September 1, 2016

President Andy Biggs
Speaker David Gowan
1700 W. Washington
Phoenix, AZ 85003

Dear President Biggs and Speaker Gowan:

Pursuant to section 32-3104 and 32-3106, Arizona Revised Statues, the Arizona Pharmacy Association (AzPA) hereby submits the attached report requesting an expansion of the scope of practice for the profession of pharmacy. It would include the development of statewide protocols to delegate prescriptive authority to pharmacists for certain preventive health services. The request consists of 5 items:

- Allow Arizona pharmacists to administer Oral Fluoride Varnish to eligible patients according to national guidelines.
- Allow Arizona pharmacists to administer the Tuberculin Skin test (TST) and interpret the results for the purposes of referral for treatment following a positive test according to national guidelines.
- Allow Arizona pharmacists the ability to prescribe over the counter nicotine replacement products as well as FDA approved prescription products indicated to aid in smoking cessation treatment for eligible patients according to national guidelines.
- Allow Arizona pharmacists the ability to prescribe FDA approved prescription medications to eligible patients testing positive for Influenza or Strep Throat consistent with current clinical guidelines.
- Allow Arizona pharmacists the ability to extend a routine, non-controlled, chronic medication for an additional 30-60 days.

The Arizona Pharmacy Association has begun meeting with stakeholders on this proposal with the intention of addressing questions, issues and/or concerns prior to a hearing before the committee of reference. We respectfully request a favorable review of this application.

Sincerely,

Kelly L Fine

Kelly Fine (Ridgway), R.Ph.
Executive Director & CEO
Arizona Pharmacy Association

1. DEFINITION OF THE PROBLEM AND WHY A CHANGE IN SCOPE OF PRACTICE IS NECESSARY INCLUDING THE EXTENT TO WHICH CONSUMERS NEED AND WILL BENEFIT FROM PRACTITIONERS WITH THIS SCOPE OF PRACTICE.

Pharmacists represent the third largest health profession and are remarkably underutilized in the U.S. health care delivery system given their level of education, training, and access to the community. Maximizing the roles and scope of pharmacists to deliver a variety of patient-centered primary care and public health, in collaboration with the health care team, is a proven and existing paradigm of care that can be efficiently implemented. According to a recent comprehensive systematic review of 298 research studies, integrating pharmacists into direct patient care results in favorable outcomes across health care settings and disease states. **Pharmacists with larger roles in patient care improve outcomes, increase access to care (especially for medically underserved and vulnerable populations), shift time for physicians to focus on more critically ill patients in need of physician-based care, improve patient and provider satisfaction, assure patient safety, enhance cost-effectiveness, and clearly advance and improve health care delivery.**[1, 3]

While pharmacists remain committed to assisting patients with access and information related to their prescription medications, pharmacists today are providing a broad spectrum of services, within their scope of practice, including conducting health and wellness testing, managing chronic diseases and performing medication management, administering medications and immunizations, and partnering with hospitals and health systems to advance health and wellness and helping to reduce hospital readmissions.[2]

It should also be noted that pharmacists are one of the most accessible partners on the patient's health care team. Over 250 million people (equivalent to almost the entire U.S. population) walk into a pharmacy every week. The average American lives within 5 miles or less of the nearest community pharmacy. Pharmacies offer convenience, accessibility and extended hours of operation. There are more than 56,000 community retail pharmacy outlets, including chain drug stores, mass merchants, supermarkets and independent drug stores in the United States and more than 1200 here in Arizona alone.

Currently, Arizona pharmacists have the ability to enter into collaborative practice agreements with physicians and nurse practitioners according to ARS 32-1970. A collaborative practice agreement (CPA) is an agreement between one or more prescribers and one or more pharmacists who work within the context of a defined protocol to provide patient care services usually involving medication management services for patients with chronic diseases such as diabetes, high cholesterol, asthma etc. A CPA is site and practice specific. While this is working to help manage patients with previously diagnosed chronic diseases it does not allow a pharmacist to intervene and assist in preventative health screenings and subsequent treatment as patients present in real time at their local pharmacy.

The introduction of statewide protocols across the country has allowed for the integration of pharmacists into the health care delivery system while also allowing them to practice to the full scope of their professional training.

Alternatively, statewide protocols, similar to collaborative practice agreements, enhance a pharmacist's ability to perform patient care services, within defined parameters, to improve public health. The statewide protocol however is published by an empowered state body (e.g. state health department or board of pharmacy) that may be followed by any pharmacist who meets the qualifying criteria specified in the protocol. The protocol is the same for all qualified pharmacists in the state, and thus not site or practice specific. The statewide protocol permits the pharmacist to prescribe medications that are used for preventative care or for acute or self-limiting conditions that require no diagnosis or are easily diagnosed. The necessary skills to provide such services are often those a pharmacist already attained as part of the education provided during pharmacy school. Statewide protocols have the benefit of allowing any pharmacist who meets the qualifications specified in the protocol to implement it into practice.

To date, statewide protocols have been implemented across the country for naloxone (opioid reversal agent), hormonal contraceptives, travel medications (vaccines and medications needed for international travel), smoking cessation products, epinephrine (treat allergic reactions), and tuberculosis testing, among others.[5, 7]

PROPOSAL: Develop Statewide Protocols to Delegate Prescriptive Authority to Pharmacists for Certain Preventive Health Services.

To some, prescriptive authority by pharmacists represents a significant departure from their traditional role of dispensing medications. Nearly all states, however, currently enable pharmacist prescriptive authority in some form or fashion. Such momentum has been building since 1979, when Washington state passed the nation's first collaborative practice authority for pharmacists. Today, 49 states and the District of Columbia enable pharmacist prescriptive authority under collaborative practice agreements (CPAs), standing orders, or statewide protocols.[5, 31, 32, 33]

SERVICE #1: ORAL FLUORIDE VARNISH

ASK:

- Allow Arizona pharmacists to administer Oral Fluoride Varnish to eligible patients according to national guidelines.

