



2018 House of Delegates

Report of the Policy Committee

- ❖ Pharmacist Workplace Environment and Patient Safety
- ❖ Use of Pharmacogenomic Data within Pharmacy Practice
- ❖ Proactive Immunization Assessment and Immunization Information Systems

Committee Members

Alex C. Varkey, Chair
Gregory Fox
Marsha Gilbreath
Christopher Grilli
Natasha Petry
Garth K. Reynolds
Annie Stella
Adam C. Welch



Ex Officio

Michael D. Hogue, Speaker of the House

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2017–18 APhA Policy Committee Report

Pharmacist Workplace Environment and Patient Safety

The committee recommends that the Association adopt the following statements:

1. APhA supports staffing models that promote safe provision of patient care services and access to medications.
[Refer to Summary of Discussion Items 3, 4, 5.]
2. APhA opposes the setting of quotas or use of time-oriented metrics that may jeopardize patient care and safety.
[Refer to Summary of Discussion Items 6, 7, 8, 9.]
3. APhA denounces reimbursement systems, including the practices of PBM and other payers that contribute to a workplace environment that negatively has an impact on patient safety. APhA calls upon public and private policy makers to establish provider payment policies that support the safe provision of medications and delivery of effective patient care.
[Refer to Summary of Discussion Items 10, 11, 12, 13.]
4. APhA urges pharmacy practice employers to establish collaborative mechanisms that engage the pharmacist in charge of each practice, pharmacists, and pharmacy staff in addressing workplace issues that may have an impact on patient safety.
[Refer to Summary of Discussion Items 8, 9, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23.]
5. APhA urges employers to regularly and systematically examine and resolve workplace issues that may negatively have an impact on patient safety.
[Refer to Summary of Discussion Items 8, 9, 19, 20, 21, 22, 24.]
6. APhA opposes retaliation against pharmacy staff for reporting workplace issues that may negatively have an impact on patient safety.
[Refer to Summary of Discussion Items 9, 19, 23, 25, 26, 27.]

Summary of Discussion

1. The committee recognizes that workplace issues is one of high importance in our profession. The breadth and depth of the issues in this space are daunting when considered in total. The committee's charge from the APhA Board of Trustees was to focus on those aspects of workplace issues which directly impact patient safety. As a result, the proposed policies necessarily do not address every possible workplace issue. The committee also recognizes that there are site-specific factors which must be taken into account when addressing the workplace as a place for safe and effective patient care, inclusive of dispensing. The committee is hopeful that these contemporary proposed policy statements adopted by the House taken together with previously adopted policy will serve as a catalyst for collaboration between pharmacists and their employers to improve workplace issues and ensure patient safety.
2. The committee's intent in addressing this issue is that it applies to all practice settings.
3. The committee reviewed existing APhA **2001 Work Schedules** policy and felt staffing models should be re-emphasized within this policy topic as it relates to patient safety.
4. The committee discussed the practice specific needs in regards to the use of pharmacy technicians and technician ratios. They felt practice settings need to address their specific needs that minimize safety risks, and therefore decided not to make a specific statement regarding pharmacist to technician ratios. The committee also recognized staffing ratios could restrict patient access to pharmacy services.
5. The committee discussed the use of the term "medications" and agreed it best reflects pharmacy practice as opposed to "drug products".
6. The committee specifically included the term "jeopardize" in the second statement to emphasize the focus on opposing harm to patients.
7. The Committee considered adding details qualifying quotas such as, "per shift" or "per week", but did not include this terminology to keep the policy statement focused on the opposition of quotas. Additionally, the Committee considered adding examples of quotas such as numbers of prescriptions filled, immunizations administered, and other services provided by a pharmacist, but determined the statement should be left broad. The Committee wished to emphasis APhA's **Impact on the Pharmacist' Working Conditions on Public Safety** policy statement related to quotas that has been in existence since 1995.

