2016 House of Delegates
Report of the Policy Committee

Biologic, Biosimilar, and Interchangeable Biologic Drug Products
Point-of-Care Testing
Medication Optimization Services within the Patient Care Process

Committee Members
Melissa Duke, Chair
Ally Dering-Anderson
Rebecca W. Chater
Karen Nagel Edwards
Elizabeth Johnson
Loren Madden Kirk
Pamela Piotrowski
John Sykora
Benjamin Y. Urick
Krystalyn Weaver

Ex Officio
Theresa Tolle, Speaker of the House

This report is disseminated for consideration by the APhA House of Delegates, but does not represent the position of the Association. Only those statements adopted by the House are official Association policy.
The committe recommends that the association adopt the following statements:

1. APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.  
   [Refer to Summary of Discussion Items 1, 2.]

2. APhA urges the Food and Drug Administration (FDA) to expedite the development of standards and pathways to evaluate the interchangeability of biologic products.  
   [Refer to Summary of Discussion Items 3, 4, 5.]

3. APhA recognizes the Food and Drug Administration’s (FDA) Purple Book as the authority on biologic product interchangeability within the United States and discourages development of nonconforming domestic interchangeability lists.  
   [Refer to Summary of Discussion Items 6, 7, 8.]

4. APhA opposes interchangeable biologic product substitution processes that require authorization, recordkeeping, or reporting beyond generic product substitution processes.  
   [Refer to Summary of Discussion Items 8, 9.]

5. APhA encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes.  
   [Refer to Summary of Discussion Items 10, 11.]
Summary of Discussion

1. The committee agreed that the term *biologic products* was the overarching and correct term that encompasses reference and originator biologics, biosimilars, and interchangeable biologics.

2. The committee recognized the need for patient access to biologic drug products and reviewed the APhA 2012, 2007 Biologic Drug Products policy statement. The committee determined that additional policy was needed to focus on the patient and build on previous policy supporting greater availability of biologic products for patients.

3. The committee recognized the importance of having timely development of standards and pathways that support the evaluation of biologic product interchangeability and access to these products. The committee specifically chose the term *expedite* to promote the development of standards and pathways as a priority for FDA and acknowledged that holdups in the creation of a pathway delay FDA approval of product interchangeability.

4. The committee’s use of the term *pathway* aligns with FDA’s use of that term to describe the biologic product approval process.

5. The committee discussed the difference between biologics and small molecule drugs based on existing science and their respective development processes (within FDA). The committee determined that current processes used or proposed for the substitution, naming, and labeling of various biologic products may be different from those for small molecule drugs and therefore need to be clarified by regulatory agencies such as FDA.

6. As the term is used within the proposed statement, the committee noted that “authority” is defined as being an accepted source of information or advice.

7. The committee reviewed existing resources in the marketplace for pharmacists to obtain information on biosimilar products and determined FDA’s Purple Book was the only
legitimate resource in the United States.\(^1\) The committee agreed that the Purple Book has the best framework to contain necessary information on interchangeable drug products even though it does not, at this time, contain this specific information. The committee noted that once populated, the Purple Book will be the authoritative source for practitioners and decision makers.

8. The committee recognized the importance of sharing clinical information among members of the health care team. After discussing the vision for biologic product interchangeability, the committee determined that the biologic product selection process should mirror the process that practitioners are using for generic product selection. The committee envisioned a process that encompasses the use of FDA’s Purple Book to identify interchangeable products and the ability of prescribers to indicate “dispense as written” (DAW) for products for which interchangeability is not desired.

9. In discussing substitution processes, the committee carefully selected the term *opposes* to communicate its strong desire for use of a process that is known by pharmacists and prescribers (i.e., generic substitution processes) and does not place excess burden on pharmacists or other practitioners.

10. The committee reviewed the potential parameters and processes that could be used in determining biosimilarity of products and recognized the importance of having the decision process guided by available scientific data. The committee indicated that such data could include approval tests and clinical trials conducted during evaluation of expanded indications or extrapolation of product indications related to biosimilar or biologic drug products. The committee noted that the term *extrapolation* is specifically used because it is used within the pharmacy industry and by FDA.

11. The committee reviewed the potential action by some states to create their own biosimilar and biologic interchangeability lists. The committee did not want to outright oppose the creation of state-based lists, because a legitimate need for such creation (such as state law prohibiting the citation of a nonstate resource) might exist. However, the committee wanted
developed lists to align with FDA’s Purple Book and used the term *discourage* when describing the creation of domestic lists that do not match the Purple Book.