RATIONALE:

Tooth decay is one of the most common chronic conditions of childhood in the United States. Untreated tooth decay can cause pain and infections that may lead to problems with eating, speaking, playing, and learning and also negatively impact a person's general health and wellbeing. **During the past 15 years, evidence from population based studies increasingly points to a connection between oral health status and serious major chronic diseases such as cardiovascular disease, diabetes, respiratory disease, stroke, kidney disease and dementia to name a few.[37]**

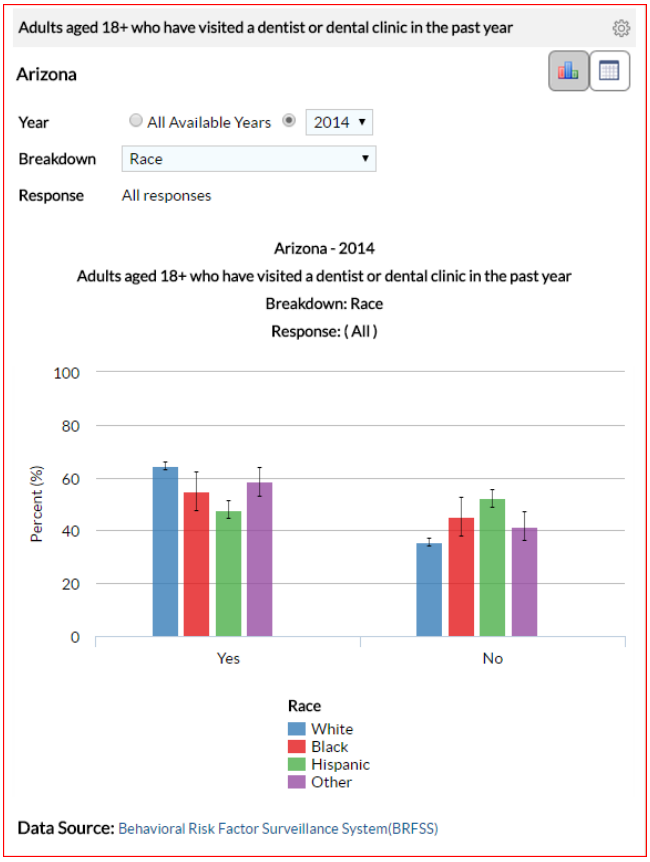
- About 1 of 5 (20%) children aged 5 to 11 years have at least one untreated decayed tooth.
- 1 of 7 (13%) adolescents aged 12 to 19 years have at least one untreated decayed tooth.
- The percentage of children and adolescents aged 5 to 19 years with untreated tooth decay is twice as high for those from low-income families (25%) compared with children from higher-income households (11%).

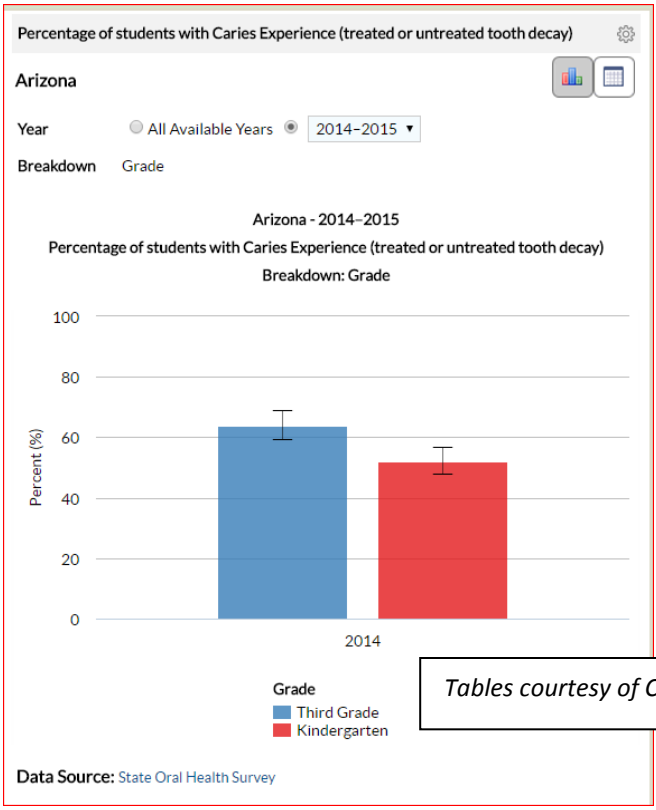
- Less than 1 of 3 children enrolled in Medicaid received at least one preventive dental service in a recent year. Arizona AHCCCS provide only emergency dental services to Medicaid-eligible adults 21 years and older.
- Many adults also have untreated tooth decay (e.g., 28% of those 35 to 44 years and 18% of those 65 and older).
- Over 40 percent of poor adults (20 years and older) have at least one untreated decayed tooth compared to 16 percent of non-poor adults.
- 1 out of 20 middle-aged adults are missing all their teeth.

