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ERRATA: In the Volume 63, No. 4 Fall issue of California Pharmacist, manuscript entitled, "Dentists and Pharmacists: Paradigm Shifts and Interprofessional Collaborative Practice Models," Figure 3 was printed incorrectly. To view the correct figure, please view page 54.
The Advanced Practice Pharmacist License Has Arrived!

We have spent considerable time and effort in this Journal writing about the array of opportunities that pharmacists have to expand their practices to include pharmacist-delivered patient care services (e.g., clinical services). These opportunities are the outgrowth of the legislative and regulatory victories that the California Pharmacists Association (CPhA) has achieved over the past three years.

As we turn the corner into 2017, I am thrilled to share some very exciting information related to the final component of CPhA-sponsored legislative bill SB 493 (Hernandez). In late December 2016, the California State Board of Pharmacy announced that it had concluded the rulemaking and would begin issuing the broadest component of SB 493, the Advanced Practice Pharmacist license.

Advanced practice licensed pharmacists are authorized to perform patient assessments, order and interpret drug-therapy-related tests, participate in the evaluation and management of disease and health conditions, refer patients to other providers, and initiate, adjust, or discontinue drug therapy for patients.

To become an Advanced Practice Pharmacist, applicants must be a California-licensed pharmacist in good standing with the California State Board of Pharmacy and must meet any two of the following three criteria. These criteria are required as a component of the legislation and can be found in California Business and Professions Code section 4210(a)(2):

- Earn a practice-based certification in a relevant area of practice from an organization recognized by the Accreditation Council for Pharmacy Education or the National Commission for Certifying Agencies.
- Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes providing direct patient care services with interdisciplinary health-care teams.
- Provide clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

To assist pharmacists with meeting the first criteria (practice-based certification program), CPhA and the National Association of Chain Drug Stores (NACDS) also announced in December 2016 the launch of a new certificate training program that will meet the Board of Pharmacy requirement. The program, which is open to pharmacists from all practice settings, provides a pathway for pharmacists who have not completed a residency or who do not have a year of experience to become an Advanced Practice Pharmacist.

The Advanced Practice Pharmacist Certificate Training Program is the product of CPhA's Institute for Advanced Pharmacy Practice and was developed in close collaboration with NACDS. The accredited certificate program consists of thirty-eight (38) hours; including thirty (30) hours of home-study and eight (8) hours of in-person skills demonstration and assessment.

For more information on the advanced practice pharmacist regulatory and application process, please visit the California State Board of Pharmacy web page at www.pharmacy.ca.gov/applicants/app.shtml.

For more information on the Advanced Practice Pharmacist Certificate Training Program, please visit the CPhA webpage at appharmacist.com.

Sincerely,

Jon R. Roth, CAE
Chief Executive Officer
Special Acknowledgments

Thank you to the authors of 2016's California Pharmacist!

In order to achieve content and editorial excellence, California Pharmacist relies on the contributions of authors. It is with utmost gratitude that we celebrate the authors for their time, efforts, and dedication to the Journal. Thank you for your contributions!

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As we take a look back and reflect on this past year, 2016 was definitely a rollercoaster of a year. Across the globe, we saw the passing of icon after icon, from legendary performers to childhood celebrity heroes as well as former world leaders and fantasy world royalty; the Grim Reaper was definitely working overtime this past year. Across the nation, we saw – after a circus of an election process – a 45th president of the United States elected to office. Across the state, we finally got to see the Advanced Practice Pharmacist (APP) designation come to life as well as seeing our first steps in securing payment for pharmacist services. Some people have said 2016 will go down as the worst year ever, while others say it has been a terrific year. Whatever the case, the one constant, even in times of uncertainty, despair, and chaos, is that the California Pharmacists Association (CPhA) will continue to push forward, fight for pharmacists, and create new hope.

When we look at hope, we see possibilities. Put possibilities and hope together and we get opportunities. As we move on from 2016 and into 2017, I am excited to see the opportunities that were created last year that will forever change the landscape of pharmacy practice in California. The Advanced Practice Pharmacist designation is now rolled out in California, and it’s exciting to see what we thought up in 2012 is now benefiting pharmacists, our profession, and, most importantly, our patients. Educational programs for certification are now underway, and I urge my colleagues to take on this opportunity and take our profession to the next level.

Payment for pharmacist services remains a top priority at CPhA, and we will continue the fight this year. It was a great thrill to see that California took the first steps in securing payment for pharmacist services via the Medi-Cal system when AB 1114 was signed last year. As we push forward, we will continue to work on more payors adding pharmacists into the system as well as expanding the clinical services that pharmacists can and will be paid for.

Even our allied organization, the California Society of Health-System Pharmacists (CSHP), underwent a change and brought in a new CEO in Loriann DeMartini. I congratulate her in her new role and wish her the very best. As we look forward, we are excited to collaborate more closely together and take California pharmacy to newer heights. As we have seen time and time again, when we work together we can move mountains and move our profession where we want it to be.

The jury may still be out on how great or disastrous of a year 2016 was, and probably only time will tell. But in the pharmacy world, from all the great things we achieved, I’ll say it was a successful year. It has been an honor and a privilege to represent such a great group of health care providers by serving as your president this past year. It was great to visit so many locals and schools of pharmacy and see the heart and soul of our organization doing the amazing work that continues our legacy since 1869. I thank you full-heartedly for this tremendous opportunity, and I am truly excited to see the achievements yet to come. As we will soon transition to our next CPhA President, I want to leave you with one final message and call to action that I have been putting forth this last year in these editorials. Continue to be engaged, build relationships, take control of your life, and have hope – that way you will have created endless possibilities to seize an opportunity of a lifetime. Stay inspired, my friends!
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Zonisamide for the Management of Essential Tremor: An Illustrative Case Report on Long-Term Effectiveness

By Jack J. Chen, PharmD, BCPS, CGP, FASCP, FCCP, FCPhA

Abstract
Essential tremor, a common adult pathologic tremor disorder, is characterized by action tremors. Mainstays of treatment include gabapentin, primidone, and propranolol. However, many patients obtain insufficient benefit or do not tolerate these medications (especially the elderly). Short-term studies demonstrate that zonisamide may be effective for essential tremor; however, long-term data are lacking. This is a case report of an 83-year-old, right-handed man with essential tremor of the upper extremities and head who previously failed several pharmacological treatments (defined as obtaining inadequate benefit from maximum tolerated dose) with gabapentin, nadalol, propranolol, and primidone and was initiated on zonisamide monotherapy. Long-term zonisamide therapy (200 mg daily) was well tolerated in this elderly patient and associated with clinically significant improvement of upper extremity tremor and clinically modest improvement in head tremor. The beneficial effects and tolerability were sustained over nearly 28 months of follow-up treatment.

Introduction and Case Report
Essential tremor (ET) is a common pathologic tremor characterized by action tremors, particularly kinetic and postural tremors. The term “essential” implies that ET is an inherent or inherited condition. In general, approximately 50% of patients will report a positive family history of tremor. Pathologic action tremors occur with voluntary contraction of a muscle and are further subdivided into postural, isometric, and kinetic tremors. A postural tremor is triggered upon voluntarily attempting to maintain a position against the force of gravity. For example, postural tremor of the upper extremities can be detected by having the patient extend their arms forward with fingers extended. An isometric tremor occurs with muscle contraction against a rigid stationary object (e.g., when making a fist, flexing the wrist against a flat surface, or squeezing the examiner’s fingers). A kinetic tremor occurs during voluntary movement and can be elicited by having the patient perform a finger-to-nose test, having patients sign their name, write a sentence, draw freehand spirals, or drink water from a cup. When severe, these tremors can be functionally disabling.

The hallmark symptom of ET is a bilateral postural or kinetic tremor affecting the distal upper extremities characterized by an insidious onset. However, tremor at rest (i.e., tremor present when a body part is fully supported against gravity in a manner not necessitating voluntary activation of skeletal muscles) is not uncommon. The second most frequent body part affected is the head. Essential tremor of the head is characterized by a horizontal “no-no” tremor pattern or a vertical “yes-yes” pattern. Other body parts, such as the legs, chin, trunk, tongue, soft palate, and, rarely, the lips and eyebrows, may also be affected.

The severity of ET is often assessed by the use of drawing or writing samples (e.g., having the patient draw spirals or write sentences). These tests provide an illustration of tremor fluctuation and magnitude. For patients with tremor that significantly interferes with daily activities, long-term pharmacotherapy should be considered. Gabapentin, propranolol, and primidone have been
well studied and are effective.\textsuperscript{2,3} Less well studied but potentially beneficial agents include benzodiazepines and topiramate. Thalamic deep brain stimulation is effective, but reserved for medically refractory ET.

This is a case report of a very elderly patient with medication-resistant essential tremor who obtained clinically significant long-term improvement from zonisamide monotherapy.

HD was an 83-year-old, right-handed male with essential tremor of the head and both upper extremities. On the initial clinic visit, the patient reported onset of mild tremor at approximately age 63 years that affected both hands, but he was not sufficiently bothered by symptoms to seek treatment at that time. At the age of 79 years, his upper extremity tremors became bothersome. Approximately six to eight months prior to the initial clinic visit, the patient noticed development of a head tremor.

The patient complained of difficulty performing simple daily activities such as holding a glass of liquid or handling utensils without spilling liquid or food due to the intensity and amplitude of tremor. He required both hands to hold a glass of liquid and often used a straw to drink in order not to spill. He utilized weighted utensils to assist with eating meals. The patient’s mother had a history of tremor of unknown cause. The patient was retired. His past medical history included hypertension, heart disease, and depression. At the time of examination, vital signs were within normal ranges, and his calculated creatinine clearance was 54 mL/min.

Neurological and physical examination revealed normal speech and extracranial movements, and no pronator drift, muscle weakness, dystonia, or resting tremor. Aside from tremor, the patient exhibited no signs or symptoms of parkinsonism or other neurologic diseases. The patient had intermittent, variable amplitude, horizontal head tremor without dystonic posturing. He also experienced moderate-amplitude and low-frequency postural and action tremor affecting both upper extremities, predominant distally (i.e., hands). His medications included celecoxib, digoxin, furosemide, indapamide, lansoprazole, lisopril/hydrochlorothiazide, paroxetine, and sucralfate. The patient was not taking any medication for essential tremor. However, previous medications for essential tremor included nadolol and propranolol, which improved tremor but were discontinued due to adverse effects (mood swings and irritability); primidone, which was initially helpful but discontinued due to lightheadedness and falls; and gabapentin, which was discontinued due to lack of efficacy and dizziness. The patient was not a candidate for thalamic deep brain stimulation due to age and cardiovascular comorbidities.

