



# APhA

AMERICAN PHARMACISTS ASSOCIATION

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## 2020 House of Delegates *Report of the Policy Committee*

- ❖ Protecting Pharmaceuticals as a Strategic Asset
- ❖ Accountability of Pharmacists
- ❖ Specialty Pharmacy and Specialized Pharmacy Services

### Committee Members

Melissa Duke, Chair

Heather Free

Christopher Kotschevar

Monica Orsborn

Brent Reed

Garth Reynolds

Reshmi Singh

Terri Smith Moore

Farah Towfic

### *Ex Officio*

Joey Mattingly, Speaker of the House

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# 2019-20 APhA Policy Committee Report

## Protecting Pharmaceuticals as a Strategic Asset

*The Committee recommends that the Association adopt the following statements:*

1. APhA asserts that the quality and safety of pharmaceutical and other medical products and the global pharmaceutical and medical product supply chain are essential to the United States national security and public health.  
[Refer to Summary of Discussion Items 9,10,11,12]
2. APhA advocates for pharmacist engagement in the development and implementation of national and global strategies to ensure the availability, quality, and safety of pharmaceutical and other medical products.  
[Refer to Summary of Discussion Items 13 and 14]
3. APhA calls for the development, implementation, and oversight of enhanced and transparent processes, standards, and information that ensure quality and safety of all pharmaceutical ingredients and manufacturing processes.  
[Refer to Summary of Discussion Items 15,16,17,18,19]
4. APhA calls on the federal government to penalize entities who create barriers that threaten the availability, quality, and safety of United States pharmaceutical and other medical product supplies.  
[Refer to Summary of Discussion Items 14 and 20]
5. APhA calls for the development of redundancy and risk mitigation strategies in the manufacturing process to ensure reliable and consistent availability of safe and high-quality pharmaceutical and other medical products.  
[Refer to Summary of Discussion Items 14,21,22,23]
6. APhA advocates for regulatory and market incentives that bolster the availability, quality, and safety of pharmaceutical and other medical products.  
[Refer to Summary of Discussion Items 14 and 24]
7. APhA calls for greater transparency, accuracy, and timeliness of information and notification to health care professionals regarding drug shortages, product quality and manufacturing issues, supply disruption, and recalls.  
[Refer to Summary of Discussion Items 25 and 26]
8. APhA encourages pharmacy providers, health systems, and payers to develop coordinated response plans, including the use of therapeutic alternatives, to mitigate the impact of drug shortages and supply disruptions.  
[Refer to Summary of Discussion Items 27 and 28]
9. APhA supports federal legislation that engages pharmacists, other health professionals, and manufacturers in developing a United States-specific essential medicines list and provides funding mechanisms to ensure consistent availability of these products.  
[Refer to Summary of Discussion Items 29,30,31]
10. APhA recommends the use of pharmacists in the delivery of public messages, through media and other communication channels, regarding pharmaceutical supply and quality issues.  
[Refer to Summary of Discussion Items 32 and 33]