12. The committee discussed concerns about potential safety issues with product naming conventions and the use of suffixes that create confusion among practitioners, patients, and others. As a result, the committee reviewed current policy related to product naming and determined no additional policy was necessary. The committee discerned that current policy allowed for adequate explanation of the need for clear naming conventions related to interchangeability.

13. The committee identified the need for product labeling and information that clearly and easily provide information related to the interchangeability of biologic products. The committee reviewed the varying nomenclature or naming options that exist in the current marketplace and focused on the importance of clear and consistent naming options for pharmacists, student pharmacists, and technicians to understand. The committee reviewed the current process for requiring additional information and determined that requiring more work by FDA may be costly and onerous. The committee determined this topic may be an area for future policy discussion if the Purple Book does not ultimately provide adequate information on product interchangeability.

14. The committee agreed that additional education for pharmacists will be needed upon the approval of an interchangeable biologic pathway. The committee discussed the need for access to biologic products from the perspective of pharmacies and pharmacists, but agreed that at this point in time, not every pharmacist has the necessary knowledge to comfortably dispense these medications because of their complexity and unclear substitution processes.

15. The committee reviewed current policy on pharmacovigilance and risk evaluation mitigation strategies and recognized the need to address patient safety with regard to biologic products. The committee determined no additional policy was necessary on these two topics because the current APhA policy is broad enough to encompass biologic products as needed.
Reference

The committee recommends that the association adopt the following statements:

1. APhA recognizes the value of pharmacist-provided point-of-care testing and related clinical services and promotes the provision of these tests and services in accordance with the Joint Commission of Pharmacy Practitioners Pharmacists’ Patient Care Process.
   [Refer to Summary of Discussion Items 3, 4, 5.]

2. APhA supports laws, regulations, and policies that enable pharmacists to order, perform, interpret, and act on the results of point-of-care testing consistent with their role in team-based care.
   [Refer to Summary of Discussion Items 3, 4, 5, 6, 7, 8, 9, 10.]

3. APhA opposes laws, regulations, and policies that create barriers to Clinical Laboratory Improvement Amendments (CLIA)–waived tests administered and interpreted by pharmacists.
   [Refer to Summary of Discussion Items 11, 12.]

4. APhA encourages use of education programs and resources to facilitate practice implementation of point-of-care testing and related clinical services.
   [Refer to Summary of Discussion Items 13, 14.]

5. APhA supports patients taking an active role in the management of their health, including the ability to request and obtain pharmacist-provided point-of-care tests and related clinical services.
   [Refer to Summary of Discussion Item 15.]

6. APhA supports access to, coverage of, and payment for both point-of-care tests and related clinical services provided by pharmacists.
   [Refer to Summary of Discussion Items 16, 17.]

Point-of-Care Testing
Summary of Discussion

1. Point-of-care testing (POCT) encompasses “performing a robust diagnostic test outside of a laboratory at or near the patient that provides a reliable result rapidly to aid in disease screening, diagnosis, and/or patient monitoring.” Examples of POCT include, but are not limited to, obtaining a serum creatinine level to gauge renal function; ordering a hemoglobin A1C level to determine blood glucose control; and performing rapid diagnostic testing (e.g., testing for Group A Streptococcus, influenza, respiratory syncytial virus, hepatitis C, human immunodeficiency virus [HIV], and so on) for the confirmation of a specific disease.

2. To ensure the accuracy, quality, and reliability of laboratory test results, the Clinical Laboratory Improvement Amendments (CLIA) were passed in 1988 and finalized in 1992. CLIA requires laboratories to meet standardized certification parameters in order to perform tests on human specimens. However, if a laboratory test could be performed with a “minimal level of complexity and low risk of erroneous results,” an exception could be granted to perform this testing in a nonlaboratory setting (e.g., pharmacy, clinic, or other nonlaboratory setting)—a CLIA-waived test. The committee acknowledged variability in state oversight and requirements related to CLIA-waived testing and therefore developed a proposed policy statement specifically addressing that issue.

3. The committee agreed that POCT provided by a pharmacist is also accompanied by clinical services, including counseling on results. The committee reviewed how patient information is used collaboratively with patients and other health care providers and determined that use of POCT in the policy statements includes the conducting of the test, use of the information within the patient care process, and appropriate follow-up.

4. The committee reviewed the following language in the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process document related to team-based care: “In addition, at the core of the process, pharmacists continually collaborate, document, and communicate with physicians, other pharmacists, and other health care professionals in the provision of safe, effective, and coordinated care.” Drawing on the guidance in the JCPP
Pharmacists’ Patient Care Process, the committee determined that following the Pharmacists’ Patient Care Process as a standard of care would avoid the potential for unnecessary duplicate tests and would optimize the use of pharmacist-based test results by all members of the health care team.