HD was started on zonisamide 100 mg at bedtime for two weeks. Aside from a transient and mild daytime sleepiness, the dose was well tolerated and increased to 200 mg at bedtime. At the subsequent follow-up two weeks later, the patient’s handwriting and spiral and line drawings had significantly improved (Figure 1). The patient reported satisfactory control of upper extremity tremor, but his mild head tremor persisted. The dose of zonisamide was increased to 300 mg at bedtime and associated with additional symptomatic benefit but was not tolerated due to excessive daytime sleepiness. Therefore, the dose was reduced back to 200 mg, and levetiracetam 500 mg twice daily was added. The patient noticed additional improvement of upper extremity tremor and levetiracetam was increased to 1,000 mg twice daily. However, the patient experienced onset of depressive symptoms attributed to levetiracetam, and the medication was discontinued. After 10 months of zonisamide treatment, the patient ran out of medication for approximately one week and reported significant worsening of hand and head tremor. He was restarted on zonisamide 200 mg with improvement of symptoms. The patient was maintained on zonisamide 200 mg at bedtime with good tolerability and improvement in handwriting and spiral and line drawings, which were sustained over 28 months, at which time the patient was lost to follow-up.

Discussion

In the United States, zonisamide is indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy, and in Japan, it is indicated for treatment of Parkinson’s disease. The exact mechanism of action for these conditions of interest is unknown, but may involve blockage of sodium and calcium channel and weak carbonic anhydrate inhibition.\textsuperscript{4} Another antiepileptic drug, topiramate, has a similar mechanism of action.
and demonstrates efficacy for ET but is less well tolerated due to adverse effects.\textsuperscript{5}

In a 2011 report, a Quality Standards Subcommittee of the American Academy of Neurology stated that “there is insufficient evidence to support or refute the use” of zonisamide as treatment for essential tremor.\textsuperscript{3}

Several investigators have reported on the short-term (up to approximately four months) efficacy and tolerability of zonisamide for ET.\textsuperscript{6,12} albeit only one study was performed in a randomized, placebo-controlled manner.\textsuperscript{8} Overall, zonisamide was well tolerated. This case report provides additional data focusing on the long-term (28 month) efficacy and tolerability of zonisamide for ET in an elderly patient.

In a retrospective study, nine of 13 patients with refractory ET experienced an improvement of symptoms with zonisamide therapy (mean dose=215 mg per day; mean duration of treatment=121 days). Zonisamide was well tolerated.\textsuperscript{6}

In a study of six patients with ET-parkinsonism syndrome, zonisamide was initiated at 50 mg per day as an add-on therapy to other drugs and titrated up to 200 mg per day. The duration of treatment was at least 60 days. Subjectively, tremor improved in four patients. The drug was well tolerated, with somnolence and paresthesias as common side effects.\textsuperscript{7}

In an open-label, three-month, pilot trial of zonisamide for medically refractory ET, 22 patients (nine males; mean age 65 years old; mean duration of ET 25.6 years) were enrolled, but six dropped out due to side effects or lack of effect, or were lost to follow-up. Of the remaining 14 patients, tremor clinical rating scores improved. However, subjectively, only four reported marked or moderate improvement, three reported mild improvement, and seven reported no change. The final dose was 200 mg (n=11), 150 mg (n=1), 100 mg (n=1), and 12.5 mg (n=1). Overall, zonisamide was well tolerated. Side effects included cognitive impairment (n=2), constipation (n=1), nocturia (n=1), abdominal pain/diarrhea (n=1), and sedation (n=1).\textsuperscript{8}

In a double-blind, placebo-controlled randomized trial, the efficacy and tolerability of zonisamide for ET was evaluated. Twenty patients (mean age=60 years) were randomized to receive zonisamide or a placebo for four weeks. Zonisamide was initiated at a dosage of 100 mg per day and increased to 200 mg per day after two weeks. At study end, the mean dose of zonisamide was 160 mg per day. There were no significant improvements in clinical rating scale scores, and the majority of patients felt that their tremor was unchanged. However, tremor amplitude as assessed by accelerometry significantly improved in the zonisamide group. Zonisamide was modestly well tolerated, with 30% of patients discontinuing the study due to side effects (fatigue, headache, paresthesias).\textsuperscript{9}

In a randomized, crossover study of propranolol and zonisamide for isolated head tremor in 12 female patients with ET (mean age=72.3 years), zonisamide was found to be more effective than propranolol. Zonisamide was initiated at 50 mg per day and titrated to 200 mg as tolerated. Propranolol was initiated at 40 mg per day and titrated up to 160 mg as tolerated. Patients were treated for two weeks with either zonisamide or propranolol, then underwent a two-week washout prior to undergoing exchange of zonisamide for propranolol (i.e., patients initially receiving zonisamide were crossed over to propranolol and vice versa). The mean doses of zonisamide and propranolol were 100 and 126.67 mg per day, respectively. In eight patients, side effects occurred during treatment with zonisamide and included mild sedative effects, diarrhea, and abdominal discomfort. With propranolol treatment, nine patients developed bradycardia.\textsuperscript{10}

In an evaluator-blinded, open-label study, 25 patients with moderate to severe upper limb ET were treated with zonisamide as monotherapy or as adjunctive therapy in a 12 week “treatment” phase, followed by a 12 week “extension” phase. Zonisamide treatment significantly reduced tremor scores at the end of the “treatment” and “extension” phases at mean doses of 252 and 225 mg per day, respectively. Doses up to 300 mg per day produced no additional benefit and were associated with more adverse symptoms, especially somnolence, poor energy, imbalance, and altered taste.\textsuperscript{11}

In an open-label, crossover trial of zonisamide for ET, 14 patients were randomized to receive either zonisamide or arotinolol for two weeks. After a two-week washout period, patients switched medications. Compared to baseline, both drugs significantly improved tremor, and there was no significant difference in the antitremor effect between zonisamide and arotinolol. The mean doses of zonisamide and arotinolol were 136 and 11.4 mg per day, respectively. However, zonisamide was noted to be more effective for tremors of cranial nerve areas (e.g., tremor affecting voice, tongue, and head). Mild sleepiness was observed in three patients after zonisamide administration and mild bradycardia was noted in four patients after arotinolol administration.\textsuperscript{12}

This case report illustrates use of zonisamide monotherapy in a very elderly patient who previously failed (defined as obtaining inadequate benefit from maximum tolerated dose) several medications for essential tremor. The patient experienced clinically significant improvement of upper extremity tremor and modest improvement of head tremor with zonisamide that was sustained over approximately 28 months of follow-up. One of the most important limitations to a case report is lack of controls and ability to generalize. Nevertheless, this case report indicates that zonisamide monotherapy may be a well-tolerated and effective therapy for essential tremor in a very elderly patient who failed or did not tolerate several other medications.

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Specialty Pharmaceuticals – The New Frontier

By Craig S. Stern, RPh, PharmD, MBA, FASCP, FASHP, FICA, FLMI, FAMCP, FCPhA, CSP

Specialty medications, both injectable and oral, have gained significant interest due to their cost. Yet cost is only one factor. Specialty medications have moved into chronic therapy from their original position as treatments for rare and “orphan” diseases that affect very few patients. Specialty medications are replacing older small-molecule medications, primarily in treatments for cancer, blood diseases, and rheumatoid arthritis. In addition, new entrants are providing treatment options for multiple sclerosis, hepatitis C, diabetes, and HIV/AIDS that improve patient lives and provide a level of effectiveness that was previously unattainable. This article will address the specialty space, definitions and coding issues, methods for evaluation, pricing/payment, and context. Our goal is to understand these agents in the context of their definitions and the resulting impact on providers and payers.

Definitions

There is a general concern that specialty pharmaceuticals are an undefined category. They don’t fit neatly into categories such as brand vs. generic, injectable vs. oral, location of service or other neatly defined categories. However, the alternative argument is that there are too many definitions, making it hard to characterize specialty pharmaceuticals under any one category. For example, specialty pharmaceuticals may be defined in the following ways:

- All injectables, self- or provider administered
- Facility administration or specialty pharmacy distribution
- Medicare Part B or D covered medications
- Medication cost greater than $600 (or some other threshold) per dose
- Special handling restrictions for distribution (e.g., refrigeration)

Consistent with the elements above, HealthInsurance.com defines specialty drugs as “high-cost prescription medications used to treat complex, chronic conditions like cancer, rheumatoid arthritis, and multiple sclerosis. Specialty drugs often require special handling (like refrigeration during shipping) and administration (such as injection or infusion).”

Each of the above definitions has limitations. For example, specialty pharmaceuticals include oral cancer chemotherapy as well as injectables. Medicare Part B contains enteral feeding, HIV/AIDS, diabetic testing, disposable medical equipment (DME), and radio-labeled diagnostics that may or may not be included in the specialty pharmacy scope or benefit. Specialty pharmaceuticals may also be dispensed by the retail network of pharmacies, and mail-service facilities, as well as specialty pharmacies. [Table 1]

The bottom line is that specialty pharmaceuticals are whatever the patient’s insurance benefit covers and include those medications covered by limitations as defined by precertification criteria.

Coding – Medical Vs Pharmacy

A major source of confusion and complication is that specialty medications are defined, billed, and priced differently by medical and pharmacy benefits. Pharmacy traditionally defines medication by package and bills for the dispensed quantity. Medical benefits, on the other hand, define specialty medications by those medications covered by Medicare and quantities as doses or fractions of a dose. To further complicate the definition of medications under Medicare, drugs are covered under two categories, Level I and II, composed of multiple codes. [Table 2]

- Level I: Common Procedure Coding (CPT) codes are referred to as Level I codes and are maintained by the American Medical Association (AMA). Level I codes are five (5) characters in length and are numerical (e.g., 99211, 30520, etc.). CPTs cover services and procedures furnished by physicians and healthcare professionals.
- Level II: Healthcare Common Procedure Coding System
HCPCS codes are referred to as Level II codes and are governed by the American Hospital Association (AHA) and the Center for Medicare and Medicaid Services (CMS). Level II codes are five (5) characters in length and are composed of one (1) letter and four (4) numbers (e.g., J1950, J9217, etc.). HCPCS cover products, supplies, and services furnished outside of physician’s offices, and DMEPOS (DME, prosthetics, orthotics, and supplies).

In addition to medication-specific codes, medical billing and payments include multiple other codes to cover every element of the patient care experience. Many of these codes are common to both medical and pharmacy. [Table 3] These additional codes include:

- **Administrative Codes** – separate codes for administration of the medication, especially vaccines
- **Place of Service Codes** – two-digit codes required for the actual place where service is provided (e.g., the pharmacy place of service code is 01)
- **Provider Codes**, also known as Medicare Specialty Codes – represent the types of providers and suppliers who are eligible to apply for enrollment in the Medicare program – these codes link to the Healthcare Provider Taxonomy Codes (www.wpc-edi.com) and are maintained by the National Uniform Claim Committee (www.nucc.org)
- **Revenue Codes** – Revenue Codes are descriptions and dollar amounts charged for hospital services provided to a patient. Their purpose is to group the same services for simplification and improved transparency of the coding process. The revenue code tells an insurance company whether the procedure was performed in the emergency room, operating room, or another department. These codes are also used by some insurers for outpatient claims, e.g., code 0250 is pharmacy general.