## Summary of Discussion

1. The Committee modified the title of this policy topic to “Protecting Pharmaceuticals as a Strategic Asset” due to initial confusion around the phrase of “National Strategic Asset.” The Committee acknowledged that “National Strategic Asset” is not specifically identified by the Federal Government and instead of calling for a new term, the committee included the more general term of “strategic asset.” “Strategic Asset” is used more frequently in business management and retains the intent of the original charge from the APhA Board of Trustees.
2. The Committee referenced APhA existing policy **2012 Drug Supply Shortages and Patient Care**, specifically statements 5 and 7, when discussing this topic and felt these were still current and did not need to be restated in new policy statements.
3. The Committee referenced APhA existing policy **2004 Protecting the Integrity of the Medication Supply** during its discussions and did not believe these statements needed to be restated.
4. The committee used the Food and Drug Administration (FDA) definition for drug, which is defined as any of the following: a substance recognized by an official pharmacopoeia or formulary, a substance intended to use in the diagnosis, cure, mitigation, treatment, or prevention of disease, a substance (other than food) intended to affect the structure or any function of the body, a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device, or biological products that meet the criteria of this definition.
5. The Committee defined “drug product” by using the Food and Drug Administration (FDA) definition of, “the finished dosage form that contains a drug substance, generally, but not necessarily, in association with other active or inactive ingredients.”
6. The committee reviewed the Merriam Webster’s dictionary definition of “medication”, defined as a “drug used to diagnose, cure, treat, or prevent disease.”
7. The committee reviewed the Merriam Webster’s dictionary definition of “pharmaceutical”, defined for use as a noun to mean a compound manufactured for use as a medicinal drug. The Committee decided to use “pharmaceuticals” to encompass all elements of the medication, including the active pharmaceutical ingredient (API), excipients, etc.
8. The Committee referenced current and future public-private partnership initiatives to mitigate drug shortage issues (CivicaRx or other new manufacturing companies).
9. The committee discussed that a policy statement with an assertion of the importance of pharmaceutical products to national security and public health would empower stakeholders to elevate the level of support needed to product pharmaceutical products as a resource of critical importance.
10. The Committee added the term “pharmaceutical products” to the statement as they felt that the term “global pharmaceutical supply chain” was not encompassing of the actual drugs themselves and both are recognized as being essential components of the statement.
11. The Committee discussed including the term “welfare” as it relates to the public but felt this was encompassed within the terminology of “public health”.
12. The committee discussed whether or not to include the term “integrity” as a descriptor, but this was resolved by inclusion of the term “quality,” which encompasses integrity.

Additionally, the Committee considered adding the terms stability in other statements, but also believed “quality” encompassed the overall intent and provided clarity to the statements.

13. The Committee intentionally added the term “global”, because strategies need to apply to processes that also exist outside of the United States.
14. The committee referenced the World Health Organization’s (WHO) definition of “medical products”, which includes medicines, vaccines or in vitro diagnostics and it may also include medical devices at an appropriate time in the future. The Committee felt it was important to include this terminology to also include items like digital therapeutics and future products. Source: [https://www.who.int/medicines/regulation/ssffc/A70\\_23-en1.pdf?ua=1](https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1)
15. The Committee discussed if the word “development” was necessary as there are already processes in place, but the word “enhanced” is believed to signify that the committee would like the processes to be reviewed and improved upon to increase safety.
16. The Committee discussed the differences and similarities between the terms “quality” and “integrity” and determined to use “quality” in this statement. The Committee agreed that integrity was a component of quality and wanted to ensure clarity and consistency among the statements by using the term “quality” throughout.
17. The Committee discussed calling for labeling where all pharmaceutical ingredients in a drug product were included. The Committee agreed that this would be ideal but would be limiting. Instead, the Committee developed the statement to call for things (processes, standards, and information) that could include this type of information while also being broader.
18. The Committee discussed the existence of drug quality standards, which are implemented during research trials and the drug development process and did not believe a separate statement was necessary on drug quality standards at this time.
19. The Committee reviewed recent stories around ARB medications with high levels of N-Nitrosodimethylamine (NDMA) in the final drug product. The Committee developed statement 3 around the issues noted in these stories that led the occurrence of NDMA in these products. It was noted that contemporary testing processes might have identified the issue sooner.
20. The Committee wanted to clarify that the term “barriers” encompasses barriers to access for inspections, barriers when allowing the drug supply to be released to the US, deceptive practices, and the counterfeiting of products.
21. The Committee discussed whether the term “pharmaceuticals” would suffice in this statement or if it needed “high quality” as an adjective. The Committee agreed that it is important to call out “high-quality” because a product might be safe, but these strategies should be aiming to protect the quality in situations where manufacturers might compromise the quality for safety.
22. The Committee debated using the term “risk management” in place of “risk mitigation”. “Risk mitigation” was specifically chosen to emphasize the need for work to be done before a situation occurs that then needs to have a separate risk management strategy. The Committee recognized that “mitigation” is referring to an action of reducing severity, seriousness, or painfulness of something.”

