2018 House of Delegates
Report of the New Business Review Committee

Committee Members
Melissa Skelton Duke, Chair
   Amber Briggs
   Kisha Gant
   Joey Mattingly
   Haniff Sealy
   Larry Selkow
   Emily Willard

Ex Officio
Michael D. Hogue, Speaker of the House
NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: ____Michael Carulli, on behalf of the 2017-18 Policy Review Committee____

(Name)

11/15/17

(Date)

APhA Policy Review Committee

(Organization)

Subject: Pharmacy Schools’ Curriculum and Contemporary Pharmacy Practice

Motion: I move, on behalf of the Policy Review Committee, that the following item be ADOPTED to replace existing APhA Policy.

2005, 1990 Pharmacy Schools’ Curriculum and Contemporary Pharmacy Needs

1. APhA supports continuous quality improvement processes at the national and school/college level to identify differences between contemporary pharmacy practice and curriculum offerings, and to provide information and resources to encourage maintenance of up-to-date curricula.

Background:
The needs of contemporary pharmacy practice are rapidly changing. While the committee acknowledges the good work of ACPE in its most recent standards revisions, the committee feels that the originators of this policy intended for there to be more regular, systematic and timely revision to school and college curricula than perhaps Standards might dictate. Thus, the suggested wording revision calls for schools and colleges to implement CQI processes which regularly assess the needs of contemporary pharmacy practice and make
revisions as necessary. Additionally, the committee felt this policy should support APhA providing information and resources to the individual schools to assist them in making changes and updates to their curricula based on the ever-growing practice of pharmacy. These resources can be in the form of information about current practice models, research on said practices and/or of other schools’ implementation and success of updated curricula, and ideas and ways to implement curriculum changes for the benefit of our student pharmacists and future practitioners. We believe this is consistent with the original intent of the 1990 policy (reaffirmed in 2005), and will provide clarity to the policy.

The text below shows the recommended changes and how they affect the existing policy language. New policy language is shown as underlined text and deleted language is shown struck through.

2005, 1990  Pharmacy Schools’ Curriculum and Contemporary Pharmacy Needs

I. APhA supports continuous quality improvement processes at the national and school/college level to identify will work with schools and colleges of pharmacy and pharmacy organizations to address differences between contemporary pharmacy practice and curriculum offerings, and to provide information and resources to encourage maintenance of up-to-date curricula.

Statement 2 of this existing policy topic will continue to be retained as it has already been approved by the APhA House of Delegates and is still relevant. For completeness sake, the second statement within this policy item states: “APhA encourages pharmacists to cooperate with schools and colleges of pharmacy by participating as preceptors and permitting their practices to be used as experiential sites.”

Current APhA Policy & Bylaws:

N/A

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: ___Laura Joglekar, on behalf of the 2017-18 Policy Review Committee
(Name)

12/3/17
(Date)

APhA Policy Review Committee
(Organization)

Subject: Revisions to the Medication and Medical Device Classification System

Motion: I move, on behalf of the Policy Review Committee, that the following item be ADOPTED to replace existing APhA Policy.

2013 Revisions to the Medication and Medical Device Classification System

1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.

2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug and medical device classification system.

3. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA’s approved conditions of safe use.

4. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA’s defined conditions of safe use.

5. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA’s approved conditions of safe use.

6. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA’s defined conditions of safe use within health benefit coverage.
Background:

In certain practice settings pharmacists are qualified to provide clinical intervention as well as input in development of medications as well as medical devices, therefore the policy statement has been updated to include “medical devices”. Over the past few years, FDA is partnering with patients, healthcare professionals and industry to establish modern requirements around various devices (e.g. stents, diagnostics, point of care testing), therefore it is pertinent that APhA continues to support pharmacists who help shape FDA’s policies.

The text below shows the recommended changes and how they affect the existing policy language. New policy language is shown as underlined text and no existing language was recommended for removal.

2013 Revisions to the Medication and Medical Device Classification System
1. APhA supports the Food and Drug Administration’s (FDA’s) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers.
2. APhA supports the implementation or modification of state laws to facilitate pharmacists’ implementation and provision of services related to a revised drug and medical device classification system.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA’s approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists’ input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA’s defined conditions of safe use.
6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA’s approved conditions of safe use.
7. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA’s defined conditions of safe use within health benefit coverage.

Existing policy statements 3 and 8 within this policy topic have been recommended to be retained by the 2017-18 Policy Review Committee and therefore have not been included in this new business item.

Current APhA Policy & Bylaws:
N/A

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by:  L. Douglas Ried, PhD and Betsy M. Elswick, PharmD

(Name)

01/16/2018   Texas House Delegation and Texas Pharmacy Association

(Date)                         (Organization)

Subject:  Direct and Indirect Remuneration Fees

Motion: Move to adopt the following policy statements.

1. APhA supports legislation that would prohibit retroactive direct and indirect remuneration (DIR) fees on pharmacies.
2. APhA supports prospective, transparent disclosure to pharmacies, employers and consumers, of all fee structures, performance-based network payments and penalties, and network participation requirements for any pharmacy benefit administrator
3. APhA opposes percentage-based or flat-rate, plan-based performance assessments in lieu of assessments based on a pharmacy’s performance on pharmacy specific quality metrics.

Background:
Relatively recently, Part D plan sponsors and Pharmacy Benefit Managers (PBMs) have begun to extract DIR (Direct and Indirect Remuneration) fees from community and specialty pharmacies. At present, nearly all pharmacy DIR fees are clawed back retroactively months later rather than deducted from claims on a real-time basis which makes it extremely difficult for community pharmacists to operate their small businesses.
The "Improving Transparency and Accuracy in Medicare Part D Drug Spending Act"¹ S. 413/ H.R. 1038 will prohibit Medicare Part D plan sponsors/PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D. According to one report², the bill would:

- Lower Medicare costs for taxpayers.
- Boost transparency in drug pricing.
- Give seniors reduced cost-sharing and greater budget predictability.
- Preserve access to independent community pharmacies.
- Address the concerns of Centers for Medicare & Medicaid Services (CMS) and Medicare Payment Advisory Commission (MedPAC).