### Specialty Space

Specialty medications are provided through medical and pharmacy subchannels, which makes the space very competitive and at the same time diverse. [Table 1] Pharmacy subchannels are dominated by specialty pharmacies that dispense medications to homebound patients. Medical subchannels are more diverse in that specialty medications are administered in physician offices, multispecialty clinics, oncology clinics, acute care hospitals, emergency medicine, etc. As a result, competition for patient business is not only competitive between medical and pharmacy channels, but also very competitive between medical subchannels, and soon between specialty pharmacies and retail network pharmacies. This competition has produced a commercial emphasis on “site-of-care optimization,” where pharmacy channels are attempting to move product sourcing and delivery from medical channels to pharmacy delivery and mail-type service.

### Specialty Benefits And Contracting

Medications were originally covered as riders to comprehensive medical benefits, but with the advent of managed care, they took a larger share of ambulatory practice that required broader benefit designs. These designs were anchored by formularies that moved from open, closed, and other restrictive models to tier-based designs that placed emphasis on the choices among various options within therapeutic categories. Elements of Medicare Part D, price competition, and manufacturer cost offsets, e.g., rebates, provided additional options to add to pharmaceutical benefit models.

Specialty medications have added yet another dimension. These medications treat previously untreatable conditions as well as replacing current treatments for common chronic conditions. These conditions are often severe and have complicated courses. Specialty medications further complicate patient care because of their molecular size, requiring special handling; complicated mechanisms of action, requiring enhanced testing; and toxicity, which adds to patient discomfort as well as needing to be managed by a team of healthcare professionals. And then there is the cost.

Pharmacy benefits have had to develop a dynamic posture in order to keep up with rapid developments in the specialty arena. This posture has led to formulary expansion to incorporate the new agents, integration of coverage for medications covered under medical benefits separate from pharmacy benefits, and channel requirements for distribution and administration. Among these, integration of medical and pharmacy benefits is a relatively new problem, because there was little prior need to be con-

<table>
<thead>
<tr>
<th>Medical Subchannels</th>
<th>Pharmacy Subchannels</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ambulatory Clinics</td>
<td>• PBMs</td>
</tr>
<tr>
<td>• Emergency Medicine</td>
<td>• Retail Pharmacy Network</td>
</tr>
<tr>
<td>• Home Care</td>
<td>• Specialty Pharmacies</td>
</tr>
<tr>
<td>• Infusion Centers</td>
<td></td>
</tr>
<tr>
<td>• Inpatient Hospital</td>
<td></td>
</tr>
<tr>
<td>• Outpatient Hospital</td>
<td></td>
</tr>
<tr>
<td>• Physician’s Office</td>
<td></td>
</tr>
<tr>
<td>• Surgery Centers</td>
<td></td>
</tr>
</tbody>
</table>

---

1. There was little prior need to be concerned with the cost of specialty medications.
2. Specialty medications have added yet another dimension. These medications treat previously untreatable conditions as well as replacing current treatments for common chronic conditions. These conditions are often severe and have complicated courses. Specialty medications further complicate patient care because of their molecular size, requiring special handling; complicated mechanisms of action, requiring enhanced testing; and toxicity, which adds to patient discomfort as well as needing to be managed by a team of healthcare professionals. And then there is the cost.

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Table 1: Specialty Locations Of Service

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cerned with the overlap of medications covered under each benefit. Generally, medical benefits covered injectables administered by physicians and nurses. Pharmacy benefits covered medications dispensed by pharmacies to patients who self-administered. The merging of benefits for medications that might be delivered and administered under either benefit places a special emphasis on coding definitions, channel competition, and purchaser-provider contract language.

The primary elements for benefits and resulting purchaser-provider contracts reflect the new reality of merging medical and pharmacy benefits. These elements are driving provider competition for patients and expanding the dynamic of how drugs are categorized. To summarize the landscape of this new perspective on therapy, consider the following:

- Dynamics of specialty introductions and expansion of covered indications
- Specialty coverage implemented through coding definitions (Level I or II)
- Categorization coding for therapeutic similarity (previously brand vs. generic)
- Channel variation and competition, including medical and pharmacy subchannels
- Preferred provider vs. nonexclusive agreements
- Bases of cost complicated by the movement of traditional average wholesale price (AWP) to wholesale acquisition cost (WAC), maximum allowable cost (MAC), average acquisition cost (AAC), national average drug acquisition cost (NADAC), average sales price (ASP), and average manufacturers’ price (AMP).
- Coding options (e.g., J-Code description of unit vs. package unit), including special use codes (e.g., miscellaneous dump, not otherwise classified – NOC/NOS)

Blood and blood derivatives are a special case. Blood factor billing codes depend on the provider type. Pharmacists must bill using the National Drug Codes (NDC). All other providers must bill according to physician-administered drug policy, CMS-1500 Billing Instructions, Physician-Administered Drugs – NDC, or UB-04 Billing Instructions. Reimbursement for blood factors is based on the lesser of the average sales price (ASP) plus 20% or the provider’s usual and customary charges (U&C).

Another special case is coagulation factors for bleeding disorders, e.g., hemophilia. These factors represent the first class of specialty medications that utilize provider contracts. The provider should refer to the codes for each state. As an example of the types of obligations required under these contracts, consider the California W&I Code:

“The Department of Health Care Services (DHCS) will contract with any specialty pharmacy that will sign a contract to meet a list of performance obligations. These include, but are not limited to, delivery time requirements, providing patient education, and submitting quarterly and yearly reports to DHCS.”

**Specialty Billing**

Since HCPCS and CPT coding is central to definitions, locations of administration, claim administration, and payment of specialty medications, it is important to understand the elements of medical claims and how they differ from pharmacy claims administration. [Table 3, Table 4 for data vendors]

The primary elements of a claim are similar for both medical and pharmacy claims; namely, patient, doctor, medication, and date of service. The primary difference is the NDC of the medication and the quantity administered or dispensed. While pharmacy claims must include NDC, historically, medical claims have not. Also, the quantity dispensed by the pharmacy is not the same as the quantity provided in the medical claim that is a multiple of the HCPCS-defined unit of dosage. All of this changed when Medicaid and Medicare issued reporting and billing requirements that mandate elements in medical claims that have interfered with accurate submissions. These requirements apply to specific circumstances, but they are being applied broadly. The requirements are, in summary:

- Medicaid Reporting Requirements are part of the Deficit Reduction Act (DRA) 2005, Section 6002, with added provisions under Section 1927. The states are directed to require physicians in their offices and hospital outpatient settings or other entities (e.g., nonprofit facilities) to collect and submit the drug NDC numbers on Medicaid claims to their state. These requirements are effective January 1, 2008, and Section 1927(a) (7)(B)(ii) of DRA eliminates federal financial participation (FFP) when states fail to collect NDCs.
<table>
<thead>
<tr>
<th>Code</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Emergent and nonemergent transportation services; miscellaneous medical and surgical supplies, including dressings, ostomy and urinary supplies, and some diabetic and DME supplies; also includes radiopharmaceutical diagnostic agents.</td>
</tr>
<tr>
<td>B</td>
<td>Enteral and parenteral therapy, including codes for supplies, formulae, nutritional solutions, and infusion pumps.</td>
</tr>
<tr>
<td>C</td>
<td>Temporary codes for use with Outpatient PPS (Prospective Payment System). C-Codes are used exclusively to report services, drugs, biologicals, and devices eligible for transitional pass-through payments for hospitals, and for items classified in new-technology ambulatory payment classifications (APCs) under the Outpatient PPS (Prospective Payment System). They may not be used to bill under other Medicare payment systems.</td>
</tr>
<tr>
<td>J</td>
<td>Permanent codes used to report injectable drugs that ordinarily cannot be self-administered: chemotherapy, immunosuppressive drugs, and inhalation solutions, as well as some orally administered drugs. Drugs and biologicals are usually covered by Medicare if: they are of the type that cannot be self-administered they are not excluded, i.e., immunizations they are necessary and necessary for the diagnosis or treatment of the illness or injury for which they are administered they have not been determined by the FDA to be less than effective In addition, they must meet all the general requirements for coverage of items as incident to a physician's services. Generally, prescription and nonprescription drugs and biologicals purchased by or dispensed to a patient are not covered.</td>
</tr>
<tr>
<td>P</td>
<td>Pathology and laboratory services codes. P-Codes are used for reporting chemistry, toxicology, microbiology, and pathology screening tests (e.g., PAP), as well as blood-related products.</td>
</tr>
<tr>
<td>Q</td>
<td>Temporary codes. Q-Codes are used for casting procedures, services, and supplies. If a permanent code is subsequently assigned (J-Code), the Q-Code is deleted and cross-referenced.</td>
</tr>
<tr>
<td>S</td>
<td>Temporary national codes (non-Medicare). S-Codes were developed by Blue Cross/Blue Shield and other commercial payors to report drugs, services, and supplies. They may not be used to bill services paid under any Medicare payment system.</td>
</tr>
<tr>
<td>WW</td>
<td>For DMERC Level III oral anti-cancer drugs. WW-Codes are for DMERC internal systems processing only. Providers should still bill using the appropriate NDC number for the oral anti-cancer drug utilized. Each WW Code has a specific NDC number that represents the drug name and strength. DMERC will be reimbursed based on this information.</td>
</tr>
</tbody>
</table>

CPT® Coding for Immune Globulins, Vaccines, and Toxoids

CPT®-Codes (Current Procedural Terminology) are assigned by the AMA and used to bill for immune globulins, vaccines, and toxoids.

Immune Globulins: Products listed include broad-spectrum and anti-infective immune globulins, antitoxins, and various isoantibodies.

Vaccines/Toxoids: Multiple codes for a particular vaccine/toxoid are provided when the schedule (number of doses or timing) differs for two or more products of the same vaccine type (e.g., hepatitis A, HiB) or the vaccine product is available in more than one chemical formulation, dosage, or route of administration. Separate codes are available for combination vaccines (e.g., DTP-Hib, DtaP-Hib, and HepB-Hib). It is inappropriate to code each component of a combination vaccine separately. If a specific vaccine, toxoid, or immune globulin code is not available, the unlisted CPT® code 90749 (vaccines/toxoids) or 90399 (immune globulins) should be reported until a new code becomes available.

Reference: http://www.j-codes.com/
Medicare Billing Requirements apply to physician billing offices, hospital outpatient departments, and outpatient clinic billing offices. They apply to dual eligibles, i.e., patients who are eligible for both Medicare and Medicaid benefits, who received physician-administered drugs as part of the medical encounter. The requirements cover bills for physician-administered drugs on claims to Medicare containing:

- NDC in 2410 LIN03, with LIN02=N4
- Quantity/unit (including fractional units) count in 2410 CPT04
- Unit of measure (IU, gm, ml, unit) in 2410 CPT05 and CPT05-1

Wastage – Waste Not, Want Not, But What To Bill?

The disparity between HCPCS units and commercial packaging has led to a problem for all providers; namely, what to do with the medication remaining in the bottle that was not administered. This is a very common problem and poses a compensation problem for physicians, hospitals, and pharmacies.

CMS has addressed this issue in Regulations and Guidance 100.2.9 - Submission of Claims with the Modifier JW, “Drug Amount Discarded/Not Administered to Any Patient.”

