li> <li>● Seek reliable information sources</li> <li>● Seek local information for current quarantine or treatment recommendations</li> <li>● Be an advocate for local citizens and be vigilant for emerging issues</li> <li>● Keep staff well informed through frequent communication via various channels and provide a forum to address questions and concerns</li> </ul>
Informing the pharmacy workforce	Information sharing to ensure a ready and engaged workforce	<ul style="list-style-type: none"> <li>● Stay up to date on the latest information about signs and symptoms, diagnostic testing, and case definitions for the epidemic/pandemic disease</li> <li>● Share information with pharmacists at other institutions experiencing the same crisis</li> <li>● Use network groups to</li> </ul>

		<p>keep colleagues at other institutions abreast of new information, guidelines, and issues</p> <ul style="list-style-type: none"> <li>● Perform literature searches and communicate with drug manufacturers to obtain unpublished information on file for emerging and investigational regimens</li> </ul>
Role in Supply Chain Management		
To prepare for	Cause	Issues
Challenges securing anticipated stocks of medications and supplies	Supply chain disruption	<ul style="list-style-type: none"> <li>● Report unusual sales volumes for medications or patient complaints</li> <li>● Determine mechanisms for obtaining drugs not available on market (e.g., emerging investigational therapies) during regular and off-hours</li> <li>● Report supply chain issues (e.g., drug shortages, PPE) to key facility staff and contact local/state health departments</li> </ul>
Role in Pharmacy Operations		
To prepare for	Cause	Issues
Supplying rapid response kits	Timely access to treatment	<ul style="list-style-type: none"> <li>● For supportive care and as investigational therapies emerge, prepare rapid response kits containing information such as management algorithms, drug dosing and administration guidelines, and pharmacist contact numbers</li> <li>● Make kits available in</li> </ul>

		relevant patient care units such as emergency departments and intensive care units
Leadership in medication use and safety	Safe patient care	<ul style="list-style-type: none"> <li>● Ensure that appropriate education and drug administration and dosing guidelines are available to guide medical, nursing, and pharmacy staff</li> </ul>
Role in Infection Prevention and Control		
To prepare for	Cause	Issues
Requests to dispose of potentially contaminated medications and supplies	Family members of potential disease cases may have unused medications they want to throw away	<ul style="list-style-type: none"> <li>● Determine local/state health department recommendations for disposing of unused medication products and supplies that have been dispensed to a patient</li> </ul>
Updating policies and procedures	Integrity of drug supply	<ul style="list-style-type: none"> <li>● Develop or revise policies and procedures pertaining to drug delivery to meet infection control precautions</li> </ul>
Protecting workforce from exposure	<ul style="list-style-type: none"> <li>● Healthcare workers are more likely to become infected if they work closely with patients with infectious diseases</li> <li>● Limiting exposure time and closeness can help prevent infection</li> </ul>	<ul style="list-style-type: none"> <li>● Orient and education workforce regarding infection control precautions</li> <li>● Use standard respiratory precautions</li> <li>● Handle items associated with potentially exposed patients while wearing gloves</li> <li>● Frequent hand washing</li> <li>● Use face masks if counseling symptomatic patients</li> <li>● Ensure that appropriate pharmacy staff have been medically cleared,</li> </ul>

		fit-tested, and trained for respirator use <ul style="list-style-type: none"> <li>● Use telephone for counseling</li> <li>● Drop off prescriptions at home</li> <li>● Bill via credit card to avoid handling checks or money</li> </ul>
Monitoring pharmacy staff	Fever, cough, and shortness of breath are early signs and symptoms of some infectious diseases.	<ul style="list-style-type: none"> <li>● Be prepared to take temperature of workers once a shift</li> <li>● If fever, cough, and shortness of breath are present, send worker to designated treatment site</li> <li>● If a family member is sick, put employee on sick leave</li> <li>● Notify occupational health services</li> </ul>
Role in Patient Care		
To prepare for	Cause	Issues
Patient/visitor surge	Patients may seek other sources of care and information if local hospitals closed or under quarantine	<ul style="list-style-type: none"> <li>● Adjust staffing to handle increased traffic, phone calls, and other electronic communications (e.g., social media)</li> <li>● Manage staff to accommodate revised or expanded responsibilities with appropriate sleep/rest cycles</li> <li>● Prepare information for patients/visitors for education and awareness programs</li> <li>● Report patient surges to key facility staff and public health officials</li> </ul>
Treating sicker patients	Patients may be sicker than	<ul style="list-style-type: none"> <li>● Review latest CDC</li> </ul>