23. The Committee acknowledged that an implementable plan needed to be in place that could be activated when needed, versus having operations in place.
24. The Committee acknowledged the need for regulatory and market incentives, including funding, to drive the overall initiative to ensure product availability and enhance safety of pharmaceuticals and other medical products.
25. The Committee developed statement 7 with the intent to call for more communication from entities to ensure continuity of care. The Committee originally considered the verb “encourages” but opted for “calls for” to strengthen the verbiage of the statement.
26. The Committee referenced existing APhA policy **2012 Drug Supply Shortages and Patient Care**, specifically statement 1, as it was a concern that this statement was possibly redundant. The Committee decided redundancy with the 2012 policy was not a concern, and this new statement is instead implying that timelier provider access to this information will avoid disruption in the continuity of care.
27. The Committee agreed that the term “coordinated response plans” encompassed the terms “policies and procedures”.
28. The Committee felt that early provider notification allows for timely and comprehensive addressing of drug shortages and supply disruptions.
29. The Committee reviewed the World Health Organization’s (WHO) Essential Medicines list but identified that it may not be the most applicable for the needs of the United States.
30. The Committee intends for pharmacists to play an active role in the development of the essential medicines list.
31. The Committee discussed the purpose of the United States National Stockpile as managed by Department of Health and Human Services (HHS) and how a potential essential medicines list would be used differently to meet the needs of a community.
32. The Committee intentionally separated this idea from other communication related statements because historically, the media has obtained information before providers, which causes confusion and a delay in the patient care process. The Committee agreed that this statement needed to stand on its own.
33. The Committee also recognized the medication use and distribution expertise of the pharmacist and felt that pharmacists should be the team members who the media utilizes in the delivery of messages regarding supply and quality issues.

## 2019–20 APhA Policy Committee Report

### **Accountability of Pharmacists’**

*The Committee recommends that the Association adopt the following statements:*

1. APhA affirms pharmacists’ professional accountability in all practice settings.  
[Refer to Summary of Discussion Items 2,3,4]
2. APhA advocates that pharmacists be granted and accept authority, autonomy, and accountability for patient-centric actions to improve health and medication outcomes, in coordination with other health professionals, as appropriate.  
[Refer to Summary of Discussion Items 5,6,7,8]
3. APhA reaffirms 2017 Pharmacists’ Role Within Value-based Payment Models and supports continued expansion of interprofessional patient care models that leverage pharmacists as accountable members of the healthcare team.  
[Refer to Summary of Discussion Items 9 and 10]
4. APhA advocates for sustainable payment and attribution models to support pharmacists as accountable patient care providers.  
[Refer to Summary of Discussion Items 11 and 12]
5. APhA supports continued expansion of resources and health information infrastructures that empower pharmacists as accountable healthcare providers.  
[Refer to Summary of Discussion Item 13]
6. APhA supports the enhancement of comprehensive and affordable professional liability insurance coverage that aligns with evolving pharmacist accountability and responsibility.  
[Refer to Summary of Discussion Item 14]