If the physician, rather than the patient and/or a facility, supplies the drug and must waste some portion in the vial that is not administered, Medicare may allow compensation for this wasted portion. The National Medicare guidelines for reporting drug waste are included in the Claims Processing Manual, chapter 17, § 40.0.

The instructions are to report wastage in addition to the drug administered. The appropriate HCPCS Level II supply code must be used to list the drug administered with the correct number of units in box 24D of the CMS-1500 claim form. The number of wasted units is reported as a second line item. Provider documentation must verify the exact dosage of the drug injected and the exact amount and reason for any waste as indicated below:

Caution: “The JW modifier must not be used on Medicare Part B Drug CAP claims (The Competitive Acquisition Program); providers shall not code for wastage for drugs furnished under the CAP. Claims for drugs provided under CAP submitted with the JW modifier will be treated as unprocessable.” (Rev. 1313; Issued: 07-23-07; Effective/Implementation Date: 08-23-07)

Medicare contractors generally require that the JW modifier is appended to the drug or biological amount discarded/not administered to identify an unused drug from single-use vials or single-use packages that are appropriately discarded. The emphasis is that Medicare will reimburse only for drugs supplied in single-use vials, and CMS officially encourages “physicians, hospitals, and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.”

Examples

1. From a single-use vial that is labeled to contain 100 units, 90 units are administered to the patient and 10 units are discarded. The 90-unit dose is billed on one line, and the 10 discarded units are billed on another line with modifier JW. Both line items would be processed for payment.

2. If the actual dose of the drug or biological administered is less than the billing unit, then the JW identifier cannot be used. “For example,” the Claims Processing Manual advises, “one billing unit for a drug is equal to 10 mg of the drug in a single-use vial. A 7 mg dose is administered to a patient, while 3 mg of the remaining drug is discarded. The 7 mg dose is billed using one billing unit that represents 10 mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10 mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3 mg of drug is not permitted because it would result in overpayment. When the billing unit is equal to or greater than the total actual dose that was administered and the amount discarded, the use of the JW modifier is not permitted.”

Caution: Unique billing rules apply when reporting discarded erythropoietin stimulating agents for home dialysis. See the Medicare Claims Processing Manual, chapter 17, § 40.1 for more details.

Biosimilars

Reminiscent of the movement to produce generics that are cheaper than their branded counterparts, now comes the introduction of biosimilars to compete with their pioneer biologics. There is also the companion concept of “bio-betters,” for which there is no currently marketed product, but which are biosimilars equal in clinical effectiveness to the pioneer biological, and multiple decisions currently block clear substitution for cheaper products, not the least of which are naming, coding, and legislative hurdles. However, the larger issue is that the selection of biosimilars, or even bio-betters, presents new decision problems for prescribers and pharmacists; namely, are biosimilars equal in clinical effectiveness to the pioneer biological, and are they similar in risk? With brands and generics, the same active ingredient is being compared for substitution. With biosimilars, there is a clinical decision to be made that requires both
Table 3: Elements Of Medical/Pharmacy Claim

<table>
<thead>
<tr>
<th>Medical</th>
<th>Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS and CPT drug-specific codes –</td>
<td>NDC</td>
</tr>
<tr>
<td>• Many NDC to each code</td>
<td></td>
</tr>
<tr>
<td>• Many codes per NDC</td>
<td></td>
</tr>
<tr>
<td>Dose or fraction of a dose</td>
<td>Included in Sig – Quantity/Days’ Supply</td>
</tr>
<tr>
<td>HCPCS unit</td>
<td>Quantity Dispensed</td>
</tr>
<tr>
<td>Date of service – single or range for institutional / hospital stays</td>
<td>Date of Service of Dispensing</td>
</tr>
<tr>
<td>Date range of duration of care – often missing</td>
<td>Days’ Supply</td>
</tr>
<tr>
<td>Prescriber ID – NPI for individual NPI for group or practice site Tax ID (historical)</td>
<td>Prescriber NPI</td>
</tr>
<tr>
<td>Location of Service (POV, hospital, clinic, EM, etc.)</td>
<td>Dispensing Pharmacy</td>
</tr>
</tbody>
</table>

Table 4: Sample Of Data Vendors (Data From Vendor Webpages)

<table>
<thead>
<tr>
<th>VENDOR</th>
<th>FEATURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Data Bank HCPCS Select™</td>
<td>NDC/HCPCS, pricing link – WAC/SWP/ASP/PAL, Part B</td>
</tr>
<tr>
<td>Medi-Span/Wolters Kluwer</td>
<td>All HCPCS values, map to NDC/UPC/HRI, Qty map</td>
</tr>
<tr>
<td>Manufacturers</td>
<td>Lists of NDCs and HCPCS Codes</td>
</tr>
<tr>
<td>Noridian Admin Services</td>
<td>NDC/HCPCS crosswalk</td>
</tr>
<tr>
<td>NovoLogix</td>
<td>NDC/HCPCS crosswalk</td>
</tr>
<tr>
<td>J Code Calculator™/Pro Pharma</td>
<td>NDC/HCPCS crosswalk, Unit/Package calc., AWP/WAC/ASP/NADAC/AAC/MAC, Brand/Generic, Part B/D, Therapeutic Class, ICD9/ICD10, Qty map, Usage Map</td>
</tr>
<tr>
<td>RJ Health Systems</td>
<td>NDC/HCPCS crosswalk, CPT, ICD9, Therapeutic Class, pricing – AWP, WAC, ASP, APC</td>
</tr>
<tr>
<td>Red Book/Truven/IBM</td>
<td>NDC, HCFA J-Codes, AWP/WAC, Brand/Generic</td>
</tr>
</tbody>
</table>

https://www.dmepdac.com/crosswalk/  
http://www.propharmaconsultants.com/JCode.html  
http://rjhealthsystems.com/drug-info-resources.php#reimbursementcodes  
http://www.redbook.com/redbook/deliverymethods/
the physician and the pharmacist to know and understand the literature, pharmacology, and adverse drug reactions for patient subpopulations at risk. Some of this risk is assumed by health plans through restricted formularies, NDC blocks, step therapy, and prior authorizations. REMS requirements will shield prescribers and pharmacists from some risk, but nothing will be a substitute for study and knowledge of these products. This is the subject of a discussion of utilization management that will be addressed in a separate article. However, as state laws allowing for substitution continue to change, much of the weight of the biosimilar substitution will fall on pharmacists.

For further information, consider “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars,” which examines both state and federal substitution policies, with citations for enacted and proposed laws and regulations, from the National Conference of State Legislatures.8

The Future

The immediate future is already defined by common digital vocabularies to allow communication between various stakeholders, evidence-based health information as a basis for decision making, the movement from managed care to population health monitoring, and the integration of pharmacy claims/medical encounter/laboratory value and biometric screening data leading to data-based decision making. The resulting incorporation of medication therapy management (MTM), medical encounters stored in electronic medical records (EMRs), and biometric screening is already leading to the expansion of population healthcare management and the impact of patient influence on decision making.

All of this integration impacts specialty medications treating more complicated conditions with medications that provide expanded options and greater risks. An educated provider team will be critical to manage the care of the population covered by specialty medications. In that regard, specialty medications are driving medicine away from art to more data-based, evidence-based scientific care.

About the Author

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References
5. DRA 2005, 42CFR447, Section 520
Implementing Pharmacy-Based Travel Health Services: Insight and Guidance from Frontline Practitioners

By Tania Gregorian, PharmD; Albert Bach, PharmD; Karl Hess, PharmD; Keri Hurley, PharmD, MPH; Edith Mirzaian, PharmD, BCACP; Jeff Goad, PharmD, MPH

Purpose
In California, the passage of SB493 in July of 2013 was a milestone in advancing pharmacy practice. Among other things, the new legislation allows pharmacists to provide routine immunizations without a protocol and furnish medications for international travelers for conditions not requiring a diagnosis. When developing a pharmacist-run travel health service, consideration must be given to multiple important factors, including pharmacist training, physician partnership, logistics, from scheduling to documentation, and the resources necessary to provide a travel health service. This article sets out to provide guidance and insight to pharmacists seeking to implement a travel health service.

Summary
Travel health requires providers with knowledge regarding epidemiology, transmission, and prevention of travel-associated infectious diseases, a complete understanding of vaccine indications and procedures, and prevention and management of noninfectious travel-associated health risks. Pharmacists seeking to implement travel health services need to seek out appropriate resources for pharmacist training, workflow and logistical considerations, and travel health-specific resources to optimally provide this service.

Conclusion
The traveling population is at significant risk for travel-related diseases, but only a small number actually get the advice, vaccines and medications they need. With the passage of SB493 in California, the 40,000 registered pharmacists and 6,000 pharmacies across California could provide the essential access, convenience and expertise that a growing traveling population needs to stay healthy while abroad. Whether in a community pharmacy or ambulatory care clinic, pharmacists must ensure they can provide or arrange for personalized, comprehensive travel health services.

Introduction
In California, the passage of SB493 in July of 2013 was a milestone in advancing pharmacy practice. SB493 expands pharmacist services in areas such as hormonal contraception, smoking cessation, immunizations, administering drugs and biologics, and travel medicine, and also created an Advance Practice Pharmacist (APP) license category. The APP designation gives pharmacists a broader scope of practice. However, APP designation is not necessary to perform all the expanded-scope practices allowed for in SB493, such as routine immunizations without a protocol and furnishing medications for international travelers for conditions not requiring a diagnosis. The term “travel medicine” is a practice specialty devoted to the health of international travelers pre- and post-travel. Travel health is often used to describe the pre-travel services of travel medicine providers. Tropical and geographic medicine entails the provision of medical care internationally. Pharmacists can provide the full range of travel health services nearly independently. This role is an appropriate next step, as pharmacists have
consistently demonstrated that they can provide evidence-based care and improve patient compliance and satisfaction in the travel clinic setting.2 3 Having this new level of trust and professional responsibility necessitates optimal practice standards to ensure the safety and quality of the services pharmacists will provide to their patients. According to the Infectious Diseases Society of America, travel health requires providers with knowledge regarding epidemiology, transmission, and prevention of travel-associated infectious diseases, a complete understanding of vaccine indications and procedures, and prevention and management of non-infectious travel-associated health risks.4 When developing a pharmacist-run travel health service, consideration must be given to multiple important factors, including pharmacist training, physician partnership, logistics, from scheduling to documentation, and the resources necessary to provide a travel health service.5

Pharmacist Training
Travel health is truly a specialty practice, one that requires a specific body of knowledge by the clinician providing this service. Pharmacists have access to training programs and resources to prepare them for the provision of travel health services as well as to ones that serve to maintain the most current information in travel medicine. The current proposed text by the California Board of Pharmacy requires pharmacists to obtain the following in order to provide travel health services: (1) Completion of an immunization certificate program that meets the requirements of Business and Professions Code section 4052.8, (2) completion of an approved travel medicine training program, which must consist of at least 10 hours of training and cover each medication- and vaccination-related element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine, (3) completion of the CDC Yellow Fever Vaccine Course, and (4) current basic life support certification.1

The discipline of travel health involves a comprehensive knowledge and resource base, including infectious diseases, epidemiology, and environmental, geographic and consular matters related to travelers’ health and safety.4 Since this field is unique, dynamic, and a rapidly growing area of practice for pharmacists, it is important to maintain a high standard of practice amongst all providers, including physicians, nurses and pharmacists.