8. The committee agreed that employers should empower their pharmacists to use their professional judgement to perform their job in a safe and effective manner for their patients.
9. The committee agreed that including the term “*may*” is more inclusive because it incorporates the possibility of harm (e.g. near miss reports).
10. The committee specifically used the term “reimbursement” as opposed to “compensation” or other similar terminology since “reimbursement” is most commonly used by the Centers for Medicare & Medicaid Services (CMS).
11. The committee considered including the term “sustainable” in front of “payment policies” in the second half of statement three. The committee excluded the term “sustainable” so as not to change the focus of the statement toward sustainable operations of a pharmacy from the promotion of safe patient care delivery.
12. The Committee recognizes that the focus of statement three is an urgent issue and is perhaps having the greatest negative impact on pharmacists’ ability to provide safe care.
13. The committee intentionally included two statements within this single policy. The purpose is to identify the systems that APhA denounces and who (i.e. public and private policy makers) should specifically establish policies on this issue.
14. By including “pharmacists and pharmacy staff” in statement four, the committee intends for front-line or practice-level staff involvement of pharmacists and pharmacy staff in assuring patient safety. The issue needs to be addressed by the broad spectrum of individuals engaged in the pharmacy practice (e.g. management, care providers, support staff, etc.)
15. The committee agreed the term “sites” is most appropriate to include any pharmacy practice regardless of specific setting. The committee acknowledge that statement four is meant to develop mechanisms that are meaningful to the practice site and provide accountability.
16. The committee acknowledged that inclusion of “pharmacist in charge”, “pharmacist”, and “pharmacy staff” are the appropriate individuals to develop practice site mechanisms. The pharmacist-in-charge may or may not be engaged in the provision of pharmacy services and therefore the committee intended for the pharmacist providing dispensing or patient care services be included in this activity. The committee acknowledged that these individuals practice on the front-line and need to be specifically involved in the process. The committee felt strongly that the accountability, responsibility and authority for practice-level activities of the pharmacist-in-charge related to patient safety, needs to be reinforced.

17. The committee discussed the importance of including the term “collaborative” when referring to mechanisms, because shared accountability is needed between the individuals and the organization for creating safe systems in the work environment.
18. The committee discussed the AHRQ definition of a “just culture” methodology. More information can be found at <https://psnet.ahrq.gov/primers/primer/5/safety-culture>.
19. The committee reviewed APhA **2012, 2007, 1970 Employment Standards Policy Statement** dating back to 1970. Specifically statement 6 in the first section states, “*employed pharmacists are obligated to unhesitantly bring to the attention of their employers all matters which will assist the employers in maintaining professional standards and successful practices.*”
20. The committee discussed current state level issues where State Boards of Pharmacy are unable to investigate anonymously reported workplace issues, which effect patient safety.
21. The committee considered combining statements four and five, but felt each of these statements needed to stand alone to focus on accountability of the employer and involvement of front-line pharmacy practice staff.
22. The committee discussed the concept of continuous quality improvement (CQI) procedures to review this process and how CQI will be an important component, among other means, to facilitate this review process.
23. The committee reviewed APhA **2009 Pharmacist’s Role in Patient Safety** and determined that statement 5 of this existing policy refers specifically to the systems for reporting and misses a focus on protecting pharmacists and pharmacy staff who report workplace issues from retaliation.
24. The committee discussed how the term “employers” was all inclusive to different pharmacy practice settings and would be the most appropriate for this statement.
25. During the committee’s discussion on the scope of retaliation, it was envisioned to protect against termination, work schedule modification, unsubstantiated performance evaluations.
26. The committee discussed the importance for pharmacy staff to report workplace issues and agreed that anyone who is implicated through a proper investigation should still have any necessary consequences be imposed if there are identified employee conduct and service issues, but just the reporting of workplace issues should not lead to retaliation by an employer. The intent of this statement is to not penalize pharmacy personnel just because they reported a potential workplace issue that could negatively impact patient safety.