A recent OIG report documented “a sharp increase in government spending on catastrophic coverage under Medicare Part D that has coincided with the steep jump in the prevalence and magnitude of pharmacy DIR fees”.³ OIG determined that these costs—borne completely by Medicare and the taxpayers who support it—have gone from $10 billion in 2010 to $33 billion in 2015. Similarly, the Medicare Payment Advisory Commission (MedPAC) has expressed concern that these post point-of-sale price adjustments shift more liability to the Medicare program and the federal government.² Moreover, most PBMs do not provide sufficient rationale for the fees. For example, approximately 67 percent of survey respondents said that PBMs provide no information as to how much and when DIR fees will be collected or assessed.⁴

The original purpose of DIRs as intended by the CMS was to lower the drug cost to the “true cost”, such as including manufacturer rebates. In the case of flat fee or percentage DIRs, these are known to both parties before the transaction takes place and can be conveniently assessed at the time of the transaction. However, in other cases, even though a medication doesn’t have a rebate assessed, such as on certain brand name products, pharmacies were assessed DIRs on these non-rebateable claims.⁶

In addition, a comprehensive report examining PBM DIR fees concluded that they “…have no legal basis in regulation and may, in fact, violate certain laws”.⁵ Examples of regulatory and statutory violations may include the Administrative Procedure Act, the Federal Any Willing Provider Law and the Federal Prompt Payment Law.

Moreover, DIR fees on pharmacies do not reduce the cost of drugs for beneficiaries at the point of sale and in fact push seniors into the ‘donut hole’ or catastrophic phase of the Part D benefit faster. Patients pay the higher prescription cost. If the cost was determined in real time, the savings that is clawed back from the pharmacy would be passed on to the patient and it would take longer for the patients’ expenditures to reach the donut hole levels. Instead, the savings are retained by the PBM ostensibly to offset higher premiums. However, in evaluating the impact of HR 1038/S 413, the Wakely Consulting Group concluded that any minor increase in beneficiary premiums would be largely offset by out-of-pocket savings at the pharmacy counter (i.e., 0.15 percent per year or a 1.5 percent increase in net costs over the course of 10 years).⁷
Sources:


Current APhA Policy & Bylaws:
To the best of my knowledge, while there is current APhA Policy on reimbursement, there is no specific policy on DIR fees and claw backs.

2017 Pharmacy Performance Networks
1. APhA supports performance networks that improve patient care and health outcomes, reduce costs, use pharmacists as an integral part of the health care team, and include evidence-based quality measures.

2. APhA urges collaboration between pharmacists and payers to develop distinct, transparent, fair, and equitable payment strategies for achieving performance measures associated with providing pharmacists' patient care services that are separate from the reimbursement methods used for product fulfillment.

3. APhA advocates for prospective notification of evidence-based quality measures that will be used by a performance network to assess provider and practice performance. Furthermore, updates on provider and practice performance against these measures should be provided in a timely and regular manner.

4. APhA supports pharmacists' professional autonomy to determine processes that improve performance on evidence-based quality measures.

(JAPhA 57(4): 441 July/August 2017)

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: Mary Elizabeth Bradley, PharmD Candidate 2018
(Name)

01/04/2018
(Date)

APhA Academy of Student Pharmacists
(Organization)

Subject: Efforts to Reduce Mental Health Stigma

Motion: Move that APhA adopt the following policy statements:
1. APhA encourages all stakeholders to develop and adopt evidence-based approaches in order to educate the public and reduce mental health stigma. This may include, but is not limited to, depression, bipolar disorder, schizophrenia, anxiety, and other disorders and conditions.
2. APhA supports the increased utilization of pharmacists and student pharmacists with appropriate training to actively participate in psychiatric interprofessional health care teams in all practice settings.
3. APhA supports the inclusion and expansion of mental health education and training in the curriculum of all schools and colleges of pharmacy and post-graduate opportunities.

Background:
As the prevalence of mental disorders continues to increase worldwide, the mental health community remains an underserved and undertreated population. Although approximately 1 in 5 adults in the United States (43.8 million, or 18.5%) suffers from mental illness in a given year, only 41% of adults in the United States with a mental health condition have received mental health services in the past year.¹ Health care providers must have a greater commitment towards educating the public on mental health disorders, including but not limited to risk factors, signs and symptoms, when and where to seek medical attention, and the safe and proper use of medications. As the most accessible health professional, pharmacists are uniquely positioned to play a greater and more patient-centered role in the delivery of mental health services.

With the 21st Century Cures Act being the largest piece of mental health legislation passed since 2008, the shortage of mental health services is more apparent now than ever.² As the pharmacotherapy experts, pharmacists’ knowledge and skills can be leveraged to increase access to mental health services in both the inpatient and outpatient settings. The most important skills pharmacists must exhibit are compassion, communication, and patient-centered care. Furthermore, pharmacotherapy is a predominant part of the treatment of mental disorders and conditions. Patient response to medication is variable and often
requires careful consideration of patient characteristics, preferences, and the medication side effect profiles. As such, pharmacists can aid in medication selection based on patient characteristics, monitor for efficacy and safety, titrate medications to optimize patient response, and encourage medication adherence through patient counseling.

Beyond medication reviews and patient education, pharmacists can perform screening and risk assessment services, in addition to referring patients to an appropriate provider. The impact of the aforementioned pharmacist-driven services in mental health is demonstrated by a study from Wang and colleagues in a Los Angeles safety-net clinic. Researchers documented clinically significant improvements where 77% of patients showed improvement from baseline. The APhA Foundation's Project ImPACT: Depression further illustrates pharmacists' impact on mental health care. Patients that enrolled and stayed in the employer-sponsored treatment study had noteworthy improvements in their Patient Health Questionnaire-9 (PHQ-9) score. The PHQ-9 is a validated, self-administered depression assessment tool which was administered by pharmacy care managers at baseline and subsequent follow-up visits during the study. Notable results include 83% of patients with severe depression at baseline achieved remission, which is defined as a PHQ-9 score less than 5, and 68% of patients had a 50% reduction in their PHQ-9 score. Not only do the pharmacist-led services increase rates of adherence and improve patient satisfaction, but they can also have a significant financial impact. One study reported an estimated cost savings of approximately $22,000 during a 15-month trial period when a psychiatric pharmacist was involved in the pharmaceutical care in a low-income setting. These are examples of the many evidence-based studies that show how valuable a pharmacist can be in improving access to mental health services.

Nonetheless, a growing body of evidence suggests that mental health professionals are a primary source of stigmatizing attitudes and behaviors. Although some studies have found pharmacists to have generally favorable attitudes towards people with mental disorders, international data from a six-country study shows suboptimal attitudes toward people with schizophrenia and severe depression were common among student pharmacists. Furthermore, pharmacists have reported being uncomfortable discussing symptoms of mental disorders and felt they were less likely to follow up with patients who have a mental disorder than with those who have a cardiovascular illness. As pharmacists interact with patients who have mental disorders on a regular basis, this professional culture has significant implications, such as social marginalization and non-adherence. The aforementioned attitudes towards mental disorders, and a lack of confidence to provide pharmacy services to patients with mental disorders, underscore the need for pharmacy education reform as it relates to mental health.