5. JCPP was established in 1977 and serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners and invited liaison members. JCPP members are the Academy of Managed Care Pharmacy, Accreditation Council for Pharmacy Education, American Association of Colleges of Pharmacy, American College of Apothecaries, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Alliance of State Pharmacy Associations, National Association of Boards of Pharmacy, and National Community Pharmacists Association.

6. The committee recognized that state laws, regulations, and policies are not consistent across the nation and that some restrict pharmacists’ ability to perform point-of-care testing services, with no clinical justification for such restrictions. The committee acknowledged the importance of calling for empowering language that facilitates pharmacists’ ability to provide these services.

7. The committee discussed key elements related to team-based care, collaboration, coordination, and communication and their effect on pharmacists’ ability to meet expectations as team members. The committee agreed that the need to report back to providers is covered by use of the term team-based care. The committee discussed the potential for duplication of testing and determined that effective involvement within a team-based care model would reduce unnecessary services.

8. The committee reviewed the National Association of Boards of Pharmacy (NABP) Model Practice Act and identified gaps in point-of-care testing language. The committee did not draft specific policy related to these gaps because point-of-care testing does not explicitly occur in a single place within a state scope of practice act. The committee indicated that the
proposed statement calling for laws and regulations supporting pharmacists’ point-of-care testing services would provide encouragement to NABP and state boards of pharmacy to make appropriate changes.

9. The committee reviewed current APhA policy related to laboratory testing. As a result, the committee determined that additional policy was necessary to specifically address the role of point-of-care testing services outside of existing APhA policy.

10. The committee agreed that use of the term policies includes company policies, payer policies, and so on that affect pharmacy practice, pharmacists’ ability to provide point-of-care testing, and procedures for providing such testing.

11. The committee reviewed policies adopted by APhA–ASP on point-of-care testing. In developing the APhA–ASP policy, the APhA–ASP committee initially focused on only CLIA-waived tests. The APhA–ASP committee subsequently broadened the statement because of concern related to the unintended exclusion of tests that were used in pharmacies but were not CLIA-waived tests. The committee noted that the proposed policy included in this document recognizes not only the broad scope of point-of-care testing, but also the specific issues with CLIA-waived testing. Therefore, the committee agreed that issues related to CLIA-waived tests should be included in policy for APhA because their use in pharmacies varies at the state level.

12. The committee agreed the term barriers includes anything that would inhibit pharmacists’ ability to perform point-of-care tests and also inhibit patient access to point-of-care tests. The committee discussed the need for required education on point-of-care tests and indicated that mandated education requirements would be a barrier. The committee also viewed inconsistencies in state laws and regulations related to CLIA-waived tests as a barrier.

13. The committee reviewed the current and new (2016) Accreditation Council on Pharmacy Education (ACPE) guidance documents for pharmacy education. The committee discussed the recent inclusion of the following language in the Standards related to point-of-care tests:
“schools and colleges of pharmacy should ensure graduates are competent to collect, interpret, and make recommendations based on the results of health and wellness screenings and diagnostic tests.” The committee determined that such language would propel students toward having increased knowledge and skills in this area and that current policy on pharmacist education and training is adequate and no additional policy is needed.

14. The committee agreed that many education documents or tools have been created to assist in the implementation of point-of-care tests. The committee discussed resources from the Centers for Disease Control and Prevention, APhA, APhA Foundation, National Association of Chain Drug Stores, colleges of pharmacy, and state pharmacy associations. The committee did not want to encourage the creation of new resources, but rather the use of existing resources.

15. The committee identified a need to articulate the role of patients in the process of point-of-care testing. The committee determined that some states do not allow patients to legally request a point-of-care test without a prescription from a provider, thereby creating a potential barrier for patients wishing to take an active role in the management of their health. The committee discussed “direct access testing” in which a patient can request a test and a pharmacist’s professional judgment in that process. The committee determined that patients should be allowed to request the tests and that health professionals receiving the request should be allowed to use their professional judgment in determining the appropriateness of the test for the patients.

16. The committee agreed that the term coverage refers to insurance plan coverage for patients and that the term payment for refers to the direct reimbursement for services to the pharmacist who provided the point-of-care test and related clinical services.

17. The committee discussed how existing payment structures for other health care providers should be used to establish coverage of and payment for pharmacists providing point-of-care tests and related services.
18. The committee acknowledged that, depending on the state, pharmacists have the authority to write new prescriptions or modify existing drug therapy based upon test results. The committee discussed the lack of insurance coverage for a prescription written by a pharmacist after a point-of-care test has been rendered. The committee determined that this topic should be reviewed as a future policy topic because it goes beyond point-of-care testing.