27. The committee reviewed and referred to the **Occupational Safety and Health Act (OSH Act), Section 11(c)** as this is the general statutory provision that provides general protection from retaliation. Additionally, the committee noted that a whistleblower protection program exists external from the existing OSH Act regulations. In general, OSHA, Equal Employment Opportunity Center (EEOC), and other whistleblower statutes and programs protect employees from retaliation and an employer cannot retaliate by taking "adverse action" against workers who report injuries, safety concerns, or other protected activity.
28. The committee reviewed existing APhA policy **2004 Automation and Technology in Pharmacy Practice** and felt statement two of this existing policy addresses the use of technology and automation to ensure safety. While drafting this report of proposed statements, the committee felt the proposed statements encompassed a call for review of current systems and system alerts (e.g. drug interaction alerts) to resolve issues that may contribute to patient safety concerns.
29. The Committee encourages pharmacists and pharmacies to utilize patient safety practice assessments and resources from the Institute for Safe Medicine Practices (ISMP) and other patient safety organizations.
30. The committee discussed the potential for a pharmacy accreditation process that evaluates the work environment, staffing, employment policies and procedures and other workplace factors which impact the safe provision of medication and patient care by pharmacists. The committee agreed that APhA **2011 Pharmacy Practice Accreditation** policy statements encompass APhA's current stance on pharmacy practice accreditation, which opposes a mandatory pharmacy accreditation.

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Use of Pharmacogenomic Data within Pharmacy Practice

The committee recommends that the Association adopt the following statements:

1. APhA emphasizes genomics as an essential aspect of pharmacy practice.
[Refer to Summary of Discussion Items 4.]
2. APhA recognizes pharmacists as the health care professional best suited to provide medication-related consults and services based on a patient's genomic information. All pharmacists involved in the care of the patient should have access to relevant genomic information.
[Refer to Summary of Discussion Items 4, 5, 6, 7, 8.]
3. APhA supports processes to protect patient data confidentiality and opposes unethical utilization of genomic data.
[Refer to Summary of Discussion Items 6, 7, 9.]
4. APhA demands payers include pharmacists as eligible providers for covered genomic interpretation and related services to support sustainable models that optimize patient care and outcomes.
[Refer to Summary of Discussion Items 8, 10, 11.]
5. APhA urges pharmacy management system vendors to include functionality that uses established and adopted electronic health record standards for the exchange, storage, utilization, and documentation of clinically actionable genetic variations and actions taken by the pharmacist in the provision of patient care.
[Refer to Summary of Discussion Items 7, 12, 13, 14.]
6. APhA recommends pharmacists lead the development of evidence-based practice guidelines for pharmacogenomic and related services.
[Refer to Summary of Discussion Items 14, 15, 16, 17, 18.]
7. APhA advocates for the involvement of pharmacists in the development of pharmacogenomic clinical support tools and resources.
[Refer to Summary of Discussion Items 18, 19, 20, 21, 22.]
8. APhA encourages pharmacists to use their professional judgment and published guidelines when providing access to testing or utilizing direct to consumer genomic test results in their patient care services.
[Refer to Summary of Discussion Items 23.]
9. APhA urges schools and colleges of pharmacy to include clinical application of genomics as a required element of the Doctor of Pharmacy curriculum.
[Refer to Summary of Discussion Items 24, 25, 26, 27.]
10. APhA encourages the creation of continuing professional development and post graduate education and training programs for pharmacists in genomics and its clinical application to meet varying practice needs.
[Refer to Summary of Discussion Items 26, 27.]
11. APhA encourages the funding of pharmacist-led research examining the cost effectiveness of care models that utilize pharmacists providing genomic services.
[Refer to Summary of Discussion Items 28.]

Summary of Discussion

1. The committee discussed that in most situations a patient's genome, for the purpose of clinical endpoints, will not change during their lifetime and it will be easier for healthcare professionals to use pharmacogenomics data proactively as more individuals obtain their genomic information.
2. The committee discussed the nature of genomic information and considered this type of information as separate and different from other health information.
3. Throughout the various policy statements, the terms genomics and pharmacogenomics are used. These terms are not interchangeable and their usage is specific to the intent of the policy statement. The committee reviewed the National Human Genome Research Institute (NHGRI) definition for genomic medicine as part of their policy development activities, "an emerging medical discipline that involves using genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use." The committee also recognized that the practice of using genomic information within pharmacy practice goes beyond pharmaco-genes and includes such things as microbiomes, metabolomics, epigenomics, etc.
4. The committee discussed how in the interest of public safety, the focus of this topic must encompass the pharmacist, the generalist, the specialist, and the sub-specialist. The subject of genomics and pharmacogenomics is a collaborative practice area, but pharmacists should take ownership of the interpretation of pharmacogenomic data. Additionally, the utilization of genomic data supports patient safety in regards to the selection and utilization of medications.
5. The committee discussed including language around patients authorizing pharmacists to have access to their genomic information and the term "relevant" was added to clarify what information should be available to pharmacists. Additionally, genomic information would be included under provisions as part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.
6. The committee recognized patient privacy concerns and how genomic and pharmacogenomics information may provide more details about a patient's health status that is unnecessary for unfettered access to this information.
7. The committee discussed the need for a mechanism to share or access genomic data less restrictively. The committee acknowledged in the current framework, the patient is the only