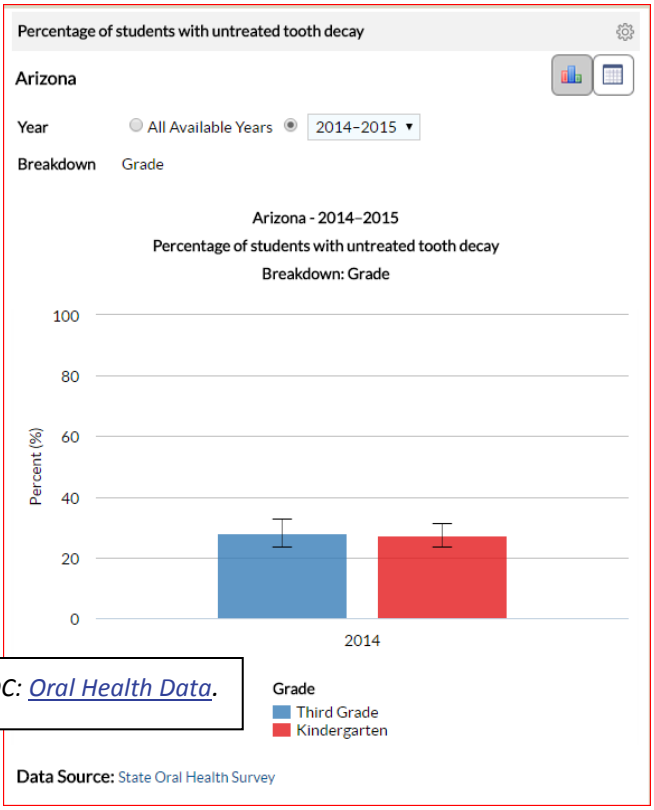
Tooth decay is preventable. Fluoride varnish, a high concentration fluoride coating that is painted on teeth, can prevent about one-third (33%) of decay in the primary teeth. Although the prevalence and severity of dental caries in the United States have decreased substantially during the preceding 3 decades. These decreases in caries prevalence and severity have been uneven across the general population; the burden of disease now is concentrated among certain groups and persons.

Populations believed to be at increased risk for dental caries are those with low socioeconomic status or low levels of parental education, those who do not seek regular dental care, and those without dental insurance or access to dental services.[23, 24, 25]

Overall, blacks, Hispanics, and American Indians and Alaska Natives generally have the poorest oral health of any racial and ethnic groups in the United States. *(See Arizona data below)*







Tables courtesy of CDC: Oral Health Data.

According to the Journal of the American Dental Association, children and adults with moderate or high risk of dental cavities should receive fluoride varnish application at three to six month intervals depending on the age of the patient. [34]

The graphs above show the percentage of Arizona children with untreated tooth decay (30%). Pharmacists can play an important role in providing preventive oral fluoride varnish to prevent further tooth decay meanwhile encouraging the parents to establish a dental home for their children to address existing tooth decay.

TRAINING:

- Initial Training: All Pharmacists will complete an ACPE accredited training program that complies with national guidelines.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

CLINICAL GUIDELINES:

Pharmacists must follow clinically relevant national guidelines:

- ADA's *"Professionally-applied and Prescription-strength, Home-use Topical Fluoride Agents for Caries Prevention Clinical Practice Guideline"*
- American Academy of Pediatric Dentistry *"Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents"*

SAMPLE PROTOCOL:

- Refer to Appendix B

SERVICE #2: TESTING FOR TUBERCULOSIS

ASK:

Allow Arizona pharmacists to administer the Tuberculin Skin test (TST) and interpret the results for the purposes of referral for treatment following a positive test according to national guidelines.

RATIONALE:

In 1989, the Centers for Disease Control and Prevention (CDC) announced the goal of eliminating TB from the United States by the year 2010. A Strategic Plan for the Elimination of Tuberculosis in the United States was published in 1989 and reassessed in 1999 to identify the actions necessary to achieve elimination. The achievement of this goal was thwarted by the TB resurgence that occurred in the late 1980s and early 1990s. This resurgence was fueled by the following factors: [30]

- The onset of the human immunodeficiency virus (HIV) epidemic;
- Increases in immigration of persons from countries where TB disease was common;
- TB transmission in congregate settings;
- The development of multidrug-resistant TB.

Elimination of TB faces some major barriers including: [30]

- TB disease in high-risk populations where it is difficult to detect, diagnose, and treat;
- Persistence and growth of the global TB epidemic; and
- Limitations of current control measures and the need for new tests and treatments, including an effective vaccine.

There were 555 deaths from TB in 2013, the most recent year for which these data are available. This is an 8% increase from the 510 TB deaths in 2012. [35]

Arizona has a higher incidence of TB compared to other states *(See chart below)*. Pharmacists are in a unique position to assist the health department in detecting TB especially in our rural communities where health care services are limited. Pharmacists often times are the only healthcare provider for many miles in some of these rural communities. [30]

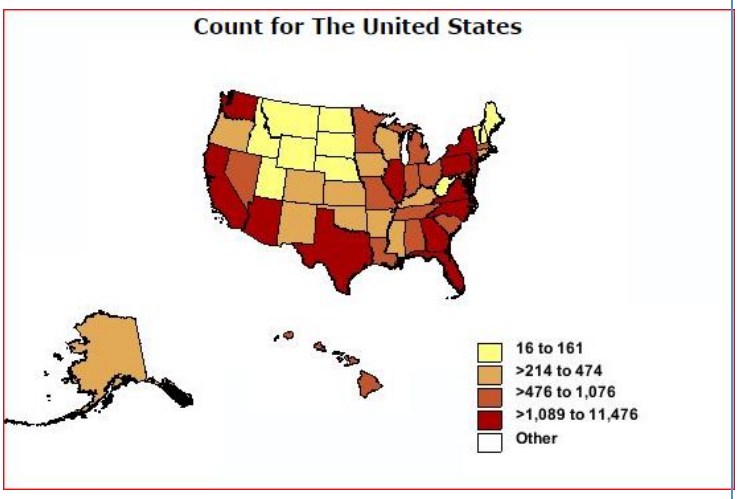
Table 1.1
TB Morbidity
United States, 2006–2011

Year	No.	Rate*
2006	13,727	4.6
2007	13,278	4.4
2008	12,895	4.2
2009	11,528	3.8
2010	11,171	3.6
2011	10,528	3.4

*Cases per 100,000, updated as of June 25, 2012

Tables courtesy of CDC[35]

Reported Tuberculosis in the United States, 2014



TRAINING:

- Prerequisite: Pharmacists must be Immunization Certified.
- Initial Training: All Pharmacists will complete an ACPE accredited training program that complies with national guidelines.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

CLINICAL GUIDELINES:

Pharmacists must follow clinically relevant national guidelines:

- Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings.
- American Thoracic Society and CDC. Diagnostic standards and classification of tuberculosis in adults and children.