Additional training within pharmacy school curriculum and post-graduate training programs will improve pharmacists’ and student pharmacists’ comfort level when speaking to patients about mental health. Given the predicted increase of clinical pharmacy outpatient positions in the future, pharmacists will likely be managing medications for most chronic conditions, including mental health disorders. Thus, it is vital that student pharmacists are aware of the increasing need to care for patients with mental illnesses. Pharmacy curriculum and training must complement the traditional focus on pharmacotherapy by adopting evidence-based approaches to reduce mental health stigma. Student pharmacists have begun addressing this matter through extracurricular efforts. For example, the Samford University McWhorter School of Pharmacy APhA-ASP Chapter created Operation Mental Health, which added depression screenings and mental health public health awareness material to their health screenings. The University of Texas at Austin College of Pharmacy APhA-ASP Chapter started Operation Brain, which focuses on mental health by working closely with a local women's shelter. As educational programming for pharmacists and student pharmacists alike are improved, pharmacists will be better positioned to provide care for their patients with mental disorders.
References:

Current APhA Policy & Bylaws:

2004, 1965   Mental Health Programs

APhA supports pharmacists’ participation in the development and implementation of all aspects of mental health programs so that the special needs and problems on the mentally ill can be effectively met.

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: Betsy Elswick and L Douglas Reid
(Name)

1/26/2018
(Date)

Texas House Delegation and Texas Pharmacy Association
(Organization)

Subject: Pharmacist’s permissive language related to medication cost

Motion: Move to adopt the following policy statement:

APhA opposes language included in contractual agreements between pharmacy benefits manager (PBM) and pharmacy that prohibit or limit a pharmacist’s ability to communicate information to patients pertaining to the cost of and access to medications.

Background:
On October 17, 2017, Thomas Menighan, Executive Vice President and Chief Executive Officer of the American Pharmacists Association, provided testimony before the U.S. Senate Committee on health, Education, Labor & Pensions. In his remarks, Mr. Menighan stated:

“As the organization representing pharmacists in all practice settings, APhA has been, and is, a strong supporter of policies which increase patients’ access to affordable and cost-effective medicines. Decisions along the entire drug supply chain impact patients’ medication costs, including arrangements between manufacturers, wholesalers, insurers, and pharmacy benefit managers, or PBMs. Because of these upstream stakeholder policies, for most patients, pharmacists have limited options to impact patients’ final drug costs.”

Pharmacists increasingly cite concerns about contractual agreements that prohibit them about speaking to their patients about the out-of-pocket cost of a drug versus a health carrier’s reimbursement rates. Effective October 1, 2017, the state of Connecticut passed Senate Bill 45 pertaining to contracts between a pharmacy and a pharmacy benefits manager. This legislation was enacted to provide permissive, non-punitive language to
allow pharmacists to disclose information related to the costs of medications to their patients/purchasers. The language does NOT require cost information to be disseminated. Rather, it leaves the communication at the pharmacist’s discretion to assist patients in making informed decisions about their health care.

According to Connecticut’s recently enacted legislation:

“On and after October 1, 2017, no contract entered into between a health care provider, or any agent or vendor retained by the health care provider to provide data or analytical service to evaluate and manage health care services provided to the health carrier’s plan participants, and a health carrier shall contain a provision prohibiting disclosure of (1) billed or allowed amounts, reimbursement rates or out-of-pocket costs, or (2) any data to the all-payer claims database program established under section 38a-1091. Information described in subdivisions (1) and (2) of this subsection may be sued to assist consumers and institutional purchasers in making informed decisions regarding their health care and informed choices among health care providers and allow comparisons between prices paid by various health carriers to health care providers.”

In addition to Connecticut, there are currently four other states (Georgia, Louisiana, Maine, and North Dakota) who have passed similar legislation that forbid PBMs from including in contractual agreements wording/language that prohibits the pharmacist from disclosing when out-of-pocket costs for a medication may be less than the traditional copayment. Maryland is also currently considering passing similar legislation.

While APhA has policy related to the access to and affordability of medications to patients, policy does not exist related to so-called “gag orders” that restrict the pharmacist from voluntarily communicating cost information with the patient or purchaser of prescription medications. This additional proposed policy statement would strengthen APhA’s ability to advocate for our patients’ access to affordable medications and provide statements that serve to protect pharmacists in their ability to communicate fully with their patients. (See addendum of Menighan’s testimony for APhA House of Delegates Policy Statements Related to Drug Pricing.)

Sources:
Current APhA Policy & Bylaws:

2013, 2001, 1994 Pharmacist-Patient-Prescriber-Payer Responsibilities in Appropriate Drug Use

1. APhA advocates the following guidelines for pharmacist-patient-prescriber-payer responsibilities in appropriate drug use:

(a) Pharmacists' Responsibilities
o Serve as a drug information resource;
o Provide primary care;
o Collaborate with the prescriber and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
o Identify formulary or generic products as a means to reduce costs;
o Intervene on behalf of the patient to identify alternate therapies;
o Educate the patient about the treatment regimen and expectations, and verify the patient's understanding;
o Identify, prevent, resolve, and report drug-related problems;
o Document and communicate pharmaceutical care activities;
o Monitor drug therapy in collaboration with the patient and prescriber to ensure compliance and assess therapeutic outcomes;
o Maintain an accurate and efficient drug distribution system; and
o Maintain proficiency through continuing education.

(b) Patients' Responsibilities
o Assume a responsibility for wellness;
o Understand the coverage policies of their benefit plan;
o Share complete information with providers, including demographics and payment mechanism(s);
o Share complete information regarding medical history, lifestyle, diet, use of prescription and over-the-counter medications, and other substances;
o Participate in the design of the treatment regimen;
o Understand the treatment regimen and expected outcomes;
o Adhere to the treatment regimen; and
o Alert prescribers and pharmacists to possible drug-related problems or changes in health status.

(c) Prescribers' Responsibilities
o Assess and diagnose the patient;
o Share pertinent information in collaboration with the pharmacist and patient in the design of cost-effective treatment regimens that produce beneficial outcomes;
o Clearly communicate the treatment plan and its intended outcomes to the patient directly or in collaboration with the pharmacist;
o Remain alert to the possible occurrence of drug-related problems and initiate needed changes in therapy;
o Collaborate with the patient and the pharmacist in drug therapy monitoring; and
o Maintain proficiency through continuing medical education.

(d) Payers' Responsibilities
o Determine the objectives and desired benefits of pharmacy service;
o Design the coverage with patient and provider input using products and services to produce beneficial outcomes;
o Contract with providers on the basis of outcomes and efficient use of resources;
o Adopt efficient, clear, and uniform administrative processes;
o Communicate requirements of compensation for levels of care;
o Educate patients and providers about current eligibility and benefit information;
o Expediently process payments; and
o Be responsive to advances in contemporary practice.