member who can share information freely and agreed that this mechanism needs to change. The committee discussed how the government may be the entity capable of creating this change and it would be useful for universal standards to be created.

8. The committee discussed the creation of billing codes for genomic interpretation services. The committee recognized it will be important for pharmacists to be recognized as the providers best suited to interpret these data and be reimbursed for these services.
9. The committee reviewed the **Genetic Information Non-discrimination Act (GINA) of 2008** as it relates to confidentiality of a patient's genomic information and felt it was important to call out the unethical use of this data in a stand-alone statement.
10. The committee discussed the use of the term "using" data and how it does not describe the role of the pharmacist accurately. The committee agreed that in order for pharmacists to be recognized as leaders in this field, terms such as "interpret" or "teach" or "create" would be more appropriate.
11. The committee discussed the use of "urges", "calls for", and "demands" regarding payment for genomic services. The committee discussed how "demands" creates a stronger statement and is based around the need for payment to see a change in practice come to fruition. The committee also discussed how the term "demand" for statement three may create the impression that the profession is looking for benefiting itself and not patients.
12. The committee discussed the need for pharmacists' access to genomic data and recognized that "in the provision of patient care" should be added to clarify that only those pharmacists who need access as part of patient care should obtain access. The phrase "authorized by the patient" was considered to address the concern over patient privacy and use of genomic data, however the committee agreed to select the term "relevant" to broaden this to all HIPAA-compliant situations for use of Personal Health Information (PHI) including emergencies where the patient may be unresponsive and unable to give authorization.
13. The committee discussed the need for technology to document clinically actionable genetic variation data in pharmacy practice settings as well as pharmacist-provided services.
14. The committee discussed the ability for pharmacists to order genome data. The committee recognized how whole-genome sequencing could have utility throughout the entire lifetime of a person and acknowledged that the question to answer in policy should not be whether the test should be ordered, but how the data is used.

15. The committee discussed how Clinical Pharmacogenetics Implementation Consortium (CPIC) and PharmGKB may not be the most appropriate resource for providing guidelines, because CPIC does not provide practice guidelines to meet all of the clinical practice needs. The committee agreed there is a need for a framework that various health professions can utilize for the integration of genomic data into their practices.
16. The committee reviewed existing APhA **2013, 1995 Pharmacists' Role in the Development and Implementation of Evidence-based Clinical Guidelines** policies and the committee felt strongly to call out guidelines related to pharmacogenomics in addition to these existing policies.
17. The committee discussed the need for pharmacists to lead the effort in developing guidelines. If pharmacists are to claim that they “own” pharmacogenomics, they need to take an active role in establishing the standard of care. The Committee felt that APhA should take a leadership role in achieving this activity.
18. The committee considered combining statements six and seven, but felt it was important to specifically call out the need for the development of specific evidence-based guidelines separate from tools and resources to implement the guidelines into practice. Additionally, the guidelines that are developed are to be used as standards of care for any health care professionals.
19. The committee discussed how tools and resources are already being developed, however pharmacists are not always involved in the creation process.
20. The committee discussed how clinical decision support (CDS) could be considered a tool and that clinical decision support should be based on reliable data.
21. The committee discussed the complexity of genomic data and the inability for clinical decision support to be as reliable as a pharmacist looking at raw data, especially when greater than one gene is being interpreted. The committee discussed how clinical decision support may therefore not be relevant to the pharmacists' role and emphasized how interpreting the relevance of the alleles presented in the genomic data would be considered appropriate.
22. The committee discussed the concern that advocating for pharmacist involvement with tool development may be ahead of its time, but the committee recognized that those working in the pharmacogenomics sector now see this as a critical time to address the development of tools as commercial industries are already creating tools without pharmacist input.
23. The committee discussed subjects related to existing direct to consumer tests (i.e. 23&Me) such as who owns the data and what pharmacists can do with data from the test. The committee

recognized that pharmacists should use their clinical judgement when working with data from these tests.