SAMPLE PROTOCOL:

- Refer to Appendix B

SERVICE #3: TOBACCO CESSATION:

ASK:

Allow Arizona pharmacists the ability to prescribe over the counter nicotine replacement products as well as FDA approved prescription products indicated to aid in smoking cessation treatment for eligible patients according to national guidelines.

RATIONALE:

Tobacco use is a major preventable cause of premature death and disease worldwide. Approximately 6 million deaths related to tobacco use occur each year, including 600,000 from secondhand smoke. In the United States, an estimated 42.1 million people – about one in five adults – currently smoke, and an estimated 480,000 people die prematurely from diseases caused by smoking or secondhand smoke exposure.

An estimated 69% of current adult smokers want to stop smoking, and 52% reported having made an attempt to quit in the past year.[17] **As a key interface between patients and the healthcare community, pharmacists are well positioned to help patients initiate attempts to quit or complement the cessation efforts initiated by other providers. Unlike most other clinicians, advice from a pharmacist does not require an appointment or medical insurance; as such, pharmacists have the opportunity to reach and assist underserved populations, which exhibit a disproportionately higher incidence of tobacco-related diseases.[18]**

Deaths in Arizona from Smoking	
Adults who die each year from their own smoking	8,300
Kids now under 18 and alive in Arizona who will ultimately die prematurely from smoking	115,000

The Toll of Tobacco in Arizona	
High school students who smoke	10.1% (37,200)
Male high school students who smoke cigars (female use much lower)	13.4%
High school students who use e-cigarettes	27.5%
Kids (under 18) who become new daily smokers each year	4,300
Packs of cigarettes bought or smoked by kids each year	11.0 million
Adults in Arizona who smoke	16.5% (858,800)

Smoking-Caused Monetary Costs in Arizona	
Annual health care costs in Arizona directly caused by smoking	$2.38 billion
Medicaid costs caused by smoking in Arizona	$382.7 million
Residents' state & federal tax burden from smoking-caused government expenditures	$725 per household
Smoking-caused productivity losses in Arizona	$2 billion

Tables courtesy of Tobacco-Free Kids[35]

TRAINING:

- Initial Training: All pharmacists will complete an ACPE accredited training program that complies with current clinical guidelines.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

CLINICAL GUIDELINES:

Pharmacists must follow clinically relevant national guidelines:

- US Department of Health and Human Services *"Treating Tobacco Use and Dependence"*

SAMPLE PROTOCOL:

- Refer to Appendix B

SERVICE #4A: TREATMENT OF PATIENTS WITH POSITIVE RAPID STREP TEST

ASK:

Allow Arizona pharmacists the ability to prescribe FDA approved prescription medications to eligible patients testing positive for Strep Throat consistent with current clinical guidelines.

RATIONALE:

Approximately 15 million patients seek care for the relief of sore throat symptoms every year and many consult a community pharmacist before other healthcare practitioners due to their accessibility. Pharmacists have a unique opportunity to provide timely access to testing for Strep Throat (caused by Group A beta-hemolytic streptococcus (GABHS), providing the prompt initiation of antimicrobial therapy to eligible patients. GABHS pharyngitis (Strep throat) is the only commonly occurring form of acute pharyngitis for which antibiotic therapy is clearly indicated.

Antibiotic therapy has been shown to shorten the duration of illness by one to two days, reduce the rate of transmission, and prevent secondary complications such as acute rheumatic fever, peritonsillar abscess, glomerulonephritis, otitis media, sinusitis, and mastoiditis. In addition, the prompt administration of therapy and early amelioration of symptoms positively impacts patient quality of life and may also reduce lost school and work days. Rapid strep test results can be obtained in minutes, whereas traditional agar culture methods provide results in 24 to 48 hours.

Offering rapid strep testing in the community pharmacy setting would improve patient care by providing prompt results in conjunction with the immediate initiation of antibiotic or appropriate over-the-counter symptomatic therapy. [8]

Rapid strep tests are considered CLIA waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS). CLIA requires that waived tests must be simple and have a low risk for erroneous results. [28] With pharmacists already having the authority to perform these tests in the pharmacy, they are in the optimal position to begin treatment for patients who test positive. The most current information on FDA-cleared waived tests can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm

Pharmacists are currently authorized to administer CLIA Waived Laboratory Tests.

TRAINING:

- Initial Training: All pharmacists will complete an ACPE accredited training program that complies with national guidelines and includes training on the use of associated point of care testing devices.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

CLINICAL GUIDELINES:
Pharmacists must follow clinically relevant national guidelines:

- Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: Infectious Diseases Society of America.

SAMPLE PROTOCOL:

- Refer to Appendix B

SERVICE #4B: TREATMENT OF PATIENTS WITH POSITIVE RAPID INFLUENZA TEST RESULTS

ASK:
Allow Arizona pharmacists the ability to prescribe FDA approved prescription medications to eligible patients testing positive for Influenza consistent with current clinical guidelines.