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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by:  _____ Carmela Silvestri PharmD
(Name)

2/13/2018    New Jersey Pharmacists Association
(Date)                                   (Organization)

Subject:  Gluten Content and Labeling in Medications

Motion:  Move to adopt the following policy statements:

1. APhA supports labeling of all prescription and over the counter medications that indicates the presence or absence of gluten (protein associated with wheat, barley, rye or their derivatives) regardless of whether the addition of these substances is intentional or inadvertent.
2. APhA supports required gluten status verification for all plant derived excipients used in the manufacture of medications to assure that no cross-contamination has occurred, and in the absence of this verification, that batch testing of medication products be required to determine if they are free of detectable gluten.
3. APhA encourages the FDA to require post manufacturing testing of gluten content in oral drug products, and making quantitative information on gluten content easily accessible to health professionals.
4. APhA encourages USP to develop assays that can accurately detect trace levels of gluten in finished drug products and set appropriate standards
5. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.
6. APhA supports a mechanism for third party payers to acknowledge the need for, and accept responsibility for providing access to, medications with no detectable gluten when medically necessary.
7. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it relates to medication absorption.
8. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.

Background:
Supporting statements
1. Several studies have been done to estimate the time required by pharmacists in determining the gluten status in medications in order to protect patients from exposure. The celiac community is riddled with anecdotal stories of patients who report being left to check with manufacturers on their own to verify gluten status of their
medications. This is presumably because of the uncompensated time burden on pharmacies associated with calling manufacturers with each prescription to determine gluten content. To compound the problem, not all drug manufacturers are able to provide information on excipients and those who can, may change their sources at any time—without informing the patient or pharmacy. Manufacturer information contacts are not available during all pharmacy hours when this information is needed. Drug product information specialists may need to research the gluten status before responding. Ingredients derived from wheat, barley or rye include Modified starch (source not specified), Pregelatinized starch (source not specified), Pregelatinized modified starch (source not specified), Dextrates (source not specified), Dextrin (source not specified but usually corn or potato), Dextrimaltose (when barley malt is used), Caramel coloring (when barley malt is used). Pharmacists may not recognize these as gluten sources. Frequently the response from manufacturers is that no gluten containing ingredients are used in the manufacturing process but that the company acknowledges that they cannot verify that the final product is gluten free.

2. It is generally accepted that grains such as oats and dried legumes are subject to cross contamination as a result of crop rotation, farming equipment and shared processing facilities. Untested foods, which would normally be considered allergen free, are frequently labeled to inform more sensitive consumers of the risk of cross contamination. These labels may take the form of the statement: “made in a facility that also processes wheat”. This labeling is voluntary in the Food Allergen Labeling and Consumer Protection Act (FALCPA). This information would be useful in excipients used in production of medications as it would indicate a need for additional determination of purity. Although use of GMPs may preclude contamination in the drug manufacturing process, this is not the case for excipients processed as foods (for which labeling of gluten content is voluntary).

3. Symptoms associated with celiac disease may be intestinal or extra-intestinal. Clinical intestinal symptoms include diarrhea, flatulence, severe stomach pain, weakness and fatigue. Extra intestinal symptoms are multi-systemic and may include neurologic symptoms such as paresthesia, migraine, and seizure and hormonal abnormalities such as amenorrhea, infertility and impotence. Continued exposure can lead to osteopenia, anemia, prothrombin deficiency, failure to thrive and growth retardation associated with malabsorption syndrome. An increased risk of gastric malignancies and B-Cell and T-cell lymphoma is seen. Research has shown that the threshold for symptoms resulting from gluten exposure is subject to significant patient variability. It is important to note that it has been estimated that up to 70% of patients with celiac disease do not report any clinical symptoms. These asymptomatic patients have no outward signs to indicate they have experienced stimulation of the autoimmune response and will experience disease-associated intestinal damage with continued exposure. In addition, up to 6 percent of the population suffers from non-celiac gluten sensitivity (NCGS) resulting in varying degrees of clinical illness as a result of gluten exposure without evidence of intestinal autoimmune damage. Standards for labeling of finished products would guarantee that patients are not exposed without their knowledge. If all products are tested, the noting of the presence of detectable gluten content on labels would allow patients, along with their pharmacist/physician, to evaluate the risk/benefit of treatment. Easily retrievable information on gluten content in products would allow a pharmacist to identify products with lower content when trace gluten exposure cannot be avoided.

4. The definition of the terminology “gluten free” was regulated in food products in 2014 as a voluntary labeling standard. The standard of 20ppm was chosen as the lowest level detectable using available technology at that time. It is now possible through Elisa testing to determine levels of intact proteins as low as 5ppm and protein fragments at 10ppm. Studies are needed to determine if peptide fragments with single receptor sites can cause as much damage as complete proteins. The Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten (May 2011) conducted by Office of Food Safety Center of Food Safety and Applied Nutrition Food and Drug Administration stated that repeated (sub-chronic) exposure of 0.4mg/day of gluten was shown to produce morphological changes in diagnosed celiac patients. FDA also determined in this report that a single exposure of 0.015mg could cause clinical symptoms in patients. Establishment of any “acceptable” gluten level in medications would need to account for regimens that require ingestion of multiple units such as dosing of 3-4 dosage units per day, as well as, the combined effect of multiple medications used in combination to treat one or more chronic disease. To
eliminate the risk of medications causing damage to susceptible patients, gluten content may need <1ppm. Since we do not currently have an assay designed for drug testing to determine trace amounts, we feel that APhA should encourage USP to develop testing methods that would allow the industry standard to be established at a level that would truly protect these patients.

5. An obvious solution to the problem of gluten exposure is the elimination of known sources of gluten that cannot be refined to a level that would be safe. Encouraging manufacturers to eliminate these excipients in their products moving forward would be helpful. Full disclosure of the inclusion of any known gluten source is essential to patient safety but currently not regulated.

6. Celiac patients who experience clinical adverse effects from a gluten contaminated medication product may either incorrectly attribute the symptoms to the active drug ingredient (assuming the medication to be unacceptable) or refuse treatment altogether. Treatment refusal can lead to worsening disease, hospitalization and additional cost and adverse effects on quality of life. Since complete abstinence from ingested gluten is the only treatment for celiac disease, third party payers need to bear the responsibility for ensuring that medication used to treat a different illness does not aggravate celiac autoimmune disease.

7. Celiac disease related malabsorption could necessitate changes in oral dosing, and adjustment as intestinal healing occurs. Research into the implications of the effects on medication absorption could allow pharmacists and prescribers to better manage these patients.

8. Pharmacists need to be aware of celiac disease and gluten sensitivity in order to guide patients to verified gluten-free products and assist in limiting inadvertent exposure.

Why this is important?