	usual but barred from hospitals	<p>information for education and awareness programs</p> <ul style="list-style-type: none"> <li>● Help triage patients in accordance with institution emergency preparedness plan</li> <li>● Inform key facility staff and contact local/state health departments for latest guidance and instructions (e.g., home quarantine)</li> </ul>
Caring for the worried well	Patients who have respiratory symptoms but no history of exposure	<ul style="list-style-type: none"> <li>● Provide information and reassurance through education and awareness programs</li> <li>● Remind patients to get other appropriate vaccines</li> </ul>
Requests for ineffective prevention and treatment options	Remedies for self-treating a disease may be requested by patients even though they are not effective	<ul style="list-style-type: none"> <li>● Provide patients with most current treatment and prevention information.</li> </ul>
Team-based care	Interprofessional expertise needed	<ul style="list-style-type: none"> <li>● Collaborate with key players (e.g., microbiologist) and communicate on interprofessional issues needed to optimize patient care</li> <li>● Be proactive and flexible in assuming new responsibilities within a pharmacist's scope of practice</li> </ul>

<sup>a</sup>Source: Adapted from Tables 3.5 and 3.6 in Carter J, Slack M. *Pharmacy in Public Health: Basics and Beyond*. ASHP: Bethesda, MD; 2009.

Table 3. Examples of patient education programs, goals, methods, and alignment with Healthy People 2030 goals.

<b>Patient Education Programs</b>	<b>Goals</b>	<b>Method</b>	<b>Aligns with Healthy People 2030 goal</b>
Birth Control <sup>42</sup>	Provide Womens Health services	Individual	Yes
Chronic Disease	Education Prevention Management	Individual Group Special Populations	Yes
Immunization <sup>43,44</sup>	Prevention Reduce epidemics Provide services Improve health of a nation	Individual Group Special Populations Community Awareness	Yes
Medication Safety <sup>45,46</sup>	Improve Patient Outcome Improve Health Literacy	Individual Health Literacy Assess Group Special Populations Community Awareness	Yes
Mental Health <sup>47,48</sup>	Reduce Stigma Direct individual to services Provide services Prevention	Individual Group Special Populations Community Awareness	Yes
Nutrition	Reduce disease Reduce cost to health system Better individual Health	Individual Group Community Awareness	Yes
Oral Chemotherapy <sup>49</sup>	Improve Patient Outcome	Individual	
Substance Abuse <sup>50,51</sup>	Prevention Direct individual to services Provide services Improve health of a nation	Individual Groups Special Populations Community Awareness Flyers or Brochures	Yes
Tobacco Cessation <sup>52</sup>	Reduce disease Reduce cost to health system	Individual Group	Yes



	Better individual Health	Resources	
Resources <sup>53</sup>	Improve Literacy and Guide to Resources and Support for: Human Trafficking Partner and Child Abuse Community Wellness Services	Individual Groups Brochures and Flyers	



# House of Delegates

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## ASHP Statement on the Pharmacist’s Role in Clinical Pharmacogenomics