RATIONALE:
The number of influenza-associated deaths varies substantially by year, influenza virus type and subtype, and age group. In a study of influenza seasons from 1976-77 through 2006-07, the estimated number of annual influenza-associated deaths from respiratory and circulatory causes ranged from a low of 3,349 (1985-86 season) to a high of 48,614 (2003-04 season), with an average of 23,607 annual influenza-associated deaths.

Influenza outbreaks and epidemics pose ongoing risks to global human public health. Recently, human infections with A/H5N1 avian influenza viruses have heightened the potential for the emergence of an influenza A virus with pandemic potential. In recent years commercial influenza rapid diagnostic tests have become available. These are mostly antigen detection tests, which can produce results within 30 minutes. They can provide results in a clinically relevant time frame to complement the use of antiviral medications for treatment and chemoprophylaxis of influenza. [12]

Clinical trials and observational data show that early antiviral treatment can shorten the duration of fever and illness symptoms, and may reduce the risk of complications from influenza (e.g., otitis media in young children, pneumonia, and respiratory failure). Clinical benefit is greatest when antiviral treatment is administered early, especially within 48 hours of influenza illness onset.

Rapid flu tests are also considered CLIA waived and something the pharmacists can already perform in their pharmacies again putting them on the front lines for being able to begin treatment for patients who test positive. According to the CDC, when indicated, antiviral treatment should be started as soon as possible after illness onset, ideally within 48 hours of symptom onset. Decisions about starting antiviral treatment should not wait for laboratory confirmation of influenza. [14]

TRAINING:

- Initial Training: All pharmacists will complete an ACPE accredited training program that complies with national guidelines.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

CLINICAL GUIDELINES:
Pharmacists must follow clinically relevant national guidelines:

- CDC: Influenza Antiviral Medications: Summary for Clinicians. http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm
- Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP).
- Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America.

SERVICE #5: REFILL AUTHORIZATIONS

ASK:
Allow Arizona pharmacists the ability to extend a routine, non-controlled, chronic medication for an additional 30-60 days.

RATIONALE:
Pharmacist are often faced with patients that present in the evening, on holidays or on weekends that are in need of additional refills. The patient may be leaving town on business or vacation and if the prescriber cannot be reached the patient will go without their medication for an extended period of time. To help ensure patients are adherent to their prescribed medications, the ability for pharmacists to authorize a one-time refill of a patient's routine chronic medication when the prescriber cannot be reached is a common sense approach to improve patient care.

Pharmacists that refill a prescription this manner must first attempt to contact the prescriber to obtain refills. If the prescriber cannot be reached and the patient is leaving town or doesn't have a sufficient supply to last them until the prescriber can be reached the pharmacist would be able to authorize a one time refill. The pharmacist would send the necessary documentation to the PCP for their records and inform the patient that they need to contact their prescriber and schedule an appointment for any additional refills.

EXCLUSIONS:

- Will not apply to prescriptions for controlled substances.
- Will not apply to medications for acute conditions.
- Patients have to be stable on the medications with no changes in the dose or frequency of the medication for a minimum of 12 months.

STATEWIDE PROTOCOL OVERSIGHT AND ADVISORY COMMITTEE:

The board of pharmacy shall appoint an advisory committee to assist the board in developing any statewide protocol exclusions. This is similar to the measure taken when the Legislature authorized pharmacists to immunize adults without a prescription.

In addition, the board, by rule, shall establish and maintain a list of statewide protocols that may be utilized pharmacists.

2. PUBLIC CONFIDENCE IN PHARMACIST'S COMPETENCE:

Pharmacists continue to be ranked number 2 as the most trusted health care professional in the United States. The Arizona State Board of Pharmacy protects the health, safety and welfare of the public by regulating the practice of pharmacy. The Board makes laws and adopts rules that are necessary for the protection of the public and that pertain to the practice of pharmacy. The Board issues licenses to pharmacists, pharmacy interns and pharmacy technicians, conducts compliance inspections of permitted facilities, investigates complaints and adjudicates violations of applicants state and federal laws and rules. Effective quality assurance standards exist in the practice of pharmacy by oversight by the State Board. Additionally, pharmacists will be required by law to follow national clinical guidelines and required to meet initial certification and annual continuing education requirements related to the services they will be performing.

Lastly, the Accreditation Council for Pharmacy Education currently mandate in their current standard that all Colleges of Pharmacy follow, *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree,* which include baseline curriculum necessary to prepare pharmacists to provide these services with minimal post graduate training.

3. EVIDENCE THAT STATE APPROVED EDUCATIONAL PROGRAMS PROVIDE OR ARE WILLING TO PROVIDE CORE CURRICULUM ADEQUATE TO PREPARE PRACTITIONERS AT THE PROPOSED LEVEL.

All pharmacy graduates earn a Doctor of Pharmacy (Pharm.D.) Degree. The Doctor of Pharmacy degree program requires at least 2-years of specific pre-professional (undergraduate) coursework followed by 4-academic years of professional study.

Pharmacists are considered the medication experts.
Pharmacists receive at least 36 hours of didactic credits in pharmacology in addition to 1500 hours of advanced practice clinical rotations.