Approximately 1% of the population or 3 million Americans have celiac disease. Celiac disease is diagnosed endoscopically when changes in intestinal morphology due to inflammatory autoimmune damage are found. These changes are the result of exposure to gluten, which is defined as the proteins found in wheat, barley, rye, and most of their derivatives. Although celiac autoimmune stimulation has been known to result in multisystem damage, no absolute safe threshold for stimulation of the autoimmune response has been established due to heightened sensitivity in some patients. Some celiac patients may be unable to tolerate even trace exposure.

The estimate of 3 million people with celiac disease in the US may be conservative. Less than half experience the clinical symptoms that would cause them to seek a diagnosis until malabsorption complications are experienced. Asymptomatic patients are diagnosed based on family screening and based on results of endoscopy performed for other reasons. Celiac related malabsorption has been linked to several forms of anemia, vitamin K deficiency coagulation abnormalities, osteopenia, and growth disruption, weight loss and failure to thrive in children. The genetic predisposition is shared by 40% of the general population and is common to all celiac patients, but the trigger to active disease is still subject to speculation. The medical community is slow to suspect celiac disease in adult patients and it takes an average of 4-8 symptomatic years before being correctly diagnosed.

In 2011, the Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten (May 2011) conducted by Office of Food Safety Center of Food Safety and Applied Nutrition Food and Drug Administration showed that adverse changes in intestinal morphology were detected with exposure to 0.4mg/day. Clinical patient specific symptoms were observed with exposure to 0.015mg. Morphological changes are associated with complications such as lymphoma and gastric carcinoma. Clinical symptoms are varied but include intestinal symptoms such as severe stomach pain, nausea and diarrhea. Extra-intestinal symptoms are varied and include dermatologic (rash), neurologic (headache including migraine, brain fog, learning disability and seizure) and musculoskeletal symptoms such as myalgia and fatigue. Although the hazard study was limited to patients with celiac disease, up to 6% of the population may suffer from non-celiac gluten sensitivity (NCGS) resulting in varying degrees of clinical illness as a result of exposure.

As a result of the existing evidence, FDA established guidelines for the voluntary labeling of food products as “gluten free”, the threshold of 20ppm was established as the standardized criteria for this designation. Although
some patients experience clinical symptoms below this threshold, this served as a guide to patients that labeled products are produced with an effort to minimize contamination and are tested for gluten content when the risk exists. It is important to recognize that patients who experience symptoms when consuming a food can make the choice to no longer purchase and consume the offending product. A medication needs to be taken on schedule for the prescribed course. Sometimes this schedule involves up to 4 or more dosage units every day. Currently, insurance does not cover the filling of more than one prescription in a specific period, all but eliminating the option to try a product from a different manufacturer. Insurance coverage may require prohibitive copays for the branded drug or more expensive generic products that may not produce the symptoms. In many cases the only option is to consider the medication a failure, and obtain a prescription for a different treatment.

Currently, the only known treatment for celiac disease is strict adherence to a gluten free diet. A prescription requiring “Gluten Free” product is meaningless if products have not been proven and labeled to be gluten free.

Few products are formulated with gluten containing ingredients listed below*. In a January 2018 article by Shah in the Journal of Pharmaceutical Sciences titled: Making All Medications Gluten Free, replacing all gluten containing starch derivatives with alternatives is explored as a way of eliminating the risk of gluten exposure. Current good manufacturing practices (cGMPs) make contamination during manufacturing highly unlikely. Unfortunately, there is no current requirement that raw materials used as inactive ingredients in medication manufacturing be tested, and proven free of gluten contamination. Without assuring that the ingredients themselves are certified to be free of gluten the risk of contamination remains. For this reason, pharmacists, and sometimes patients, who call a drug manufacturer, are often told that their product “contains no gluten containing ingredients”. They are unable to state that the finished product is gluten free because gluten contamination is not included in post-production batch testing. For food, the product must either have no risk of contamination based on the content and manufacturing process or that batch test results are less than 20ppm in order to be labeled “Gluten Free”.

Labeling of GF for products with gluten content below 20ppm is voluntary in food products (which may be avoided by choice in highly sensitive patients who experience adverse clinical effects). We believe that standards stringent enough to eliminate the risk of symptoms for most celiac patients (0.015mg of daily exposure at standard dosing) should be imposed on all drug products in the interest of patient safety. Any product that is not certified at this level of purity should be labeled differently than those that can verify purity. No one should refuse their medications based on fear of undisclosed gluten contamination. In 2014 the National Foundation for Celiac Awareness conducted a study resulting in a report, “Gluten in Medication: Qualifying the Extent of Exposure to People with Celiac Disease and Identifying a Hidden and Preventable Cause of an Adverse Drug Event”. The study collected reports of celiac patients who experienced symptoms consistent with gluten exposure while taking medications. A number of these medications were tested for gluten content using the most sensitive tests available. Gluten contamination above the 20ppm threshold for gluten free food was identified in some of the reported products even though the manufacturers had stated that they were made without gluten containing ingredients.

As the elimination of even the smallest amount of gluten is the current treatment plan for millions of Americans, identifying presence or absence of gluten and labeling this on drug products should be a part of drug safety standards. Products using excipients with any risk of contamination through processing should be flagged so that the patient along with their pharmacist can determine the risk/benefit of use. Quantitative assessment of any known gluten content should ALWAYS be available on request in order to help pharmacists assist with product selection.

Why now? In December the FDA posted proposed Gluten in Drug Products and Associated Labeling Recommendations Guidance for Industry-. Comments were received until February 12th, 2018. NJPhA believes that the APhA should take a stand on labeling of gluten in medications in order to protect patients this year while FDA is considering options for dealing with the problem. It is essential that pharmacists be educated on the disease state and demand the information needed to care for these patients.
**References:**


Health Hazard Assessment for Gluten Exposure in Individuals with Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten. Office of Food Safety-Center of Food Safety and Applied Nutrition Food and Drug Administration-May 2011


Gluten in medication: Qualifying the Extent of exposure to people with celiac disease and identifying a hidden and preventable cause of an adverse drug event” by NFCA (Robert Mangione-Chief investigator)


**Other information:**

*Ingredients which can be derived from a gluten containing grain:

Wheat, barley or rye may be the source of a limited number of excipients. Examining a medication’s inactive ingredient list for a red-flag ingredient is the only way that people following a medically necessary gluten-free diet and their healthcare providers have to assess for gluten in a drug. The following inactive ingredients may be sourced from wheat, barley or rye:

- Wheat
- Modified starch (source not specified)
- Pregelatinized starch (source not specified)
- Pregelatinized modified starch (source not specified)
- Dextrates (source not specified)
- Dextrin (source not specified but usually corn or potato)
- Dextrimaltose (when barley malt is used)
- Caramel coloring (when barley malt is used)
Historical Timeline of Progress in Gluten Labeling of Medications

2008-Private citizen submits a petition to the FDA requesting regulation specifying that no medication, either prescription or OTC, contain wheat gluten as an ingredient, and if this is refused that this ingredient be made known.