## Summary of Discussion

1. The Committee discussed existing APhA policy statements at length and felt that there was enough urgency and timeliness related to these topics that warranted the reaffirmation of existing policy statements. Additionally, the committee felt it was important to have a complete set of policy statements organized around the specific topic of accountability of pharmacists.
2. The Committee considered adding the term “responsibility” to the topic title and within Statement 1 but decided against including this term as the intent of the policy statements is focused on the individual pharmacist as opposed to the shared responsibility of a team. The Committee discussed how the healthcare team has a shared responsibility to provide care and each individual team member is accountable for various aspects of that care. The Committee discussed that the term accountability more specifically addressed the charge to the committee to focus on the individual pharmacist.
3. The Committee included the term “professional” to infer that a pharmacist is accountable for actions taken in alignment with their pharmacy practice act. They acknowledged that a pharmacist’s accountability will depend on their practice setting and roles and responsibilities, but all pharmacists are accountable for the actions they take to impact patient outcomes.
4. The Committee viewed and intends for this statement to reiterate APhA’s stance on the role of the pharmacist in any practice setting and support existing APhA policy that acknowledges the pharmacist’s role on the patient care teams.
5. The Committee discussed using the term “collaboration” as opposed to “coordination,” but agreed that collaboration insinuates that the pharmacist must have discussion with other members of the healthcare team prior to making a decision about patient care within the pharmacists’ scope of practice. Coordination is when team members share information needed for patient care in a way that coordinates care and empowers each individual member of the healthcare team.
6. The Committee discussed whether the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacist’s Patient Care Process should be included in this statement and reasoned that inclusion of the Pharmacist’s Patient Care Process could exclude decisions unrelated to direct patient care.
7. The Committee recognizes that pharmacists use the patient care process to guide and formalize their practice.
8. The Committee felt that it was important to include both autonomy and authority in this statement. Authority refers to the pharmacist’s ability to *execute* their decision and autonomy refers to the pharmacist’s ability to *make* the decision on their own. In addition to the actions for which a pharmacist is presently accountable, more authority and autonomy will expand the opportunity for more accountability.
9. The committee believed that existing APhA policy **2017 Pharmacists’ Role Within Value-based Payment Models** covered multiple points relevant to pharmacist accountability (attribution, compensation, and coordinated care) and reaffirming the language in new policy was the most streamlined process to emphasize its importance in the context of accountability.

10. The committee considered additional language not covered in the **2017 Pharmacists' Role Within Value-based Payment Models** policy statement and agreed upon the importance to call for continued expansion of care models. The terminology of leverage was specifically selected to emphasize the pharmacist's role.
11. The Committee specifically included "sustainable" to recognize that various types of payment and incentives are emerging to support health care practitioners in health care practices, including pharmacists. The approaches used to financially justify a pharmacist need to be sufficient and scalable. Likewise, attribution models need to be developed so that pharmacists' contributions to meeting quality metrics and cost targets can be better recognized and valued.
12. The Committee further referenced existing APhA policy **2017 Pharmacists' Role Within Value-based Payment Models** when considering language around the attribution of pharmacists' services within value-based models.
13. The Committee discussed that "resources" in statement 5 would include, but are not limited to, education and training for pharmacists and student pharmacists.
14. The Committee acknowledged the importance of professional liability insurance and wants to ensure that future insurance options advance in parallel with the advancing level of accountability and responsibility of pharmacists.



2019–20 APhA Policy Committee Report

**Specialty Pharmacy and Specialized Pharmacy Services**

*The Committee recommends that the Association adopt the following statements:*

1. APhA recognizes that certain complex medications require more specialized care and resources; and APhA asserts that delineation of medications as specialty versus non-specialty, and associated payer and manufacturer practices, introduces risk of continuity of care disruption, patient access issues, and financial inequities.  
[Refer to Summary of Discussion Items 4,5,6]
2. APhA supports pharmacists and pharmacies that choose to specialize or incorporate specialty pharmacy services into their practice and provide enhanced patient care and other services to optimize patient outcomes.  
[Refer to Summary of Discussion Item 7 and 8]
3. APhA opposes payer policies and practices that limit patient choice of qualified pharmacy providers, disrupt continuity of care, or compromise patient safety through the creation of specialty drug lists, and restrictive specialty pharmacy networks.  
[Refer to Summary of Discussion Items 7,8,9,10,11,12,13,14,15]
4. APhA opposes manufacturer distribution and related business practices that restrict patient and pharmacy access to medications, medical products, and patient care services.  
[Refer to Summary of Discussion Items 16,17,18,19]
5. APhA advocates for the adoption of pharmacy profession-developed, harmonized practice standards for specialized pharmacy practices, and specialty pharmacy services and products.  
[Refer to Summary of Discussion Items 5,6,20,21,22,23,24,25,26,27,28,29]
6. APhA encourages increased availability and use of clinical practice, data integration, patient financial assistance, and other resources to support the provision of specialized pharmacy practices and specialty pharmacy services.  
[Refer to Summary of Discussion Items 8,11,30,31]
7. APhA supports the availability of education and training for pharmacists and student pharmacists related to specialized pharmacy practices and specialty pharmacy services.  
[Refer to Summary of Discussion Items 32,33,34]