24. The committee discussed the wide variation of pharmacogenomics education in schools and colleges of pharmacy. Although there is a requirement through the Accreditation Council for Pharmacy Education (ACPE) for pharmacogenomics education, the amount of pharmacogenomics education is not consistent with the needs of employers who are looking for potential employees with knowledge of pharmacogenomics. Additionally, the committee discussed the lack of education in clinical application (eg. Classroom, experiential education) of pharmacogenomics and how ACPE accreditation standards are not specific enough to address this gap.
25. The committee discussed the necessary training for student pharmacists regarding pharmacogenomics. The committee acknowledged that perhaps knowing the specific alleles is not as necessary as understanding how to interpret the information. The committee discussed how instructors of pharmacogenomics curricula should have some practice experience and not be limited to only a research background.
26. The committee discussed the potential for public education in pharmacogenomics. The committee agreed that pharmacists must be educated first before public education is addressed.
27. The committee reviewed APhA **2005, 2000 Pharmacogenomics** policy as it specifically relates to statement 3 on education. The committee felt proposed statements nine and ten do not conflict with the existing policy and it was important to re-emphasize the importance of education as it relates specifically to PharmD curricula, continuing professional development, and post-grad opportunities.
28. The committee discussed the importance of clarifying research as “pharmacist-led” in order to further solidify the pharmacists’ role as leaders in pharmacogenomics. The comment was discussed that if you don’t own research, you don’t own the practice.

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Proactive Immunization Assessment and Immunization Information Systems

The committee recommends that the Association adopt the following statements:

1. APhA supports mandatory requirements for ALL immunization providers to report pertinent immunization data into Immunization Information Systems (IIS).
[Refer to Summary of Discussion Items 1, 2, 3, 4.]
2. APhA calls for government entities to fund enrollment and engagement of all immunization providers in Immunization Information Systems (IIS). This engagement should support lifetime tracking of immunizations for patients.
[Refer to Summary of Discussion Items 1, 5, 6, 7, 8, 9.]
3. APhA supports nationwide integration of Immunization Information Systems (IIS) that incorporate federal, state, and local databases for the purpose of providing health care professionals with accurate and timely information to assist in clinical decision making related to immunization services.
[Refer to Summary of Discussion Items 10, 11, 12.]
4. APhA advocates that all appropriate health care personnel involved in the patient care process have timely access to Immunization Information Systems (IIS) and other pertinent data sources to support proactive patient assessment and delivery of immunization services while maintaining confidentiality.
[Refer to Summary of Discussion Items 3, 4, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20.]
5. APhA urges pharmacy management system vendors to include functionality that uses established and adopted electronic health record standards for the exchange of data with Immunization Information Systems (IIS).
[Refer to Summary of Discussion Items 11, 21, 22.]

Summary of Discussion

1. The committee discussed whether vaccination reporting should be mandated across all immunization providers and not only pharmacists. The committee recognized that in several states, pharmacists are required to report to the IIS while other immunization providers are not required. Additionally, the committee discussed how one of the major barriers to IIS use is incomplete data and how incomplete data makes an IIS relatively ineffective as a screening tool.
2. The committee agreed to capitalize “ALL” to emphasize the all-encompassing nature of the statement to immunization practice.
3. The committee recognized a discrepancy between the expectation of pharmacists in some states to report the provision of an immunization into an IIS while other immunization providers are not sending information in a timely manner or at all.
4. The committee included the term “pertinent” as some IISs have data fields that are not captured by pharmacy management software systems or within the pharmacists’ patient care process. Additionally, some IISs capture inventory management data, which may not be pertinent for all vaccine providers.
5. The committee agreed that using the terminology “calls for” is stronger and more appropriate terminology than “suggests” or “advocates”.
6. The committee specifically included “lifetime tracking” to reference the importance behind including vaccine data throughout the entirety of an individual’s life rather than a discrete time point of vaccine history, such as only pediatric data.
7. The committee acknowledged that currently, state and local health departments are the main funders for IISs which led to their specific inclusion in statement two.
8. The committee discussed the barrier of financial considerations for community pharmacies to access IISs and other software programs that assist with communication between the pharmacy management system and an IIS. Additionally, the committee recognized a need for funding to onboard pharmacists into IIS and integrate IIS practices into the pharmacy workflow.
9. The committee initially discussed using the term “onboarding” and recognized the term did not encompass all aspects of funding requirements. The committee agreed to change “onboarding” to “enrollment and ongoing engagement” to reflect the need for ongoing support.