2011- Federal Register includes discussion of gluten hazard study: “Based on this health hazard assessment, a conservative tolerable daily intake level for gluten in individuals with celiac disease is 0.4 milligrams (mg) gluten per day for adverse morphological effects and 0.015 mg gluten per day for adverse clinical effects”.

2013- FDA enacts regulation governing the voluntary use if the term “gluten free” to specify finished food products that will test at <20ppm of gluten. Manufacturers had until August 2014 to comply

2014-September- Results of “Gluten in Medication: Qualifying the Extent of Exposure to People with Celiac Disease and Identifying a Hidden and Preventable Cause of an Adverse Drug Event” by NFCA(Robert Mangione-Chief investigator)

2015- May 12, 2015-FDA responds to citizen petition labeling; request denied because: “Based on drug formulation information, we estimate that these ingredients may contribute no more than 0.5 mg gluten to a unit dose of an oral drug product.”

2015-September-Representatives Tim Ryan (OH-13) and Nita Lowey (NY-17) introduce the Gluten in Medicine Identification Act to Congress

2015-The FDA responds to the citizen petition which is made public by the recipient that guidance for labeling will be forthcoming.

2017-December- FDA published Gluten in Drug Products and Associated Labeling Recommendations Guidance for Industry in the Federal Register with a comment period opened until Feb 12th 2018

2018-March APhA considers gluten content labeling in the House of Delegates.

Current APhA Policy & Bylaws:

APhA supports legislation or regulation to require a full disclosure of therapeutically inactive, as well as active ingredients of all drug products.


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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: LT William Christopher Charles
(Name)

2/14/2018
(Date)

United States Public Health Service
(Organization)

Subject: Pharmacists Electronic Referral Tracking

Motion: Move to adopt the following policy statements:

1. APhA supports the development of electronic systems that enhance and simplify the ability of pharmacists in all practice settings to receive, send, and track referrals between all members of the health care team irrespective of the health care system, model, or network the patient participates in.

2. APhA supports the interoperability and integration of referral tracking systems with electronic health records so patients can receive the benefit of optimally coordinated care from all members of the health care team.

Background:

In recent years, APhA has adopted several policies acknowledging the positive impact of pharmacist-provided services. Currently, outside of pharmacy academia, the majority of these services are provided to patients within closed systems such as Veterans Affairs and Kaiser Permanente. Common threads within these systems’ electronic health records (EHR) are universal access of information, and ease of patient referrals to pharmacist services. APhA policy advocates for national EHR integration and pharmacists’ access to the same. A piece that is missing in current policy is a statement focused specifically on the enhancement of referrals within such a system.

Several initiatives have been launched in recent years to expand the successes seen in these systems to more patients. Medical Home Models, Value-Based Payment structures, and Performance Networks are examples of these initiatives. APhA policy also addresses pharmacists’ activities within these structures. The purpose of this proposal is to address the aforementioned missing piece, so pharmacists across practice settings have an avenue to effectively and efficiently coordinate with providers. This will allow many more pharmacists to use their training to the fullest for all patients, whether or not the patients receive their care within a closed health system or innovative health care model.

The National Committee on Quality Assurance (NCQA), which certifies Patient Centered Medical Homes (PCMH), publishes standards and guidelines for practices wishing to provide care in this innovative fashion. PCMHs provide many services inhouse, but often need to refer patients out for specialty care. Complete referrals require the transmission of many pieces of information including the reason for referral, the patient’s PMH, HPI, labs, test results, accurate
medication list, current care plan, therapies previously tried, etc\textsuperscript{1,2}. Inaccurate, incomplete, or delayed transfer of information might result in delayed access to care, duplicate testing, polypharmacy, inappropriate medication use, erosion of trust in the medical system, and increased costs\textsuperscript{1}. To avoid these pitfalls and to ensure good coordination of care between PCMHs and outside specialists, NCQA has highlighted efficient referral tracking and follow-up as a must-pass element to gain recognition as a PCMH in each update of its standards since 2011\textsuperscript{3-5}.

The University of California San Francisco (UCSF) in conjunction with San Francisco General Hospital (SFGH), San Francisco’s main safety net provider of specialty care, developed a web-based referral system that allows for interactive communication between referring and specialty providers\textsuperscript{2}. A survey of users after the first two years of implementation revealed a host of positive results. Highlights include decreased duplication of diagnostic tests, improved instructions and education back to the primary provider, reduced time to specialist appointment from 5-12 months to 1-2 months, prioritization of referrals based on patients’ needs, time saved for most users, and the reduction of unnecessary referrals. While this referral system did not include pharmacists, some organizations have shown success integrating pharmacists’ services into theirs.

Mountain Area Health Education Family Health Center (MAHEC) is one such NCQA certified PCMH that utilizes pharmacists in an embedded Pharmacotherapy Clinic to provide several services. All clinic activities, which include MTM, osteoporosis management, anticoagulation, diabetes, and medication assistance, are initiated by referral\textsuperscript{6}. MAHEC patients also benefit from referrals to unaffiliated community pharmacies for immunization services\textsuperscript{5}. The Indian Health Service’s (IHS) National Clinical Pharmacy Specialist Committee has applied this concept directly to pharmacists as well. Their recently updated Comprehensive Pharmacy Services Handbook makes documented, trackable, multidirectional referrals part of their standard operating procedure\textsuperscript{7}. The IHS referral-consultation process provides a seamless, electronic transfer of complete, relevant information between providers, allowing pharmacists to coordinate and manage disease states such as Hypertension, Hyperlipidemia, Diabetes, Nicotine Dependence, Asthma, Immunizations, COPD, Hypothyroidism, Spirometry, and more\textsuperscript{7}.

The APhA Foundation’s Project IMPACT has devoted many resources to developing collaborative practice agreement (CPA) structures that expand the high level of success seen in the previously described systems to patients in communities across the nation. The Diabetes Ten-City Challenge connected pharmacists with 573 patients who achieved statistically significant improvements in their average A1C, LDL, systolic blood pressure, influenza vaccination rate, eye exam rate, and foot exam rate over an average 14.8-month period\textsuperscript{8}. Project IMPACT: Diabetes produced similar results for 1,836 patients in 25 communities in 17 states over an average 11-month period\textsuperscript{9}. Notably at the end of the project in 2014, 92% of the communities intended to sustain pharmacists’ services beyond the conclusion of the grant\textsuperscript{9}.