Certificate Training Programs
Providing comprehensive travel health services involves determining patients’ specific travel health needs, providing immunizations, furnishing necessary medications, and counseling patients on health and safety risks specific to their destination and itinerary. Pharmacists interested in providing travel health services should begin by completing a comprehensive immunization training program such as the American Pharmacists Association’s (APhA) Pharmacy-Based Immunization Delivery Certificate Training Program, composed of a self-study and live training seminar offering 20 hours continuing education (https://www.pharmacist.com/pharmacy-based-immunization-delivery). Although a general immunization training program such as this one does not address specific travel-related vaccines, it provides a very robust and strong foundation of knowledge, practices, decision-making skills, regulations, and techniques related to immunizations necessary in patient care and travel health.

APhA has developed the Advanced Competency Pharmacy-Based Travel Health Services Training Program to prepare pharmacists to offer travel health services (https://www.pharmacist.com/pharmacy-based-travel-health-services). The successful completion of the APhA Pharmacy-Based Immunization Delivery Certificate Training Program and being an authorized provider of immunizations in their state, which pharmacists in California are, are prerequisites to enroll in the APhA Pharmacy-Based Travel Health Services Training Program. This program, which offers 10 hours of continuing education, includes self-study and live seminar components that will prepare pharmacists to evaluate travel itineraries, assess health and safety risks based on travelers’ destinations, reasons for travel and medical history, and create and communicate a plan for patients to receive the necessary medications, immunizations, counseling and nonprescription medications and supplies for their trip.

The gold standard in travel health knowledge is the Body of Knowledge developed by the International Society of Travel Medicine (ISTM). This Body of Knowledge serves as the basis for the Certificate of Knowledge examination that is available through the ISTM for all travel health professionals. Those who successfully complete the exam are awarded the Certificate in Travel Health (CTH®) by the ISTM. The CTH® is one of few credentials offered across health disciplines and recognized internationally by health care providers (http://www.istm.org/bodyofknowledge).

Continuing Education
According to the California board proposed text, pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.1 The Centers for Disease Control and Prevention (CDC) offers brief and focused online continuing education courses related to travel medicine (http://wwwnc.cdc.gov/travel/page/ce-courses-training). These programs include webinars and other types of web-based courses discussing topics including emerging threats such as chikungunya virus and Zika, yellow fever, malaria, and tuberculosis and rabies risk assessments. These courses are intended for practicing travel health providers needing updates on current topics of interest in travel medicine.

References and Resources
Certificate training programs provide a solid foundation on which to build a travel health practice. Once initial training is complete, pharmacists should maintain a com-
prehensive knowledge base of travel-related issues in order to be prepared for any itinerary that may come their way. A well-informed travel health provider must have the appropriate resources to remain up to date on information such as disease outbreaks, changes in country entry requirements, and vaccine recommendations. The current proposed text from the board of pharmacy in California requires that pharmacists use the CDC’s Health Information for International Travel, commonly known as the Yellow Book, when determining what medications may be furnished. However, multiple other resources may also be consulted in the decision-making process. Outlined below are some resources and suggestions for staying up to date on travel medicine.

**ISTM Body of Knowledge**

The ISTM Body of Knowledge is the scope and extent of knowledge required for professionals working in the field of travel medicine. Major content areas include the global epidemiology of health risks to the traveler, vaccinology, malaria prevention, and pre-travel counseling designed to maintain the health of the traveling public (http://www.istm.org/bodyofknowledge).

**CDC Yellow Book**

One of the most comprehensive travel health resources written specifically for health care professionals, the Yellow Book is available both online and in print. It contains information on everything travel related, from updated vaccine requirements and recommendations to guidance for travelers with special needs (http://wwwnc.cdc.gov/travel/page/yellowbook-home).

**Web-Based Subscriptions**

There are several web-based subscription resources available for use by travel health providers. Many of them now include information, training, and resources specifically tailored for use by pharmacists. Research into each reference prior to committing to any one reference or subscribing to multiple references may be advisable, as contradictory information can be found among even reputable web resources. The Infectious Diseases Society of America has a comprehensive list of available resources available for use by travel health providers.

**Pharmacist and Physician Partnership for Travel Vaccination Protocols**

According to California pharmacy law, when administering vaccines that are routinely recommended by the Advisory Committee on Immunization Practices (ACIP) to individuals three years of age and older, a protocol is not required. However, since the ACIP statements are not written in a protocol, standing orders or standard operating procedure format, pharmacists should develop their own documents consistent with ACIP statements or use ones readily available from other sources, such as the Immunization Action Coalition (http://www.immunize.org/standing-orders/). When administering non-ACIP routinely
recommended vaccines for travel (e.g., yellow fever, rabies, Japanese encephalitis, and typhoid fever vaccines), a physician-signed protocol is still required. Information on what to include in such a protocol is covered below; however, it is important that this protocol be up to date and evidence based, using the ACIP recommendation for these vaccines as a guide.7

According to the APhA Immunization Certificate Training Program, items that should be included in any vaccine protocol include:

1. Statement of physician authorization for the pharmacist to administer vaccines
2. Qualifications of person(s) administering vaccines
3. Vaccine(s) covered in the standing order/protocol
4. Policies
5. Screening patients for indications and contraindications
6. Information to provide to patients (e.g., VIS)
7. How to administer vaccine (e.g., dose, route, anatomic location)
8. Documentation requirements
9. Communication to physician and reporting requirements
10. Emergency precautions (e.g., use of epinephrine for allergic reactions), including specific protocol

Below are some ways in which pharmacists can partner with a physician in order to establish a travel vaccine protocol.

1. Contact the local/county health department. Physicians involved in public health may be more inclined to collaborate with a pharmacist on such a protocol. Information on California county health departments can be found here: https://www.cdph.ca.gov/services/Pages/LocalServices.aspx
2. Partner with a physician though a local university or college of pharmacy. This may be advantageous if the pharmacist also serves as a preceptor for that university or college of pharmacy.
3. Reach out to those physicians who most commonly prescribe medications at your pharmacy. These physicians may be more willing to sign off on a travel vaccine protocol given that there may be more history between the individual physician and pharmacy/pharmacist.
4. Partner with an infectious diseases physician. Physicians specializing in ID, particularly tropical medicine, make great referral sources for ill returned travelers, but also may want to partner with you to take care of the pre-travel patients.

If necessary, pharmacies/pharmacists may need to pay a physician to be their immunization protocol consultant, but this relationship must never be construed to mean that physicians are being paid for individual referrals to a clinic. Once a physician has been identified who will sign off on a travel vaccine protocol, it is important to apply for a yellow fever stamp through the California Department of Public Health (California Yellow Fever Vaccine Provider Application). Without a yellow fever stamp, yellow fever vaccine cannot be ordered or shipped to the pharmacy. Information on applying for a yellow fever stamp can be found on the California Department of Public Health’s website (https://www.cdph.ca.gov/programs/immunize/Pages/CaliforniaYellowFeverVaccineProviderProgram.aspx). Please note that only physicians can apply to become yellow fever vaccine stamp holders, but they can designate other appropriate licensed individuals at designated yellow fever vaccine centers (http://wwwnc.cdc.gov/travel/yellow-fever-vaccination-clinics/search) to administer yellow fever vaccine and sign the ICV-P. Both the physician and pharmacist need to complete the California Yellow Fever application and take the CDC Yellow Fever Immunization online course.

Logistical Considerations of a Travel Health Service

Appropriate staffing and resources for starting a travel health clinic are critical for program success, to limit the interference with everyday operations and services, and create time for the pharmacist to dedicate to the travel service. Below are some areas for consideration and suggestions for effectively incorporating a travel health clinic into a pharmacy or ambulatory care clinic. It is important that the pharmacist in a community pharmacy or ambulatory care setting ensure that patients get comprehensive travel health services. The basic elements that must be provided or arranged are:

- Patient education (provided)
- Immunization (provided and/or arranged)
- Prescription medications (provided and/or arranged)
- Travel-related supplies (provided and/or arranged)

Workflow

To create time for the pharmacist to provide patient care, one should identify all essential tasks performed in the pharmacy or practice setting and consider redefining roles and activities as needed. In a travel clinic, the pharmacists’ primary responsibilities are to perform the risk assessment based on the patient’s pre-travel health history, prepare patient-specific education documents and recommendations, provide travel consultation, and provide appropriate
immunizations and documentation. Other tasks involved in a travel clinic, such as marketing, patient scheduling and reminders, and vaccine/prescription input and billing can be designated to a pharmacy technician, clerk, or intern. In an ambulatory care setting, nurses may be utilized to perform clerical responsibilities and administer vaccinations. A pharmacy intern may also assist in the preparation of the consultation documents and recommendations, and preparation and administration of vaccinations if appropriately trained. Performing a time-motion analysis or estimation can help your site better determine the required time and personnel needed.

Space
The space used for existing services such as medication therapy management or routine immunizations is usually appropriate for providing travel health services. A private clinic room is ideal, as patients may feel more comfortable discussing medical history and receiving immunizations in an enclosed area. However, in a pharmacy not equipped with a private room, a designated semiprivate space with a desk or table and seating for a pharmacist and one or more patients is sufficient.

Scheduling of Patients
Developing an effective scheduling system for your practice will increase patient, provider, and staff satisfaction, and boost overall productivity and minimize interference with normal workflow and services. Travel clinic services can be provided by appointment, on a walk-in basis, or through a combination of both. Appointment-based services tend to be less disruptive to the pharmacy’s normal workflow, as patient volume is planned and expected; however, they can limit the number of patients who can be accommodated. Walk-in-based services are more convenient for patients, but may cause disturbances to the normal workflow to accommodate the patients. Walk-in services might also mean that the pharmacy has to stock a wide range of, if not all, vaccines at all times, because the required vaccines and patient/destination risk assessments cannot be determined in advance. For walk-in-based services, patients may also not come prepared or with all required information for the pharmacist to make a proper assessment and plan.

Establishing specific travel clinic hours of operation may also help the pharmacist and site anticipate and adjust workflow needs in advance. For example, the pharmacy or site may only schedule travel appointments on specific day(s) of the week or do block scheduling where only certain blocks of time in the day are set aside for travel appointments. A combination of these two methods may also work, depending on the needs of the site, and the hours can always be expanded as patient volume increases.

Other considerations for scheduling appointments are consultations for multiple travelers with the same itinerary (e.g., a family, a study abroad cohort, or a group of friends). When all travelers have the same itinerary, group consultations regarding fundamental risks and hazards of the group’s destinations can be conducted with all travelers at once. However, the individual risk management and individualized care plan must be conducted individually with each traveler, since each patient’s specific vaccination history, allergies, medical conditions, and recommendations must be taken into consideration.