1 **Position**

2 The American Society of Health-System Pharmacists (ASHP) believes pharmacogenomic testing  
3 can improve medication-related outcomes across the continuum of care in all health-system  
4 practice settings. These improvements include improved clinical outcomes, decreased side  
5 effects, lower cost of treatment, increased medication adherence, more appropriate selection  
6 of therapeutic agents, decreased length of treatment, and enhanced patient safety.<sup>1-4</sup> Because  
7 of their distinct knowledge, skills, and abilities, pharmacists are uniquely positioned to lead  
8 interprofessional efforts to develop processes for ordering pharmacogenomic tests and for  
9 reporting and interpreting test results. Pharmacists are also singularly qualified to lead efforts  
10 to guide optimal drug selection, drug dosing and provide patient as well as provider education  
11 based on those results. Pharmacists therefore have a fundamental responsibility to ensure  
12 that pharmacogenomic testing is performed when needed and the results are utilized to  
13 optimize medication therapy.<sup>1</sup> Pursuant to this leadership role, pharmacists share  
14 accountability with other health-system leaders, such as physicians, laboratory professionals,  
15 and genetic counselors, for the ongoing implementation and application of pharmacogenomics



16 across the continuum of care. Because test results will have implications throughout a  
17 patient's lifetime, all pharmacists should serve as advocates for preemptive and reactive  
18 testing and have a basic understanding of pharmacogenomics in order to provide appropriate  
19 patient-care recommendations. ASHP therefore encourages pharmacist education on the use  
20 of pharmacogenomics and advocates inclusion of pharmacogenomics and its application to the  
21 therapeutic decision-making process in student and resident training, continuing education  
22 offerings, and Board of Pharmacy Specialties certification processes. Some advanced  
23 pharmacist functions in applying clinical pharmacogenomics may require specialized  
24 education, training, or experience.

25

## 26 **Background**

27 Clinical pharmacogenomics uses genetic information to guide optimal drug selection and drug  
28 dosing for patients to maximize therapeutic effects, improve outcomes, and minimize toxicity.<sup>3</sup>  
29 Although early applications of pharmacogenomics were in the oncology and cardiology realms,  
30 the use of pharmacogenomic data has expanded to other across therapeutic areas, for  
31 example psychiatry, neurology, and infectious diseases.<sup>5-8</sup>

32 Pharmacogenomic testing can be performed reactively or preemptively. Reactive testing  
33 generally occurs when a patient is experiencing adverse effects unexplained by dose or drug-  
34 drug or drug-disease interactions, or when the use of a drug that is affected by  
35 pharmacogenomic variations is anticipated. In contrast, preemptive testing occurs when  
36 patients are genotyped prior to developing an indication for specific pharmacotherapy; usually  
37 multiple pharmacogenomic genes are assessed at the same time. Preemptive testing yields the

38 highest value and quality of care for the patient by preventing undesirable drug responses  
39 such as toxicity or therapeutic failure.<sup>9</sup>

40 Application of pharmacogenomic information requires an understanding of how genetic  
41 variations impact the pharmacokinetic and pharmacodynamic properties of a drug and prevent  
42 the occurrence of adverse drug events. The combined influence of factors such as age, sex,  
43 race, ethnicity, diet, pathophysiologic conditions, and current medication use, as well as their  
44 relationship to genetic variability, must also be understood. The development of patient-  
45 individualized therapeutic regimens should therefore include an assessment of the patient's  
46 pharmacogenomic profile in addition to their allergy and adverse reaction history, drug  
47 interactions, dietary and lifestyle factors, patterns of adherence, and other therapeutic drug-  
48 monitoring parameters.<sup>10</sup> There are more than a dozen comprehensive, ASHP-endorsed  
49 therapeutic guidelines from the Clinical Pharmacogenetics Implementation Consortium (CPIC)  
50 to guide pharmacotherapy decisions when pharmacogenomic information is available.<sup>11-13</sup>

51 From a regulatory perspective, the FDA also provides a list of drugs for which  
52 pharmacogenomic markers are included in the drug labeling<sup>14</sup> as well as a table of  
53 pharmacogenomics associations.<sup>15</sup> Pharmacogenomic information is emerging in other  
54 sources, such as specialty guidelines and widely used drug information resources, so  
55 pharmacists should consult a variety of evidence-based resources in therapeutic decision-  
56 making.