Personal interviews with one of the participating pharmacists based in an independent community pharmacy revealed challenges that ultimately ended the CPA for that community. CPAs were entered into with two physicians to see 60 patients. The pharmacist was embedded in one office so had easy access to the EHR and the physician partner. Patients from the other practice were seen in the pharmacy. Referrals were hand written on prescription pads, and all information was transmitted by fax, phone, or hand-delivered by the pharmacist to be scanned into the physician’s EHR later. With the slow flow of information, many patients became confused as to which provider to see for their diabetes care – the physician or the pharmacist. The CPA for the embedded practice was able to sustain for nearly an additional 3 years. The CPA with the remote, paper-based referral system ended shortly after the end of the study period. Based on the successes seen in various previous examples, enhanced & simplified referrals and free-flow of electronic health information likely would have enabled the remote CPA to continue and perhaps expand to more patients and practices.

APhA’s 2015 policy on Interoperability of Communications shows APhA’s support for enhancing electronic communication between healthcare providers and pharmacists, and to that end the Pharmacy Health Information Technology Collaborative (PHITC) has been working with stakeholders to include pharmacists in those standards. Unfortunately, according to the PHITC, the digitization of multidirectional referrals between pharmacists and providers not integrated into a closed health system or innovative health care model is not currently being targeted by any entities.

Due to the work of APhA over the past several years, more states and Congress are moving ever closer toward granting provider status to pharmacists. Now is the time for APhA to pointedly advocate for the development of electronic systems that improve all aspects of the referral interface between providers and pharmacists. Easing this critical transaction of information will do much to enhance pharmacists’ ability to implement CPAs for the care of our patients.
References:


Current APhA Policy & Bylaws:

2017 Patient Access to Pharmacist-Prescribed Medications

4. APhA urges prescribing pharmacists to coordinate care with patients’ other health care providers through appropriate documentation, communication, and referral.

2015 Interoperability of Communications Among Health Care Providers to Improve Quality of Patient Care

1. APhA supports the establishment of secure, portable, and interoperable electronic patient health care records.
2. APhA supports the engagement of pharmacists with other stakeholders in the development and implementation of multidirectional electronic communication systems to improve patient safety, enhance quality care, facilitate care transitions, increase efficiency, and reduce waste.
3. APhA advocates for the inclusion of pharmacists in the establishment and enhancement of electronic health care information technologies and systems that must be interoperable, HIPAA compliant, integrated with claims processing, updated in a timely fashion, allow for data analysis, and do not place disproportionate financial burden on any one health care provider or stakeholder.
4. APhA advocates for pharmacists and other health care providers to have access to view, download and transmit electronic health records. Information shared among providers using a health information exchange should utilize a standardized secure interface based on recognized international health record standards for the transmission of health information.
5. APhA supports the integration of federal, state, and territory health information exchanges into an accessible, standardized, nationwide system.
6. APhA opposes business practices and policies that obstruct the electronic access and exchange of patient health information because these practices compromise patient safety and the provision of optimal patient care.
7. APhA advocates for the development of systems that facilitate and support electronic communication between pharmacists and prescribers concerning patient adherence, medication discontinuation, and other clinical factors that support quality care transitions.
8. APhA supports the development of education and training programs for pharmacists, student pharmacists, and other health care professionals on the appropriate use of electronic health records to reduce errors and improve the quality and safety of patient care.
9. APhA supports the creation and non-punitive application of a standardized, interoperable system for voluntary reporting of errors associated with the use of electronic health care information technologies and systems to enable aggregation of protected data and develop recommendations for improved quality.
2014 Care Transitions

4. APhA supports the development and utilization of standardized processes that facilitate real-time, bidirectional communication of protected health information during care transitions.

2009 Health Information Technology

1. APhA supports the delivery of informatics education within pharmacy schools and continuing education programs to improve patient care, understand interoperability among systems, understand where to find information, increase productivity, and improve the ability to measure and report the value of pharmacists in the health care system.

2. APhA urges that pharmacists have read/write access to electronic health record data for the purposes of improving patient care and medication use outcomes.

3. APhA encourages inclusion of pharmacists in the definition, development, and implementation of health information technologies for the purpose of improving the quality of patient-centric health care.

4. APhA urges public and private entities to include pharmacist representatives in the creation of standards, the certification of systems, and the integration of medication use systems with health information technology.


2006 Continuity of Care

3. APhA supports patient access to pharmacists with specialized skills and expertise. The patient’s pharmacist should make patient referrals where appropriate.

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NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: LT Kinbo Lee
(Name)

2/13/2018
(Date)

United States Public Health Service
(Organization)

Subject: Pharmacist’s Role in Chronic Disease Prevention

Motion: Move to adopt the following policy statements:

1. APhA advocates for the recognition and utilization of pharmacists as providers to address chronic disease prevention.
2. APhA advocates for pharmacy campaigns focused on increased community wellness awareness and health benefit knowledge in areas such as healthy eating and physical exercise.
3. APhA encourages the development of pharmacy curriculum and continuing education on the topics of chronic disease prevention and health promotion through improvements in modifiable risk factors.

Background:

A cursory search for “prevention” in the APhA Policy Manual leads to results such as “Poison Prevention,” “Opioid Abuse Prevention,” and preventing the spread of human immunodeficiency virus (HIV) and other sexually-transmitted diseases. However, when it comes to chronic diseases, in general, the profession has largely remained passive in its engagement of primary prevention programs.

According to the CDC, in 2015, an estimated 30.3 million people (9.4% of the U.S. population) had diabetes and more than a third of U.S. adults had prediabetes. Despite current diabetes prevention efforts, an estimated 5,200 adults aged 20 years and older were newly diagnosed with diabetes each day. In 2015, diabetes was the seventh leading cause of death in the U.S., which cost the U.S. an estimated $245 billion in 2012. Possible complications from diabetes include cardiovascular disease, lower-limb amputation, vision loss, kidney failure, and peripheral neuropathy. One of the primary contributors to prediabetes and diabetes is obesity through decreased insulin sensitivity. More than 70% of adults in the U.S. are considered overweight. Moreover, over one-third of adults, 20% of adolescents, and 17% of grade-school youth in the U.S. are categorized as obese. It is estimated that the medical care costs of obesity alone totaled $147 billion in 2008 dollars. Being obese has been found to increase the risk of heart disease, stroke, high blood
pressure, and cancer. Given the health and societal burden of diabetes and obesity on society, individualized lifestyle interventions are paramount to decreasing the incidence of obesity and preventing or delaying onset of diabetes and related complications.