The time it takes to provide comprehensive pre-travel consultation service can vary depending on the number of pharmacists or student pharmacists available, pharmacy dispensing volume, insurance billing versus paying out of pocket, completeness of the patient’s pre-travel history form, number of patients traveling with the same itinerary, and individual patient needs. For each appointment, the pharmacist’s primary responsibilities in a travel clinic, stated above, should take between 30 to 60 minutes, with the face-to-face travel consultation between the pharmacist and the patient ideally taking between 20 and 30 minutes. When scheduling patients, these estimations of time should be considered.

Consideration should also be given to the fact that immunity generally takes approximately two weeks to develop after vaccination, and some vaccines may require multiple doses to provide immunity. Travelers should be scheduled and seen at least four to six weeks before departure. However, many travelers often seek out travel consultations shortly before their departure date. Such travelers should still receive consultation, appropriate medications and vaccinations, after a thorough discussion of risks, benefits

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<table>
<thead>
<tr>
<th>Figure 1: CDC Conditions Not Requiring a Diagnosis</th>
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<tr>
<td><strong>Self-treatable conditions</strong></td>
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<tr>
<td>Traveler’s diarrhea</td>
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<tr>
<td>Altitude Sickness</td>
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<td>Jet lag</td>
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<tr>
<td>Motion sickness</td>
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<td>Upper Respiratory Infection (URI)</td>
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<tr>
<td>Neuraminidase inhibitors (NAI) for influenza</td>
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<td>treatment</td>
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<tr>
<td>Urinary Tract Infection (UTI)</td>
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<tr>
<td>Bacterial skin infections</td>
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<tr>
<td>Vaginal yeast infections</td>
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<tr>
<td>Human Immunodeficiency Virus Post-</td>
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<tr>
<td>Exposure Prophylaxis (HIV PEP)</td>
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<td>Malaria Stand By Emergency Treatment (SBET)</td>
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<tr>
<td><strong>Prophylaxis</strong></td>
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<tr>
<td>Malaria</td>
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<tr>
<td>Traveler’s Diarrhea</td>
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<tr>
<td>Leptospirosis</td>
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<tr>
<td>Deep Vein Thrombosis (DVT)</td>
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<tr>
<td>Influenza</td>
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</tbody>
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and efficacy of medications and vaccinations so close to departure.

**Furnishing Medications**

According to California law, pharmacists may furnish all prescription medications not requiring a diagnosis as recommended by the CDC for international travel. This is in addition to the authority to initiate and administer vaccines as recommended by the Advisory Committee on Immunization Practices. The medications recommended for international travel are relatively limited in number (see Figure 1 for a list of conditions), and their directions for use generally do not vary significantly between patients. For these reasons, many travel health practices opt to use prepopulated checklist-type prescription forms. This may help to increase efficiency and consistency and potentially reduce furnishing errors. All furnishing pharmacists need to obtain an individual National Provider Identification (NPI).

**Vaccines**

With the exception of yellow fever vaccine, most immunizations are available to order through pharmacy wholesalers or other vaccine distributors. Yellow fever vaccine is supplied directly by the manufacturer and may only be ordered by facilities associated with an official yellow fever vaccine provider. As with basic immunization services, it is important that all necessary supplies and equipment for administration are available and easily accessible. This includes syringes and needles, alcohol swabs, cotton swabs, gloves, adhesive bandages, sharps containers, diphenhydramine for hives, and emergency supplies such as injectable epinephrine. In addition, a refrigerator with continuous temperature monitoring is necessary, as nearly all currently available travel vaccines require storage between 2° and 8°C (35° and 45°F). Close attention should be paid to the storage requirements of all vaccines. See the CDC’s recommendation for proper storage and handling of all vaccines (http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

**Ordering Tests**

California law allows all pharmacists to “order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies” (B&P4052(a)(12)). In the course of providing a travel consultation, laboratory monitoring may become necessary in certain situations, such as looking for antibody titers for a patient with an unclear vaccination history or checking for contraindications to medications. The Joint California Pharmacist Association and California Society of Health-Systems Pharmacists Sub-Committee on SB493 Travel Medicine Provision document provides a list of commonly ordered tests used in travel medicine. In order to be adequately prepared for these situations, a working relationship with a laboratory must be established. For pharmacists at ambulatory care sites, this may mean undergoing credentialing within their institution to obtain lab-ordering privileges. For pharmacists practicing in a pharmacy setting, this will involve getting approval and beginning a relationship with a commercial laboratory to obtain a contract and lab-ordering privileges in order to send patients to laboratory locations for blood draws. California law requires that a laboratory test order be “done in coordination with the patient’s primary care provider or diagnosing prescriber” and documented within 24 hours in a system readily accessible by the PCP.

**Documentation**

It is important to ensure proper documentation of patient care activities to serve as a legal record of care and as a communication tool when shared with other health care providers. Specific requirements for documentation of travel health services are put forth in the board of pharmacy’s proposed text regarding travel health services:

1. For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner and be readily retrievable during the pharmacy or facility’s normal operating hours.

2. The pharmacist shall provide the patient’s primary care provider, or the patient themselves, if the PCP is unknown, with a progress note that fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the board’s website.

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There are also important documentation essentials for vaccine administration, including:

1. Documentation of the administration of vaccines (vaccine name, lot number, expiration date, site vaccine administered, initials of pharmacist, date vaccine given, date of VIS).
2. Documentation of yellow fever vaccination on the International Certificate of Vaccination or Prophylaxis (ICV-P) with associated official stamp from the state health department when yellow fever vaccine is administered. The ICV-P can be purchased through the Government Printing Office at https://bookstore.gpo.gov/products/sku/017-001-00566-5.
3. Documenting refrigerator and freezer temperatures at least twice a day following CDC recommendations. Please note that this is also a requirement of being a yellow fever vaccine provider.
4. Informing the patient’s primary care physician that vaccines were administered. This can be accomplished through electronic health record documentation, phone calls, or faxes to the physician’s office.
5. Immunizations must also be documented in the California Immunization Registry (CAIR) (http://cairweb.org/pharmacies-and-cair/).¹

Billing

In order to bill pharmacy insurance providers, both private and those administered through CMS, health care providers who prescribe or furnish medications are required to obtain an individual National Provider Identifier. This is in addition to the health care organization NPI issued to facilities such as pharmacies and clinics. An NPI can be obtained at no cost from the National Plan and Provider Enumeration System (NPPES). Required information for application includes demographics, provider type, license number, and contact information, Social Security number, practice location, provider type and state license number. After submission of an application, providers can expect an assigned NPI via email within three weeks. An individual DEA number is also required for providers who prescribe controlled substances.

Conclusion

The traveling population is at significant risk for travel-related diseases, but only a small number actually get the advice, vaccines and medications they need. With the passage of SB493 in California, pharmacists now have the opportunity to provide vital comprehensive travel health services to the public. These enhanced practice abilities include independently furnishing prescription medications for travel-related conditions, ordering appropriate tests, and independently administering routine vaccines. Pharmacists are also now mandated to complete specific immunization and travel health training before starting their travel health service. Whether in a community pharmacy or ambulatory care clinic, pharmacists must ensure they can provide or arrange for personalized, comprehensive travel health services. With more than 40,000 registered pharmacists and 6,000 pharmacies, pharmacist-based travel health services could provide essential access, convenience and expertise that a growing traveling population needs to stay healthy while abroad.

References

1. “California Board of Pharmacy - Regulations.” Board of Pharmacy - Regulations: Business and Professions code 4052. (a)(10)(A)(3) and https://www.google.com/url?q=http://www.pharmacy.ca.gov/laws_regs/1746_5_pt.pdf&sa=U&ved=0ahUKEwiq5MHMqMHNAhULZWMKHaMoABsQFggEMAA&client=internal-uds-cse&usg=AFQjCNGoDnHQjLKZG6oCDKSsUeUlMvNh1Vg

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Provider: California Pharmacists Association
Target Audience: Pharmacists, Student Pharmacists, Interns, Pharmacy Technicians
Release Date: February 1, 2017
Expiration Date: February 1, 2019
Learning Level: 1
UAN Number: 0113-0000-17-063-H04-P; 0113-0000-17-063-H04-T
ACPE Activity Type: Knowledge-based
CPE Credit: 1 hour (0.1 CEU)
Fee: There is no fee associated with this activity.
Development: This home-study continuing pharmacy education activity was developed by the California Pharmacists Association.
Support: This activity does not have any financial support.
Disclosures: No disclosures to report.

Article Title
Implementing Pharmacy-Based Travel Health Services: Insight and Guidance from Frontline Practitioners

Learning Objectives
At the conclusion of this knowledge-based activity, the pharmacist will be able to:

1. Understand the travel health legislation and expanded scope of pharmacist services under SB493.
2. Describe the SB493 requirements pharmacists must fulfill in order to provide travel health services.
3. Identify appropriate resources and references for providing travel health services.
4. Describe logistical considerations for implementing a travel health service.

Continue to CE Quiz on next page.
1. To satisfy the requirements of the travel portion of SB493, pharmacists must complete an approved travel medicine training program consisting of how many hours?
   a. 5  
   b. 10  
   c. 15  
   d. 20

2. In addition to appropriate travel health training, pharmacists must also obtain ________ training prior to providing travel health services.
   a. Board Specialist  
   b. Immunization  
   c. Advanced Cardiopulmonary Life Support  
   d. Advanced Pharmacist Provider

3. Pharmacists providing travel health services must complete how many hours of continuing education focused on travel medicine every two years?
   a. 2  
   b. 4  
   c. 6  
   d. 8

4. The California board of pharmacy text requires that pharmacists use which resource when determining what medications may be furnished?
   a. Green Book  
   b. Yellow Book  
   c. Pink Book  
   d. Red Book

5. According to California pharmacy law, when administering vaccines that are routinely recommended by the Advisory Committee on Immunization Practices (ACIP) to individuals three years of age and older, a protocol is required.
   a. True  
   b. False

6. For which of the following vaccines would a physician-signed protocol be necessary for an adult?
   a. Hepatitis A  
   b. Influenza  
   c. Yellow fever  
   d. Tdap

7. A pharmacist’s license number can be used for the yellow fever stamp in California.
   a. True  
   b. False

8. A patient must have a primary care physician in order for a pharmacist to provide travel health services for the patient.
   a. True  
   b. False

9. Ideally, patients should be seen at least ________ prior to their trip for consultation and vaccination.
   a. 3 days  
   b. 5 days  
   c. 1 week  
   d. 2 weeks

10. Which of the following considerations are important prior to implementing a travel health service in any pharmacy setting?
    a. Workflow  
    b. Space  
    c. Scheduling  
    d. All of the above.

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ENROLLMENT CODE: 3N7LCV37

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For CPE instructions, refer to the previous page.

cpha.com/certificateprograms

February
   4 Immunization: Los Angeles
   4 Travel Health: Los Angeles
   22 APP: Palm Springs

March
   4 Diabetes: San Francisco
   18 APP: Elk Grove (Tentative)

April
   1 MTM: Claremont
   8 Anticoagulation: Fullerton
   22 Immunization: Elk Grove

May
   13 Lipid Management: Irvine

June
   3 Diabetes: La Jolla
   10 APP: Los Angeles
   17 Immunization: Pasadena

July
   15 Anticoagulation: Irvine
   29 Lipid Management: San Francisco

August
   12 Immunization: La Jolla
   19 MTM: San Francisco

September
   9 Anticoagulation: Bay Area
   23 APP: San Francisco (Tentative)

October
   7 Diabetes: Los Angeles

November
   4 Travel Health: San Francisco
   4 Immunization: San Francisco
   18 MTM: La Jolla

December
   9 APP: Fullerton

Dates and locations subject to change.