57 The pharmacist's patient-care responsibilities include education as well as appropriate and  
58 cost-conscious medication selection and monitoring, which now increasingly include

59 pharmacogenomic profile assessment. The purpose of this statement is to describe  
60 pharmacists' responsibilities and accountabilities in the field of clinical pharmacogenomics.

61

## 62 **Pharmacists' Responsibilities**

63 Pharmacists' responsibilities for pharmacogenomics include promoting the optimal use and  
64 timing of pharmacogenomic tests; interpreting pharmacogenomic test results; and educating  
65 healthcare professionals, patients, and the public about the field of pharmacogenomics. The  
66 following are responsibilities that should be part of any clinical pharmacogenomics program:

- 67 • Advocating for the rational and ethical use of pharmacogenomics testing as part of  
68 routine patient care.<sup>16</sup>
- 69 • Ordering pharmacogenomics tests, when appropriate, and providing test result  
70 interpretation and clinical guidance for the return of pharmacogenomic results to  
71 providers and patients in collaboration with other healthcare professionals.
- 72 • Optimizing medication therapy based on pharmacogenomic test results.
- 73 • Providing information and educating healthcare professionals, patients, and members of  
74 the public on the evidence-based, clinical application of pharmacogenomics.
- 75 • Supporting and participating in research, consortia, and networks that guide and  
76 accelerate the application of pharmacogenomics in clinical practice.
- 77 • Facilitating the seamless integration of pharmacogenomics in the electronic health  
78 record (EHR) with clinical decision support.
- 79 • Promoting EHR interoperability and portability of patient-specific pharmacogenomic  
80 test results across health systems and to pharmacies.<sup>17,18</sup>

81 Using these responsibilities as a guide, ASHP has developed the following recommendations  
82 for pharmacists' roles in pharmacogenomics.

83

#### 84 **Pharmacists' Roles**

85 All pharmacists should have a basic understanding of pharmacogenomics to provide patient  
86 care incorporating pharmacogenomic recommendations regarding medication response.

87 Elements of a basic understanding of pharmacogenomics should enable pharmacists to  
88 perform the following responsibilities:

89 • Recommending or ordering preemptive or reactive pharmacogenomic testing to aid in the  
90 process of drug and dosage selection.

91 • Designing patient-specific drug and dosage regimens based on a person's  
92 pharmacogenomic profile and other pertinent factors, such as the pharmacokinetic and  
93 pharmacodynamic properties of the drug, drug-drug and drug-gene interactions,  
94 comorbidities, patient demographics, and laboratory data to optimize patient outcomes.

95 • Educating healthcare professionals about pharmacogenomic principles and appropriate  
96 indications for cost-effective pharmacogenomic testing.<sup>19</sup>

97 • Communicating pharmacogenomics-based drug therapy recommendations to the  
98 healthcare team, including documentation of and interpretation of results in the patient's  
99 health record.<sup>17, 18, 20</sup>

100 • Providing resources and education that empower patients to make informed healthcare  
101 decisions about undergoing pharmacogenomic testing and understanding their test  
102 results.<sup>21</sup>

103 • Ensuring pharmacogenomic test results are handled in an ethical manner and that patients  
104 are provided access to their genetic data when applicable.

105 Pharmacists with specialized education, training, or experience in pharmacogenomics should  
106 also assume the following additional roles:

107 • Developing institutional guidelines and processes for or leading the use and  
108 implementation of a clinical pharmacogenomic program.

109 • Applying collaborative drug therapy management principles to a clinical  
110 pharmacogenomics program, including advocating for the reimbursement of testing and  
111 pharmacist interpretation by health insurance plans.

112 • Serving as a subject matter expert for clinical pharmacogenomics. Pharmacists who  
113 practice in the oncology setting should also incorporate results of tumor genomics (somatic  
114 variations) to personalize and optimize pharmacotherapy. Pharmacists typically have  
115 leadership roles on institutional tumor boards in this practice setting.