## Summary of Discussion

1. The committee discussed existing APhA policy statements at length and felt that there was enough urgency and timeliness related to these topics that warranted the reaffirmation of pieces of existing policy statements within these proposed statements. Additionally, the committee felt it was important to have a complete set of policy statements organized around the specific topic of specialty pharmacy and specialized pharmacy services.
2. The Committee reviewed existing information that provides a clarification for Medicare Part D plans and noted that, “Centers for Medicare and Medicaid Services (CMS) Part D plans may not restrict access to certain Part D drugs to “specialty” pharmacies within their Part D network in such a manner that contravenes the convenient access protections of §1860D-4(b)(1)(C) of the Social Security Act and 42 CFR §423.120(a). Specifically, Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies, except when necessary to meet FDA limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. Therefore, Part D plans may not restrict access based solely on the placement of a Part D drug in a “specialty/high cost” tier because this tier placement alone is not indicative of any special requirements associated with such drug.” CMS goes on to clarify reasonable requirements must be put in place for network pharmacies by Part D plans and “requiring pharmacies to accept different reimbursement rates for certain “specialty” drugs is inconsistent with standard industry practice.” Source: [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess\\_051706.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf).
3. We also recognize that specialization in pharmacy occurs and naturally blends in this specialty pharmacy space. As of October 2019, over 10% of pharmaceutical drug spend is tied to ‘specialty pharmacy medicines.’ There is only growth anticipated in this space, creating a sense of great urgency for APhA’s House of Delegates to create policies that support continuity of care and ultimately improve patient safety as well as patient access to critical, lifesaving medicines.
4. The Committee discussed that the term “financial inequities” could also apply to pharmacies, patients, or other entities outside of the pharmacy profession.
5. The Committee noted that pharmacists providing specialized pharmacy services are encountering barriers from payers when working with medications that are identified as a specialty pharmacy product because the pharmacist is not practicing at a “specialty pharmacy.” The Committee believes standards should be developed to use existing definitions of “specialty pharmacy” to distinguish the difference between services, location of service provision, and products.
6. The Committee acknowledged limitations among the multiple existing definitions for specialty pharmacy and therefore did not call for the development of another definition, but instead practice standards that work from existing definitions and practices.
7. The Committee reviewed existing APhA policy **1978 Post-Marketing Requirements (Restricted Distribution)** and **2004, 1966 Distribution Programs: Circumvention of the Pharmacist** and believes Statements 2 and 3 are more specific to current practices and policies that are limiting patient access.

8. The Committee discussed evolving pharmacy practice environments and wanted to reaffirm APhA's support for pharmacists and pharmacies advancing into specialized practices. The Committee reviewed existing APhA policy **2006 Continuity of Care**, which "supports patient access to pharmacists with specialized skills and expertise."
9. The Committee specifically used the terminology "policies and practices" to have broad and inclusive language that would apply to any business, payer, system, company or other entity that may have control over patient choice.
10. The Committee reviewed existing APhA policy **2004, 1990 Freedom to Choose** and believes a reemphasis of patient choice is important to mention in this proposed policy statement in addition to this existing policy.
11. The Committee discussed the importance of maintaining the continuity of care to continue any existing relationship with a patient. The Committee also reviewed existing APhA policy **1995 Continuum of Patient Care** and referenced the importance to patient safety.
12. The Committee included "qualified" before "pharmacy providers" to note that additional criteria may need to be achieved to provide services, but the committee noted that the criteria need to be reasonable to achieve and could be determined within practice standards.
13. The Committee noted that some pharmacies are still encountering barriers to provide specialty pharmacy services, even after achieving accreditation through recognized programs.
14. The Committee reviewed existing APhA policy **2019 Consolidation within Healthcare** and believed these policies do not need to be restated but are relevant to the intent behind statement 3.
15. The Committee considered specifically referencing "payers and health systems" within this statement, as they acknowledged the practices highlighted in this policy are occurring in these two settings. The Committee considered health-system networks and the Centers for Medicare and Medicaid as a payer.
16. The committee referenced the World Health Organization's (WHO) definition of "medical products", which includes medicine, vaccine or in vitro diagnostic and it may also include medical devices at an appropriate time in the future. The Committee felt it was important to include this terminology to also include items like digital therapeutics and future products. Source: [https://www.who.int/medicines/regulation/ssffc/A70\\_23-en1.pdf?ua=1](https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1)
17. The Committee reviewed and recognized the following World Health Organization definition for "distribution practices": "That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products."
18. The Committee agreed that the terminology of "business practices" would also include those business practices or tactics that health-systems or other entities may use but wanted to specifically include manufacturer in the statement.
19. The Committee reviewed and considered reaffirming existing APhA policy **1994 Product Licensing Agreements and Restricted Distribution**, but believes the proposed statement is broader and addresses more current issues than what are specifically mentioned in the