Pharm.D. curriculum pertaining to drug therapy specifically:

- 7-credit units of Pharmacology
- 18-credit units of Pharmacotherapeutics
- 2-credit units of Self-Care Pharmacotherapeutics
- 6-credit units of Pharmacokinetics
- 3-credit units of Advanced Patient Care (capstone course where students put it all together)
- 1500 hours of clinical advanced practice rotations

Pharmacology is the science that deals with the origin, nature, chemistry, effects, and uses of drugs; it includes pharmacognosy *(A branch of pharmacology concerned with the physical characteristics and botanic and animal sources of crude drugs)*, pharmacokinetics *(study of the movement of drugs in the body, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion)* , pharmacodynamics *(study of the biochemical and physiological effects of drugs and the mechanisms of their actions, including the correlation of their actions and effects with their chemical structure)*, pharmacotherapeutics (the study of the therapeutic uses and effects of drugs) and toxicology

(The science of poisons, including their source, chemical composition, action, tests, and antidotes). Physicians know a great deal about pharmacology and toxicology; yet, as the expert about drugs, the pharmacist must maintain this knowledge to an even greater extent.[21, 22]

All college of pharmacy are required to comply with the Accreditation Council for Pharmacy Education (ACPE) Standards. In the current ACPE standards, *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree,* Standard 2 supports the fact that pharmacists are educated on preventative health services in addition to their education on drug therapy and chronic diseases.[20]

Standard 2: Essentials for Practice and Care
The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to provide patient-centered care, manage medication use systems, promote health and wellness, and describe the influence of population-based care on patient-centered care.

- Key Elements:
  - **2.1. Patient-centered care – The graduate is able to provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).**
  - 2.2. Medication use systems management – The graduate is able to manage patient healthcare needs using human, financial, technological, and physical resources to optimize the safety and efficacy of medication use systems.
  - **2.3. Health and wellness – The graduate is able to design prevention, intervention, and educational strategies for individuals and communities to manage chronic disease and improve health and wellness.**
  - 2.4. Population-based care – The graduate is able to describe how population-based care influences patient-centered care and the development of practice guidelines and evidence-based best practices.

4. POTENTIAL HARM TO THE PUBLIC

(a) To what extent if any does an increase in scope of practice restrict entry into practice?
The proposed sunrise application does not restrict entry into the profession. The pharmacy curriculum adequately covered the necessary baseline knowledge to perform these services with minimal post graduate training.

(b) Does the proposed legislation require pharmacists in other states who migrate to this state to qualify in the same manner as state applicants for licensure?
Pharmacists moving to Arizona will have to formally reciprocate their license and take the state law exam. In addition they will have to complete all necessary training and continuing education that is required of Arizona pharmacists.

(c) Do other states have substantially equivalent requirements for licensure as those in this state?
Yes the licensure requirements for pharmacists are the same in all 49 states and the District of Columbia. We have to pass the same national examination NAPLEX and the corresponding state law exam for each state we wish to be licensed.

In addition the college of pharmacy accrediting body, the Accreditation Council for Pharmacy Education, employs the same standards on every school of pharmacy in the United States so graduates are receiving an equivalent curriculum in all states.

5. COST TO THE STATE AND GENERAL PUBLIC

Health care cost impact is difficult to calculate. However, there should be a significant decrease in cost to the Arizona health care system in general due to improved access to preventive health services for those who may not have access to any other health care provider. Additionally, savings will come from lowering disease rates thereby decreasing unnecessary physician and emergency room visits. Implementation costs to the state should be minimal. Board of Pharmacy regulations as they exist, already oversees the pharmacist according to their scope of practice.

REFERENCES:

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8. Rapid Strep A Testing with Prescriptive Authority http://communitypharmacyfoundation.org/grants/grants_list_details.asp?grants_id=70126
9. Rapid Antigen Group A Streptococcus Test to Diagnose Pharyngitis: A Systematic Review and Meta-Analysis. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4219770/
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APPENDIX A: COLLABORATIVE PRACTICE AGREEMENTS VS. STATEWIDE PROTOCOLS

Collaborative Practice Agreement	Both	Statewide Protocol
Individual agreement negotiated between prescribers and pharmacists. Requires pharmacist(s) to identify a collaborating physician.	Expand the depth and breadth of services pharmacists can provide to patients and as part of the healthcare team.	Standardized agreement for any willing and qualified pharmacist in the state.
Applies to a defined pharmacist or group of pharmacists.	Specific authority is variable state to state.	Could apply to all pharmacists in the state who meet the requirements of the protocol.
Could be: patient-specific, disease state-specific, or patient population-specific depending on state regulations and the conditions of the agreement.	Additional pharmacist training/education may be needed to participate.	Not patient-, pharmacist-, or provider-specific. Instead, the protocol defines the patient populations eligible for services, as well as the minimum qualifications of pharmacists in order to participate. Educational training is consistent with national evidence based guidelines.
48 states + the District of Columbia allow CPAs. Services may be broad and address a variety of conditions, both acute and chronic.	Both enhance care for the patient.	26+ states have established 1 or more protocols already in place. To date, protocols have tended to focus on preventative health services, such as naloxone, oral fluoride varnishes, TB testing, rapid flu and strep tests, hormonal contraception, travel meds, and smoking cessation therapies.
Pharmacist authority under the agreement may or may not be protocol driven.	Opportunity to optimally use pharmacists' capabilities to improve individuals' health and achieve public health goals.	Protocol-driven authority.
Authority provided by the CPA is at the discretion of the collaborating practitioner based on local clinical needs. Parameters are modifiable based on the negotiations of the collaborating practitioners.		Pharmacist follows a protocol which is usually developed by the Board of Pharmacy, Department of Health, or jointly with the Board of Medicine. Parameters are not modifiable by individual pharmacists.

APPENDIX B

SAMPLE PROTOCOL GUIDELINES: TOBACCO CESSATION

PURPOSE: To assist Pharmacists in providing safe and effective tobacco cessation drug therapy.

GUIDELINES: All pharmacists participating in prescriptive authority for tobacco cessation drug therapy will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guidelines.

PHARMACIST MANDATES:

- Pharmacists will document all prescription orders and with patient authorization, provide notice to the patient's primary practitioner within 72 hours of writing the prescription.
- Pharmacists will take patient histories and consult with patients' medical providers as appropriate.
- Pharmacists will follow up with patients according to recommended guidelines.