California Pharmacists Association
The Rise of Digital Health and Potential Implications for Pharmacy Practice

By Mickayla Clark, PharmD candidate 2017; Thomas Clark, PharmD candidate 2017; Afeefa Bhatti, PharmD candidate 2017; Timothy Aungst, PharmD

Abstract
The rise of technology in healthcare has led to dramatic changes in approaches to patient care by healthcare professionals. The realm of digital health has created new opportunities for pharmacists to engage patients in clinical practice. Pharmacies and industry are increasingly integrating these innovations into their businesses and practice. This article highlights areas of digital health for pharmacists to be aware of, in particular regarding areas of medication adherence and disease management.

Technology plays a massive role in our individual lives; it has morphed the human experience in ways that were simply unimaginable 50 years ago. We use technology in nearly every facet of our lives. From detecting an appropriate intensity with which to brush our teeth to counting calories lost through the course of a day, technology has made a major impact on individual health. The integration of technology into our everyday lives has changed the way we communicate, how we capture and share our lives with others, how we seek answers, and how we experience life overall. Given this change in the way people operate, it is important that pharmacists adapt to these trends and incorporate technology into daily practice. The incorporation of mobile devices and technology into healthcare has been coined as mobile health (mHealth), which falls under the broader spectrum of digital health.1-4 Digital health focuses on the integration of mobile tools (e.g., smartphones), wearable devices, and telehealth to help personalize the treatment of patients through the widespread adoption of wireless technology. The idea of involving pharmacists in mHealth has been a topic of recent interest, due in large part to the potential ramifications for the profession.4 Today, patients are using the Internet to research their health questions and help guide their personal health choices, and some of the information they find can be misleading and unreliable. It is of the utmost importance that healthcare professionals ensure there are credible sources for patients to research their questions. As pharmacists, we can research and recommend tools to patients to help solve problems related to drug information, medication adherence, and access, which includes the recent rise of novel technological devices. All of our patients will have different comfort levels with technology; despite this spectrum, there is a place for everyone to feel comfortable using digital health tools. However, there are recent technological advances coming to the field, which are already providing a benefit to patients, ranging from mobile applications to wearable technologies to ingestible medications that notify providers of patient medication adherence. We seek to help pharmacists understand the different areas of digital health, which may have substantial influence on the realm of pharmacy practice in the years to come by addressing current and upcoming digital health developments.

Smartphones and Mobile Apps – How Pharmacies Are Leveraging Mobile

The ubiquitous smartphone has changed the way users approach their daily activities thanks to the myriad mobile applications (apps) available. This includes apps that can help with dating, sharing rides, and tracking daily activities. Along with this, there is no shortage of mobile apps available
INDICATION
EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients. EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. EVZIO is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION
EVZIO is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the ingredients in EVZIO.

Seek emergency medical assistance immediately after use. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

The following warnings and precautions should be taken when administering EVZIO:

- Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeated doses of naloxone using a new EVZIO, as necessary, while awaiting emergency medical assistance.
- Risk of Limited Efficacy With Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.
- Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for the development of opioid withdrawal.
- Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were most commonly observed in EVZIO clinical studies: dizziness and injection site erythema.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, and hyperactive reflexes.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on the following pages. For more information, please visit EVZIO.com or call 1-855-773-8946.


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Dispense EVZIO 2 mg for your patients taking opioids.
EVZIO (naloxone hydrochloride injection) Auto-Injector for intramuscular or subcutaneous use

INDICATIONS AND USAGE
EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients. EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. EVZIO is not a substitute for emergency medical care.

Important Administration Instructions
EVZIO is for intramuscular and subcutaneous use only. Because treatment of suspected opioid overdose must be performed by someone other than the patient, instruct the prescription recipient to inform those around them about the presence of EVZIO and the Instructions for Use.

Instruct the patient or caregiver to administer EVZIO according to the printed instructions on the device label or the Instructions for Use.

Instructions for Use
Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers the naloxone hydrochloride injection, and retracts the needle fully into its housing. Post-injection, the electronic voice instruction guide the user through each step of the injection (e.g., if the injection is performed properly). Do not attempt to replace the red safety guard once it is removed.

EVZIO must be administered according to the printed instructions on the device label or the electronic voice instructions (EVZIO contains a speaker that provides voice instructions to guide the user through each step of the injection). If the EVZIO electronic voice instruction system does not operate properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on its label.

Initial Dosing
Administer the initial dose of EVZIO to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Administer EVZIO as quickly as possible because prolonged delay in treatment of suspected, potentially life-threatening opioid emergency after administration of the first dose of EVZIO.

Additional doses of EVZIO may be required until emergency medical assistance becomes available.

Do not attempt to reuse EVZIO. Each EVZIO contains a single dose of naloxone.

Dosing in Pediatric Patients Under Age One Year
Dosing Information

Contraindications
EVZIO is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the other ingredients.

Warnings and Precautions
Risk of Recurrent Respiratory and Central Nervous System Depression
The duration of action of most opioids is likely to exceed that of EVZIO resulting in a return of respiratory and/or central nervous system depression after an initial improvement in symptoms. Therefore, it is necessary to seek emergency medical assistance immediately after delivering the first dose of EVZIO. Keep the patient under continued surveillance, and administer additional doses of EVZIO as necessary. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Risk of Limited Efficacy With Partial Agonists or Mixed Agonist/Antagonists
Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses of naloxone hydrochloride may be required to antagonize buprenorphine because the latter has a long duration of action due to its slow rate of binding and subsequent slow dissociation from the opioid receptor. Buprenorphine antagonism is characterized by a gradual onset of the reversal effects and a decreased duration of action of the normally prolonged respiratory depression.

Precipitation of Severe Opioid Withdrawal
The use of EVZIO in patients who are opioid dependent may precipitate an acute abstinence syndrome characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piorrhea, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes. Monitor patients for the development of the signs and symptoms of opioid withdrawal.

Abrupt postoperative reversal of opioid depression after using naloxone hydrochloride may result in nausea, vomiting, sweating, tachycardia, hypertension, hypotension, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. These events have primarily occurred in patients who had pre-existing cardiovascular disorders or received other drugs that may have similar adverse cardiovascular effects. Although a direct cause and effect relationship has not been established, after use of naloxone hydrochloride, monitor patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects for hypotension, ventricular tachycardia or fibrillation, and pulmonary edema in an appropriate healthcare setting. It has been suggested that the pathogenesis of pulmonary edema associated with the use of naloxone hydrochloride is similar to neurogenic pulmonary edema, i.e., a centrally mediated massive catecholamine response leading to a dramatic shift of blood volume into the pulmonary vascular bed resulting in increased hydrostatic pressures.

ADVERSE REACTIONS
The following serious adverse reactions are discussed elsewhere in the labeling:

• Precipitation of Severe Opioid Withdrawal

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The following adverse reactions were observed in EVZIO clinical studies involving two pharmacokinetic studies with a total of 54 healthy adult subjects exposed to 0.4 mg EVZIO, 0.8 mg EVZIO (two 0.4 mg EVZIs), or 2 mg EVZIO, adverse reactions occurring in more than one subject were dizziness and injection site erythema.

The following adverse reactions have been identified during postapproval use of naloxone hydrochloride in the postoperative setting. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: hypotension, hypertension, tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in postoperative patients have resulted in significant reversal of analgesia and have caused agitation.

Other events that have been reported in postmarketing use of EVZIO include agitation, disorientation, confusion, and anger.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated an acute withdrawal syndrome. Signs and symptoms have included: body aches, fever, sweating, runny nose, sneezing, piorrhea, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, and hyperactive reflexes.

USE IN SPECIFIC POPULATIONS
Pregnancy

Risk Summary
The limited available data on naloxone use in pregnant women are not sufficient to inform a drug-associated risk. However, there are risks to the fetus of the opioid-dependent mother with use of naloxone. In animal reproduction studies, no embryotoxic or teratogenic effects were observed in mice and rats treated with naloxone hydrochloride during the period of organogenesis at doses equivalent to 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.
EVZIO (naloxone hydrochloride injection) Auto-injector

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Naloxone hydrochloride crosses the placenta and may precipitate withdrawal in the fetus as well as in the opioid-dependent mother. The fetus should be evaluated for signs of distress after EVZIO is used. Careful monitoring is needed until the fetus and mother are stabilized.

Data

Animal Data

Naloxone hydrochloride was administered during organogenesis to mice and rats at doses 4-times and 8-times, respectively, the dose of 10 mg/day given to a 50 kg human (when based on body surface area or mg/m²). These studies demonstrated no embryotoxic or teratogenic effects due to naloxone hydrochloride.

Lactation

There is no information regarding the presence of naloxone in human milk, or the effects of naloxone on the breastfed infant or on milk production. Studies in nursing mothers have shown that naloxone does not affect prolactin or oxytocin hormone levels. Naloxone is minimally orally bioavailable. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for EVZIO and any potential adverse effects on the breastfed infant from EVZIO or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of EVZIO (for intramuscular and subcutaneous use) have been established in pediatric patients of all ages for the emergency treatment of known or suspected opioid overdose. Use of naloxone hydrochloride in all pediatric patients is supported by adult bioequivalence studies coupled with evidence from the safe and effective use of another naloxone hydrochloride injectable product. No pediatric studies were conducted for EVZIO.

Absorption of naloxone hydrochloride following subcutaneous or intramuscular administration in pediatric patients may be erratic or delayed. Even when the opiate-intoxicated pediatric patient responds appropriately to naloxone hydrochloride injection, he/she must be carefully monitored for at least 24 hours as a relapse may occur as naloxone is metabolized.

In opioid-dependent pediatric patients, (including neonates), administration of naloxone hydrochloride may result in an abrupt and complete reversal of opioid effects, precipitating an acute opioid withdrawal syndrome. There may be clinical settings, particularly the postpartum period in neonates with known or suspected exposure to maternal opioid use, where it is preferable to avoid the abrupt precipitation of opioid withdrawal symptoms. Unlike acute opioid withdrawal syndrome in adults, acute opioid withdrawal in neonates manifesting as seizures may be life-threatening if not recognized and properly treated. Other signs and symptoms in neonates may include excessive crying and hyperactive reflexes. In these settings where it may be preferable to avoid abrupt precipitation of opioid withdrawal symptoms, consider use of an alternate naloxone hydrochloride product that can be dosed according to weight and titrated to effect.

In pediatric patients under the age of one year, the caregiver should pinch the thigh muscle while administering EVZIO. Carefully observe the administration site for evidence of residual needle parts, signs of infection, or both.

Geriatric Use

Geriatric patients have a greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Therefore, the systemic exposure of naloxone can be higher in these patients.