116 • Contributing to the evaluation and implementation of clinical pharmacogenomics testing  
117 as an integral part of medication therapy.

118 • Promoting collaborative relationships with healthcare professionals and key departments  
119 within the institution to encourage the development and appropriate use of  
120 pharmacogenomic principles in patient care.

121 • Advocating for the use of standardized pharmacogenomic nomenclature, including the use  
122 of standardized terms from the Systematized Nomenclature of Medicine Clinical Terms  
123 (SNOMED-CT) and Logical Observation Identifiers Names and Codes (LOINC) in EHRs.<sup>22,23</sup>

- 124 • Developing pharmacogenomic-specific clinical decision support tools in EHR systems that  
125 guide prescribers on the appropriate use and dosing of medicines based on a patient's  
126 pharmacogenomic profile.<sup>24-26</sup>
- 127 • Encouraging EHR vendors to assist in the seamless integration of pharmacogenomics in the  
128 EHR and promote interoperability and portability of pharmacogenomic data.
- 129 • Developing and planning pharmacogenomic-specific advanced training opportunities for  
130 pharmacists and other healthcare professionals.
- 131 • Establishing processes for communicating patient-specific results with healthcare  
132 professionals, including documentation of results in the patient's health record and  
133 informing healthcare providers outside of the institution whose care would be impacted by  
134 the results.
- 135 • Developing a process for return of results to patients, including patient-specific educational  
136 materials explaining the importance and lifelong significance of their pharmacogenomic  
137 test results.
- 138 • Developing processes to document patient outcomes and economic benefits as a result of  
139 pharmacogenomic testing.
- 140 • Establishing a process for reinterpretation and updating of pharmacogenomics test results  
141 based on the emergence of new findings.
- 142 • Designing and conducting pharmacogenomic research.
- 143 • Actively contributing to the body of knowledge in pharmacogenomics by publishing articles on the  
144 topic in the biomedical literature.
- 145



**146 Future Directions**

147 As pharmacogenomic testing continues to evolve, genotyping will likely be performed using  
148 next-generation sequencing (NGS) technologies, and more patients will get tested for a larger  
149 number of variants.<sup>27</sup> Pharmacists will need to have a basic understanding of NGS , including  
150 its limitations and how to address variants of unknown significance.<sup>28</sup> The roles of pharmacists  
151 must therefore expand and evolve as well, including but not limited to include the following:

- 152 • Routinely utilizing a patient's pharmacogenomic test results as standard practice within  
153 comprehensive medication management workflows.
- 154 • Working closely with other medical specialties (e.g., close collaboration with medical  
155 geneticists or genetic counselors) to provide pharmacogenomics expertise and return of  
156 results to patients when broad testing (e.g., whole-genome sequencing) is ordered.
- 157 • Assessment of the economic value of clinical pharmacogenomics and pharmacogenomic  
158 test reimbursement policies. Payer policies are maturing and are expected to expand as  
159 further evidence is generated. The unique expertise of pharmacists will be essential in the  
160 development of these best practices policies.<sup>29-31</sup>
- 161 • Data interoperability and sharing of pharmacogenomic test results with other healthcare  
162 institutions, including community pharmacies, will be a critical factor to enable continuing  
163 use of the information over a patient's lifetime.
- 164 • For pharmacists who practice in the oncology setting, aiding in the replication of the  
165 successful principles of germline pharmacogenomics integration in the EHR to somatic  
166 variations will help optimize medication therapy.

167

168 **Conclusion**

169 ASHP believes all pharmacists have a responsibility to take a prominent role in the rational,  
170 ethical use and clinical application of pharmacogenomics. Clinical pharmacogenomics  
171 initiatives should be spearheaded by pharmacists to promote safe, effective, and cost-efficient  
172 medication use. Pharmacists should also lead the efforts of patient and interprofessional  
173 pharmacogenomic education.

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