GENERAL RECOMMENDATIONS:

- Pharmacists will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline – Treating Tobacco Use and Dependence.
- Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco.
- Pharmacists will include an education component including both face to face and telephonic/electronic interventions to patients.

EDUCATION AND TRAINING:

- Initial Training: The pharmacist must successfully complete an ACPE accredited training program that complies with the US Department of Health and Human Services, Public Health Services, Clinical Practice Guidelines.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

HEALTH SCREENING: Must include the following

- Patient history
- Family history
- Current living environment
- Concurrent illness
- Allergies and hypersensitivities
- Medication history

APPROVED MEDICATIONS:

- Over the counter and prescription only nicotine replacement therapies: patch, gum, inhaler, lozenge, nasal spray
- Bupropion, Varenicline
- Any other FDA approved products for tobacco cessation unless prohibited by this protocol

RECORDS:

- The prescribing pharmacist must generate a written or electronic prescription for any medication prescribed and maintain the hardcopy according to current state laws.

CONTRAINDICATIONS AND PRECAUTIONS:

- Current seizure disorder for bupropion therapy
- Current eating disorder for bupropion therapy
- Current or past history of mental illness for bupropion or varenicline therapy
- Refer to clinical practice guidelines and FDA package inserts

PATIENT EDUCATION:

- Shall include withdrawal symptoms, drug information including side effects, and lifestyle modifications.
- Bupropion and Varenicline: Must counsel all patients on black box warning according to FDA package insert.

REFERRAL:

- Patients less than 16 years of age
- Pregnancy

SAMPLE PROTOCOL GUIDELINES: TUBERCULIN SKIN TESTING (TST)

PURPOSE: To assist Pharmacists in providing safe and effective TB skin test screenings.

GUIDELINES: All pharmacists will follow:

- Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings.
- American Thoracic Society and CDC. Diagnostic standards and classification of tuberculosis in adults and children.

PHARMACIST MANDATES:

- Pharmacist will follow all Arizona laws relating to Tuberculosis Control as defined in ARS 36-711 through 738 as well as AAC R9-10-113.
- Pharmacists will document all patient authorizations and provide notice of positive test results to the patient's primary practitioner within 24 hours.
- Pharmacists with prescriptive authority will take patient histories and consult with patients' medical providers as appropriate.
- Pharmacists with prescriptive authority will follow patients according to recommended guidelines.

EDUCATION AND TRAINING:

- Initial Training: The pharmacist must successfully complete an ACPE accredited training program that complies with the Centers for Disease Control recommendations.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

APPROVED TESTS:

- FDA approved and CDC recommended products for tuberculin skin testing.

RECORDS:

- The prescribing pharmacist must generate a written or electronic prescription for any TB test administered.
- Informed consent must be documented in accordance with the approved protocol for TB testing and a record of such consent maintained in the pharmacy for a period of at least three years.
- Documentation of test and result must be maintained by the pharmacist indefinitely.

NOTIFICATION:

- Upon signed consent of the patient, the pharmacist shall notify the patient's designated physician or primary care provider and the department of health of any positive TB test within 24 hours.

HEALTH SCREENING: must include the following

- Patient history
- Family history
- Current living environment
- Concurrent illness
- Allergies and hypersensitivities

- Medication history
- Any vaccines received in the last 4 weeks

CONTRAINDICATIONS AND PRECAUTIONS:

- Receipt of live virus vaccine less than 4 weeks prior to TST unless preformed on same day.
- Refer to clinical practice guidelines.

PATIENT EDUCATION:

- Shall include the following: Skin test reaction drug information.

REFERRAL:

- All positive reports must be sent to the Department of Health and to the patient's primary care practitioner for follow up within 24 hours.
- Patient test results, either positive or negative, may be provided to others upon patient request. This can include employers when testing is provided as a requirement for employment.

SAMPLE PROTOCOL GUIDELINES: ORAL HEALTH ASSESSMENT AND FLUORIDE VARNISH

PURPOSE:

- Oral health assessments assist in identifying risk for early childhood caries and spotting early decay. The purpose of applying fluoride varnish is to retard, arrest, and reverse the process of cavity formation. Assessments should begin at the eruption of the first tooth and no later than 6 months of age and parents should be encouraged to find a dental home.

GUIDELINES:

- All pharmacists will follow:
    - All pharmacists participating in prescriptive authority for Fluoride Varnish will follow ADA's *"Professionally-applied and Prescription-strength, Home-use Topical Fluoride Agents for Caries Prevention Clinical Practice Guideline"* and American Academy of Pediatric Dentistry "*Guideline on Caries-risk Assessment and Management for Infants, Children, and Adolescents*"

PHARMACIST MANDATES:

- Pharmacists will document all prescription orders and with patient authorization, provide notice of Fluoride Varnish to the patient's Dentist within 7 days.
- Pharmacists with prescriptive authority will take patient histories and consult with patients' medical providers as appropriate.
- Pharmacists with prescriptive authority will follow patients according to recommended guidelines.

EDUCATION AND TRAINING:

- Initial Training: The pharmacist must successfully complete an ACPE accredited training program that complies with the Centers for Disease Control recommendations.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

AUTHORIZED DRUGS:

- FDA approved oral fluoride varnish with concentration of 2.26%

RECORDS:

- The prescribing pharmacist must generate a written or electronic prescription for any Fluoride Varnish
- Informed consent must be documented in accordance with the approved protocol for Fluoride Varnish and a record of such consent maintained in the pharmacy for a period of at least three years.

NOTIFICATION:

- Upon signed consent of the patient, the pharmacist shall notify the patient's designated dentist of any Fluoride Varnish application.