10. The committee discussed how some states have more than one IIS and a lack of communication between IISs on a local or regional level is limiting access to the most up-to-date vaccine history information. The committee discussed specifically how California has 10 systems and other states are in the development of regional IIS models. The committee agreed that multiple systems would not be an issue as long as the systems are interoperable.
11. The committee identified interoperability as an issue especially when patients cross state borders. Although states manage their own databases, it is necessary for databases to be interoperable for the most accurate vaccine history information to be available.
12. The committee referenced NABP's *PMP Interconnect* program that allows for interoperability of PDMP networks. The committee considered a similar prospect for IIS systems to encourage sharing of pertinent IIS data.
13. The committee specifically incorporated the term "proactive" to call for immunization providers to actively assess a patient's vaccine history consistent with CDC and the HHS-NVAC Adult Immunization Standards.
14. The committee discussed the lack of a concrete definition for the term "timely", but felt this is the best term to use to describe the access to IIS data. The committee's intent for including "timely" is to allow the pharmacist the ability to view a patient's full vaccine history in order to utilize that immunization data when delivering patient care.
15. The committee discussed the need for system wide access in a timely manner to be used for proactive assessment of immunization status. The committee agreed "timely" and "proactive" were clearer in comparison to "real-time" which could indicate a sense of urgency that may not be feasible.
16. The committee recognized the lack of bidirectional access to IIS data as a barrier to implementation. After further discussion, the committee agreed that immunization data should be used to meet the intent of NVAC adult immunization standards and other guidelines.
17. The committee discussed including the term "immunization neighborhood" to include the concept of interdisciplinary care as part of a cohesive team. The committee reconsidered the use of the term "immunization neighborhood" given that the immunization neighborhood includes community leaders that do not have a need to access patient-specific vaccine information and chose instead to use the term "immunization providers" to make this distinction.

18. The committee recognized that pharmacists were not the only pharmacy staff member providing immunization services and specifically included “pharmacy personnel” to include the important role technicians, student pharmacists, and other pharmacy staff play in this process.
19. The committee discussed the issue of patient confidentiality and included the term “appropriate” when referencing pharmacy personnel to clarify that only those staff members involved in the pharmacy’s immunization delivery workflow would have access to this information.
20. The committee discussed the possibility of technician access to IIS for documentation. The committee discussed how all pharmacy personnel should have access and referenced the Walgreens model which is more efficient when pharmacy technicians assist with manual input of vaccine information into an IIS. The committee referenced how medical assistants and clerical staff in primary care settings assist with documentation and how we may capture a similar strategy.
21. The committee discussed how “interoperability standards” may refer to various coding structures such as American Society for Automation in Pharmacy (ASAP) standards or HL7. The committee agreed that those standards approved and adopted for use by electronic health records (i.e. HL7) would be the best to reference within the policy statement.
22. The committee discussed ongoing dialogue between the pharmacy profession, American Immunization Registry Association (AIRA), CDC, and pharmacy computer vendors regarding recognized standards for the transmission of immunization data between pharmacies and IIS. IISs currently utilize HL7 standards for the transmission of immunization data and are reluctant to support additional standards.
23. The committee reviewed APhA’s **Guidelines for Pharmacy-Based Immunization Advocacy and Administration** and recommends a review and potential revision of the content based on outcomes from the adoption of any new policy statements on this topic.