Pharmacists have demonstrated improved health outcomes in patient care through increased medication adherence, patient education, and lifestyle interventions that address modifiable disease risk factors. Specifically, evidence has shown that when pharmacists are involved in management of diabetes and obesity, hemoglobin A1C (HbA1C) and Body Mass Index (BMI) significantly decrease. Meta-analyses of pharmacist interventions to improve diabetic and obesity outcomes report significant A1C reduction (-0.18% to -2.1%) and lowering of BMI (-0.19 kg/m² to -0.9 kg/m²). This is notable given that a 5% reduction in weight loss is associated with lower blood pressure, blood sugar, cholesterol, and insulin resistance, and follows the American Diabetes Association's recommendation of weight loss for all overweight or obese individuals who have or are at risk for diabetes. In addition, results from Project IMPACT: Diabetes, a program that spanned 25 communities in 17 states, over two years, showed that patients with diabetes who received pharmacist care via customized diabetes education and medication consultation had a statistically significant decrease in mean A1C levels (-0.8% ± 2). However, given the large adult population with prediabetes in the U.S. and that 90% of these individuals are unaware of their condition, additional emphasis is needed on diabetes and obesity preventative strategies. In meta-analysis comparing standard of care in patients with type 2 diabetes to patients with treatment methods that specifically included lifestyle or educational interventions relating to dietary behavior, exercise, or physical activities, A1C (-0.32%, p=0.001) and BMI (-1.05 kg/m², p=0.014) significantly decreased in the intervention group, respectively. In addition, overweight or obese individuals as a cohort who received intensive diet, exercise, and behavioral modification lifestyle modifications in the Diabetes Prevention Program (DPP) had a 58% reduction of risk for diabetes compared to a 31% risk reduction with metformin. Those that received intensive lifestyle modifications in the DPP had a per capita medical costs savings of $4,572 compared to metformin ($2,281) over a 10-year period. Further, it has been shown that pharmacist-led weight loss programs for individuals who are overweight or obese can lead to significant weight reduction (5 kg, p<0.001). This gives rise to the importance of pharmacist-provided healthy diet, physical activity, and self-management skill support during patient encounters. Given pharmacists are arguably the most accessible healthcare providers (43% of 312,500 pharmacists work in the community setting; greater than 93% of Americans live within 5 miles of a community pharmacy), it seems sensible to further engage pharmacists in preventative patient lifestyle interventions - nutrition intake, physical activity, and weight control - to turn the tide on the diabetes and obesity epidemic.

In November 2017, the Centers for Disease Control and Prevention (CDC) announced a 5-year partnership with the APhA Foundation to implement Project IMPACT: Diabetes Prevention. The program will “build infrastructure within community pharmacies to expand access to innovative evidence-based lifestyle change program designed to prevent or delay the onset of type 2 diabetes among adults with prediabetes” to be delivered through pharmacists, dieticians, and technicians. It will scale up the existing National Diabetes Prevention Program to cover underserved areas through pharmacies. In addition, the CDC will release a new action guide for pharmacists wanting to get involved in the National Diabetes Prevention Program titled “Rx for the National Diabetes Prevention Program: An Action Guide for the Community Pharmacy Workforce.” Furthermore, the Centers for Medicare and Medicaid Services (CMS) issued a second final rule to implement the Medicare Diabetes Prevention Program (MDPP) that opens reimbursement for pharmacists that coordinate a CDC-approved curriculum. This effort complements campaigns from other healthcare professional organizations to prevent or delay type 2 diabetes such as Prevent Diabetes STAT: Screen, Test, Act Today, which is a 2015 partnership between the American Medical Association and the CDC. Through this national effort, pharmacists can now be recognized for their integral role in advancing and promoting public health.
References


Current APhA Policy & Bylaws:

2013 Pharmacists Providing Primary Care Services

1. APhA advocates for the recognition and utilization of pharmacists as providers to address gaps in primary care.

(JPhA 53(4): 365 July/August 2013)

2013 Ensuring Access to Pharmacists' Services

1. Pharmacists are health care providers who must be recognized and compensated by payers for their professional services.
2. APhA actively supports the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists' services.
3. APhA supports pharmacists' ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
4. APhA supports recognition by payers that compensable pharmacist services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
5. APhA advocates for the development and implementation of a standardized process for verification of pharmacists' credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.
6. APhA advocates for pharmacists' access and contribution to clinical and claims data to support treatment, payment, and health care operations.
7. APhA actively supports the integration of pharmacists' service level and outcome data with other health care provider and claims data.

(JPhA 53(4): 365 July/August 2013)

2012, 1981 Pharmacist Training in Nutrition

1. APhA advocates that all pharmacists become knowledgeable about the subject of nutrition.
2. APhA encourages schools and colleges of pharmacy as well as providers of continuing pharmacy education to offer education and training on the subject of nutrition.


2012, 2005, 1992 The Role of Pharmacists in Public Health Awareness

1. APhA recognizes the unique role and accessibility of pharmacist in public health.
2. APhA encourages pharmacists to provide services, education, and information on public health issues.
3. APhA encourages the development of public health programs for use by pharmacists and student pharmacists.
4. APhA should provide necessary information and materials for student pharmacists and pharmacists to carry out their role in disseminating public health information.
5. APhA encourages organizations to include pharmacists and student pharmacists in the development of public health programs.


2012 Contemporary Pharmacy Practice

1. APhA asserts that pharmacists should have the authority and support to practice to the full extent of their education, training, and experience in delivering patient care in all practice settings and activities.
2. APhA supports continuing efforts that lead to the establishment of a consistent and accurate perception by the public, lawmakers, regulators, and other health care professionals of the role and contemporary practice of pharmacists.
3. APhA supports continued collaboration with stakeholders to facilitate adoption of standardized practice acts, appropriate related laws, and regulations that reflect contemporary pharmacy practice.
4. APhA supports the establishment of multistate pharmacist licensure agreements to address the evolving needs of the pharmacy profession and pharmacist-provided patient care.

5. APhA urges the development of consensus documents, in collaboration with medical associations and other stakeholders, that recognize and support pharmacists’ roles in patient care as health care providers.

6. APhA urges universal recognition of pharmacists as health care providers and compensation based on the level of patient care provided using standardized and future health care payment models.

**2011 The Role and Contributions of the Pharmacist in Public Health**

1. In concert with the American Public Health Association’s (APhA) 2006 policy statement, “The Role of the Pharmacist in Public Health,” APhA encourages collaboration with APhA and other public health organizations to increase pharmacists’ participation in initiatives designed to meet global, national, regional, state, local, and community health goals.

**2004, 1978 Roles in Health Care for Pharmacist**

1. APhA shall develop and maintain new methods and procedures whereby pharmacists can increase their ability and expand their opportunities to provide health care services.

2. APhA supports legislative and judicial action that confirms pharmacists’ professional rights to perform those functions consistent with APhA’s definition of pharmacy practice and that are necessary to fulfill pharmacists’ professional responsibilities to patients they serve.

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