ASSESSMENT FORMS:

- UTILIZE ADA Caries Risk Assessment Forms
  http://www.ada.org/~/media/ADA/Member%20Center/FIles/topics_caries_under6.ashx

CONTRAINDICATIONS FOR FLUORIDE VARNISH APPLICATION:

- Children with a low risk of cavity formation who consume optimally fluoridated water or children who receive routine fluoride treatments through a dental office

POST-APPLICATION INSTRUCTIONS:

Tell the family that the child should:

- Not have hot foods or beverages and avoid hard foods for the rest of the day. The child may eat warm or cold foods.
- Not brush or floss until the next morning

Remember:

- Even though the child may fuss, the varnish application is not unpleasant or painful.
- Varnish must be applied more than once per year to be effective. For high risk children, apply varnish every three to four months.

SAMPLE PROTOCOL GUIDELINES: INFLUENZA AND GROUP A STREP POINT-OF-CARE TESTING

PURPOSE:

- Allow Arizona pharmacists the ability to prescribe FDA approved prescription medications to eligible patients testing positive for Strep or Influenza for eligible patients consistent with current clinical guidelines.

GUIDELINES:

All pharmacists will follow:

Strep:

- Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. Clin Infect Dis. (2012) 55 (10): e86-e102. http://cid.oxfordjournals.org/content/55/10/e86

Influenza:

- CDC 2015-2016: Influenza Antiviral Medications: Summary for Clinicians. http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm
- Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP).
- Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America. Clin Infect Dis.-2009-Harper-1003-32

APPROVED TESTS:

Pharmacists are authorized to administer any FDA approved CLIA waived test for the following:

- Influenza Testing
- Group A Streptococcus (GAS) Testing

PHARMACIST MANDATES:

- Pharmacists must have a valid pharmacist license in the state of Arizona, have completed an ACPE accredited certification course for performing Point-of-Care tests and interpreting their results and maintain current CPR certification.
- Only pharmacists or interns certified to perform Point-of-Care tests shall administer the tests. The results of the test must also be evaluated by the certified pharmacist.
- Prior to prescribing of any medication, appropriate screening will be conducted to rule out clinical instability. A standard form will be used to document patient pre-screening and Point-of-Care test results.
- The pharmacist will follow the guidelines for testing found in the package materials provided with each test and will maintain a current and legal CLIA waiver.
- The pharmacist will report the findings of the tests indicated above as well as any medication prescribed to the patient's identified primary care provider within 48 hours.

EDUCATION AND TRAINING:

- Initial Training: The pharmacist must successfully complete an ACPE accredited training program that complies with the Centers for Disease Control recommendations.
- Continuing Education: The pharmacist must successfully complete 2 hours of ACPE accredited CE programs upon license renewal.

PATIENT INCLUSION CRITERIA-INFLUENZA:

Under this protocol, pharmacists may dispense a fixed dose of an antiviral to patients who meet the following criteria according to clinical guidelines and FDA package insert:

- Complain of signs/symptoms consistent with influenza-like illness (fever/feverish AND cough OR sore throat) that began within the past 48 hours
- Positive nasal swab Point-of-Care influenza test
- Clinical stability, defined as the absence of the following:
    - Altered mental status
    - Systolic blood pressure < 90mmHg or diastolic blood pressure <60mmHg
    - Pulse > 125 beats/minute
    - Respiratory rate > 30 breaths/minute
    - Oxygen saturation < 92% on room air
    - Temperature > 103°F

PATIENT INCLUSION CRITERIA-STREP:

Under this protocol, pharmacists may dispense a fixed dose of an antibiotic to patients who meet the following criteria according to clinical guidelines and FDA package insert:

- Complain of signs/symptoms consistent with Group A Streptococcus (GAS) illness (sudden onset of sore throat, fever, etc.)
    - Sudden onset of sore throat
    - Fever
    - Headache
- Positive throat swab Point-of-Care strep test
- Clinical stability defined by the absence of the following:
    - Altered mental status
    - Systolic blood pressure <90mmgHg or diastolic blood pressure <60mmgHg
    - Pulse >125 beats/minute
    - Respiratory rate > 30 breaths/minute
    - Oxygen saturation <92% on room air
    - Temperature >103° F

AUTHORIZED DRUGS:

Pharmacists may prescribe the following according to current guidelines from the US Centers for Disease Control (CDC), Clinical guidelines and/or and FDA approved package information specific to each medication.

- Antivirals approved by the FDA for the treatment of Influenza
- Antibiotics approved by the FDA for the treatment of Strep A

RECORDS:

- The prescribing pharmacist must generate a written or electronic prescription for any antiviral or antibiotic dispensed.
- Informed consent must be documented in accordance with the approved protocol and a record of such consent maintained in the pharmacy for a period of at least three years.

NOTIFICATION:

- Upon signed consent of the patient, the pharmacist shall notify the patient's designated physician or primary care provider of any positive test results and subsequently within 48 hours.

FOLLOW-UP PLAN FOR POSITIVE TESTS:

- The pharmacist will contact the patient for follow-up assessment 24-48 hours after initial presentation to assess clinical status and the need for any additional medical interventions.
- If the patient's condition has not stabilized, is worsening, or additional symptoms have emerged, the patient will be instructed to contact their primary care physician and/or be referred to an urgent care center as appropriate.

FOLLOW-UP PLAN FOR NEGATIVE TEST:

- Patient counseling by pharmacist on false negative rates –referral to primary care provider, urgent or quick care clinics if patient presents with symptoms and/or clinically appropriate.
- Pharmacist will recommend influenza vaccine as appropriate for patient.
- The pharmacist or technician will contact the patient for follow-up assessment 24-48 hours after initial presentation.