19. The committee reviewed the role of credentialing in the process of offering point-of-care tests. The committee acknowledged that credentialing may be perceived as a barrier to offering such services, but then discussed use of proper policies and procedures when conducting these services, which could be achieved through education, resources, and appropriate regulations and procedures.

References


Medication Optimization Services within the Patient Care Process

The committee recommends that the association adopt the following statements:

1. APhA asserts that pharmacist-directed “medication optimization services” encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access.
   [Refer to Summary of Discussion Items 1, 2, 3.]

2. APhA calls for the interprofessional development and adoption of a framework to describe the spectrum of medication optimization services.
   [Refer to Summary of Discussion Items 4, 5, 6, 7, 8.]

3. APhA calls for pharmacists and student pharmacists to provide medication optimization services in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process in any practice setting.
   [Refer to Summary of Discussion Items 8, 9, 10.]

4. APhA supports technologies and standards for multidirectional data exchange related to medication optimization services that facilitate timely communication among pharmacists, patients, other health care providers, pharmacies, health systems, and payers.
   [Refer to Summary of Discussion Item 11.]

5. APhA encourages health care providers, including pharmacists, to refer patients for pharmacist-provided medication optimization services, as appropriate.
   [Refer to Summary of Discussion Item 12.]

6. APhA supports coverage of and payment for pharmacist-provided patient care services, including medication optimization services within traditional and value-based payment systems in accordance with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacist’s Patient Care Process.
   [Refer to Summary of Discussion Items 8, 13.]
Summary of Discussion

1. The committee reviewed terminology used for more than the past 20 years and the relationship of each term to the current provision of patient care services. The committee determined that the term *medication optimization* encompassed all of these terms, including pharmaceutical care, medication therapy management, medication management, medication adherence services, and so on and is not a substitute term.

2. The committee discussed the current use of the term *medication optimization*. The committee noted that this term has an international presence together with growing use by government agencies within the United States.

3. The committee agreed that the term *access* encompasses cost and availability of a medication or service for a patient.

4. The committee did not want to define a new term within the House of Delegates. Instead, the committee focused on what services could be considered medication optimization services based on a framework of how those services are delivered to the patient.

5. The committee reviewed the terms *interprofessional* and *interdisciplinary* and agreed that although pharmacists are best equipped to provide medication optimization services, other health care practitioners need to understand and embrace the pharmacists’ role in medication optimization.

6. The committee discussed the importance of having consensus regarding the terminology used to describe pharmacist services. The committee highlighted the confusion related to variations in implementing medication therapy management services. The committee reviewed the Pharmacy Practice Activity Classification as a resource that categorizes pharmacy services, but agreed that a more formal framework was necessary.
7. The committee considered using the term *define* in place of *describe* to determine the action related to a framework regarding the spectrum of medication optimization services. The committee agreed on the difficulty in defining every service included within medication optimization services in contrast with describing them along a spectrum of low patient contact to high patient contact.

8. The Joint Commission of Pharmacy Practitioners (JCPP) was established in 1977 and serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners and invited liaison members. JCPP members are the Academy of Managed Care Pharmacy, the Accreditation Council for Pharmacy Education, American Association of Colleges of Pharmacy, American College of Apothecaries, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Alliance of State Pharmacy Associations, National Association of Boards of Pharmacy, and National Community Pharmacists Association.

9. The committee carefully selected the verb *calls* to elicit a call to action rather than using a less forceful verb such as *encourages* or *supports*. In view of the current issues with terminology and the desire by pharmacists for support of the JCPP Patient Care Process, the committee acknowledged its preference for the profession to avoid any delay in addressing the identified issues.

10. The committee reviewed the JCCP’s Pharmacists’ Patient Care Process and modeled the proposed policy wording “in any practice setting” after it. The committee noted that the process was designed to apply to any practice setting.

11. The committee discussed the importance of closing the information loop with other members of the health care team and reviewed current APhA policy related to interoperability of patient health information. Because current APhA policy is focused on transitions of care, the committee specifically noted the need for data exchange among all stakeholders related to medication optimization service delivery and payment, beyond care transitions only.
12. The committee discussed the need for an established patient referral system for use by health care providers. The committee acknowledged that the referral system should allow pharmacists to refer patients among other pharmacists or between pharmacists and other health care providers, acknowledging patient complexity, access issues, and skill sets of individual team members.

13. The committee discussed the history and differing models of value-based and pay-for-performance systems, noting that such systems vary from traditional models in that they use incentives to improve quality and reduce costs, thereby increasing value. The committee acknowledged that the Centers for Medicare and Medicaid Services plans for 75% of payments to be value based by 2020. The committee indicated that coverage of and payment for pharmacist-provided medication optimization services needs to be incorporated in whatever system is developed.