- 1994 policy. The Committee recommends modifications be considered by the Policy Review Committee as appropriate based on the final adopted policy.
20. The Committee originally discussed including descriptions on the standards, such as cost, limited distribution, and coverage, but shifted away from being prescriptive in the description of the standards and instead intends that these items would be identified and discussed through the process to develop and harmonize standards.
  21. The Committee considered modifiers to practice standards such as evidence based, or consensus based. The Committee did not want to limit any standards to only be evidence based to allow for consideration of new or potential standards that may lack direct evidence. Consensus based was replaced with “pharmacy profession developed” as the intent is for the pharmacy profession to drive the process instead of just having a consensus of stakeholders that may not involve pharmacy profession representatives.
  22. The Committee discussed existing practice standards and noted that some of these standards were developed by non-pharmacy groups or did not have representation from pharmacy organizations during the standard development process. The Committee specifically chose the word “harmonized” to incorporate these existing standards into a single standard that the profession of pharmacy can collectively support. The Committee also noted and discussed that some standards are not only developed by but are imposed on pharmacy practice by other entities such as payers, manufacturers, or other external accreditation agencies.
  23. The committee agreed that the word “adoption” in statement 4 includes the use and establishment of the practice standards.
  24. The Committee discussed calling for consensus on a “definition”, but instead used the terminology of “practice standard” as this will use the multiple definitions that have already been developed and apply the definitions to an actionable set of standards.
  25. The terminology “pharmacy practice” was intentionally used to ensure that the profession of pharmacy is driving the development of these standard and engaged in review and implementation of the standards.
  26. The Committee reviewed existing specialty pharmacy accreditation programs by the Center for Pharmacy Practice Accreditation (CPPA) and URAC.
  27. The Committee discussed the topic of pharmacist certification in specialty practices and reviewed the current Certified Specialty Pharmacist certification offered by the National Association of Specialty Pharmacy. The Committee decided to not propose a potential statement in this area as they believed a pharmacist should pursue certification in the area in which they specialize.
  28. The Committee reviewed APhA policy **2012, 1989 Recognition of Pharmacy Practice Specialties** when considering a statement on pharmacist certification and still believes the process set forth by the Board of Pharmacy Specialties should still be the preferred method for consideration of future certification opportunities.
  29. The Committee reviewed multiple examples of specialized pharmacy services and agreed that any specialized pharmacy service is focused in a specific practice area. This would include specific disease-state related services provided by a pharmacist in any type of pharmacy practice setting. For example, the Committee discussed HIV pharmacy services, diabetes management services, and hypertension management services as initial examples.

30. The Committee discussed the importance of a pharmacist to have access to resources and does not intend for APhA to create new resources, but to more so promote the access and use of existing resources in the marketplace.
31. The Committee's intent with this statement is to ensure continuity of care across all providers of services.
32. The Committee debated not including a statement on education and training as they believed there is clinical care information included in the PharmD curriculum. However, the Committee identified specialty pharmacy and service components such as pharmacy operations, medication supply management, patient assistance programs, and administrative functions that are not currently well covered in the PharmD curriculum.
33. The committee agreed that education and training does not need to be focused in the didactic portion of the PharmD curriculum but could be a component in experiential learning.
34. The committee did not believe education and training should be mandated or required for all PharmD students, but rather this information should be available for any students interested in this practice area.