Clinical studies of naloxone hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified responses in differences between the elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term animal studies to evaluate the carcinogenic potential of naloxone have not been completed.

Mutagenesis

Naloxone was weakly positive in the Ames mutagenicity and in the in vitro human lymphocyte chromosome aberration test, but was negative in the in vitro Chinese hamster V79 cell HGPRT mutagenicity assay and in the in vivo rat bone marrow chromosome aberration study.

Impairment of Fertility

Reproduction studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (when based on surface area or mg/m²), demonstrated no adverse effect of naloxone hydrochloride on fertility.

PATIENT COUNSELLING INFORMATION

Advise the patient and family members or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Instruction patients and their family members or caregivers to:

- Become familiar with the following information contained in the carton as soon as they receive EVZIO:
  — EVZIO Instructions for Use
  — Trainer for EVZIO Instructions for Use
  — Trainer for EVZIO

- Become familiar with the device labeling color scheme of EVZIO and the Trainer for EVZIO:
  — The 2 mg dosage form of EVZIO is blue and purple.
  — The Trainer for EVZIO is black and white.

- Practice using the Trainer before EVZIO is needed.
  — Each EVZIO can only be used one time; however, the Trainer for EVZIO can be re-used for training purposes and its safety guard can be removed and replaced.
  — Both EVZIO and the Trainer for EVZIO incorporate the electronic voice instruction system

- It is recommended that patients and caregivers become familiar with the Trainer for EVZIO provided and read the Instructions for Use; however, untrained caregivers or family members should still attempt to use EVZIO during a suspected opioid overdose while awaiting definitive emergency medical care.

Recognition of Opioid Overdose

Instruct patients and their family members or caregivers how to recognize the signs and symptoms of an opioid overdose requiring the use of EVZIO such as the following:

- Extreme sleepiness — inability to awaken a patient verbally or upon a firm sternal rub.
- Breathing problems — this can range from slow or shallow breathing to no breathing in a patient who cannot be awakened.
- Other signs and symptoms that may accompany sleepiness and breathing problems include the following:
  — Extremely small pupils (the black circle in the center of the colored part of the eye) sometimes called “pinpoint pupils.”
  — Slow heartbeat and/or low blood pressure.

Risk of Recurrent Respiratory and Central Nervous System Depression

Instruct patients and their family members or caregivers that the reversal of respiratory depression caused by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete and may require higher doses of naloxone hydrochloride or repeated administration of EVZIO.

Precipitation of Severe Opioid Withdrawal

Instruct patients and their family members or caregivers that the use of EVZIO in patients who are opioid dependent may precipitate an acute abstinence syndrome characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes.

Administration Instructions

Instruct patients and their family members or caregivers about the following important information:

- Make sure EVZIO is present whenever persons may be intentionally or accidentally exposed to an opioid to treat serious opioid overdose (ie, opioid emergencies)
- Administer EVZIO as quickly as possible if a patient is unresponsive and an opioid overdose is suspected, even when in doubt, because prolonged respiratory depression may result in damage to the central nervous system or death. EVZIO is not a substitute for emergency medical care.
- EVZIO is user actuated and may be administered through clothing (eg, pants, jeans) if necessary.
- Inject EVZIO while pressing into the anterolateral aspect of the thigh. In pediatric patients less than 1 year of age, pinch the thigh muscle while administering EVZIO.
- Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers the naloxone, and retracts the needle fully into its housing. The needle is not visible before, during, or after injection.
- Each EVZIO can only be used one time.
- If the electronic voice instruction system of EVZIO does not work properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on its label.
- The electronic voice instructions are independent of activating EVZIO, and it is not necessary to wait for the voice instructions to be completed prior to moving to the next step in the injection process.
- Post-injection, the black base locks in place, a red indicator appears in the viewing window and electronic visual and audible instructions signal that EVZIO has delivered the intended dose of naloxone hydrochloride.
- EVZIO’s red safety guard should not be replaced under any circumstances.
- Periodically visually inspect the naloxone solution through the viewing window. If the solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
- Replace EVZIO before its expiration date.


on Google Play and the Apple App Store related to health, fitness, and medical services. These applications revolve around many topics including, but not limited to, nutritional eating, weight loss, medication adherence, and informatics. In many ways, the modern smartphone is an advanced personal digital assistant (PDA) that has garnered much interest in the past as a tool for clinicians. Many pharmacists have been quick to gravitate to the use of mobile apps to supplement their daily medical references (e.g., Lexicomp, Micromedex), and there are many apps they can use to help in patient care. Beyond the use of smartphones as mobile reference points, the use of apps for other services is captivating areas of pharmacy practice, such as order verification and communication amongst healthcare practitioners.

Community pharmacies have not been late to this trend and have developed apps to promote their services and provide patients with essential tools. For instance, Walgreens, CVS, and other community pharmacies have created applications with different resources available for patients. After creating a login, patients are able to manage their medications from the convenience of their mobile device. They can choose to refill or transfer prescriptions, or simply access their medication profile from their mobile devices. These community pharmacies have attempted to help increase adherence to medications by embedding “pill reminder” technology in their applications. Walgreens has been particularly innovative in adding tools designed to convenience patients. For instance, patients can submit their new insurance information simply by taking a picture of their prescription insurance card from their mobile device. Having access to the correct insurance information is helpful in saving time for patients, as they do not have to wait while pharmacy personnel submit their claim, and patients know in advance if their insurance does not cover the medication. Furthermore, Walgreens is on the forefront of revolutionizing the way patients communicate with medical personnel. From their mobile app, you can have a secure conversation with a pharmacist regarding health or receive medication-related answers. Lastly, given that pharmacists are playing a larger role in immunizations, this pharmacy has taken the initiative to have a section on their app dedicated to recording immunizations. Those received at Walgreens are automatically included, but patients can also add their own history. This allows patients to carry their immunization record everywhere they go, helping them to avoid any duplication in vaccinations. Interestingly, recent studies have been conducted amongst users of pharmacy mobile apps. Results demonstrated that interviewees wanted an app to provide an improved pharmacy experience, to have features that supported self-management of their health, to have the ability to grant access to pharmacists directly, and to address concerns about privacy and access. It may come as no surprise that with time, many large pharmacies will gravitate toward a central mobile platform to meet many of their patients’ needs and expectations in the future. Taking that into consideration, CVS has recently launched its own digital innovation laboratory in Boston, Massachusetts to help foster new ideas and services related to the tech industry to help boost its technological developments.

One area being actively explored by pharmacies is extending services that include telehealth platforms. There have been a number of mobile health companies that have recently developed online platforms to answer and address patients’ medical questions, as seen in Table 1. One example is HealthTap, an online company that allows members to pose online questions to healthcare professionals (e.g., physicians, pharmacists) about medical issues and receive online consults from their phones. Looking to capitalize on this new means of reaching patients, pharmacy companies are seeking to develop telehealth services as well, utilizing physicians and pharmacists.

Another layer of intrigue in the mobile app market has been a plethora of start-up companies seeking to create apps to help patients access and purchase their medications using their smartphones. These new companies look to provide patients with online services whereby they may scan their prescription and have it sent to the pharmacy to be filled to provide same-day drug delivery via these apps, as seen in Table 1. Many of these start-up companies are based in California, primarily around the San Francisco region, where they are looking to garner attention and investment with their business models. While these services are rather new and may be attractive to patients with the rise of on-demand services (e.g., Uber), the drawback will be less face time with pharmacists, which may prove detrimental to patient care. Nonetheless, with technology advancing, community pharmacies must continue to be innovative in their design in order to remain relevant, and pharmacists should be aware of how pharmacies are using technology to maximize patient care and services in a highly competitive market.

**Digital Health for Medication Adherence – New Tools in Patient Care**

Pharmacy-related digital health technology is not limited to mobile apps and technology tailored to a specific pharmacy. Rather, it branches out in the form of thousands of smartphone mobile apps and wearable technologies, encompassing medication adherence, monitoring of various disease states, and overall health and wellness, as seen in Table 1. This mobile health (mHealth) subset of digital health is being actively explored by pharmacists as a means of increasing clinical interventions amongst patient populations. Perhaps the main area in which many researchers believe pharmacists can make the largest impact on digital health is increasing medication adherence.

Medication adherence is a serious concern the healthcare system faces, with medication nonadherence...
accounting for nearly $300 billion dollars of avoidable healthcare spend-
ing.\textsuperscript{21} Medication adherence is crucial, especially when it comes to patients with one or more chronic conditions. Recent technological innovations have included customized short-messaging services (SMS) (i.e., texting), mobile apps, and smart devices to help improve medication adherence. While SMS is a relatively older intervention, with more than a decade’s worth of studies, it is still being actively pursued due to its low cost and large scalability to reach patients who may lack a smartphone.\textsuperscript{22} Moving beyond SMS, the creation of mobile apps to serve as a “virtual pillbox” have gained much interest, and many apps have entered the market. A review conducted by Dayer and colleagues sought to review the medication adherence apps available on the market and help identify apps that would be best for patients.\textsuperscript{23} During the course of their review, Dayer and colleagues identified that many apps lacked key qualities that would help with adherence. Their overall work has culminated in identifying apps they have evaluated to be beneficial for patients, and they have created a website called medappfinder.com to help healthcare professionals recommend medication reminder apps for their patients.\textsuperscript{24} One limiting factor behind the use of medication adherence apps at present is the current state of medical research demonstrating significant impact. There have been a number of studies investigating the use of text-based messaging to help with medication adherence, though research on the use of apps has been limited. Ongoing studies may help identify which apps and what interventions may prove beneficial in practice in the near future.\textsuperscript{25,26}

While apps themselves are a relatively novel approach to helping patients with their medication adherence, there have been several different approaches to solving the medication adherence issue with digital health. These include “smart” pill bottles that have the ability to remind patients to take their medications, can track when a patient removes a medication from the bottle, and broadcast that information via Bluetooth, as seen in Table 1. One example is Adheretech, a pill bottle that senses when the bottle is opened and how many pills are contained based on weight, which is currently involved in several ongoing clinical studies to evaluate efficacy in practice.\textsuperscript{27,28} Even more advanced approaches include ingestible biosensors that can detect when a patient takes a medication. One of the main developers is Proteus Digital Health, which has been actively testing its FDA-approved product in multiple areas of healthcare.\textsuperscript{29} Proteus is currently in the process of pursuing approval of a “smart” pill with Otsuka Pharmaceuticals’ Abilify drug product to address medication adherence in patients with mental health disorders. These smart pill products are also being tested for adherence in other disease states, and a recent publication in JAPhA identified the use of these ingestible biosensors to help pharmacists guide therapy in patients enrolled in a hypertension treatment program in Great Britain.\textsuperscript{30} Lastly, pharmaceutical companies are actively exploring ways to integrate digital health technology into their existing products, including creating inhalers with integrated Bluetooth-enabled sensors, allowing providers to track their adherence and utilization with the hope of identifying nonadherence or the need for therapy escalation.\textsuperscript{31}

While the premise is these new tools can help objectively assess patients’ adherence rates, especially in populations prone to nonadherence, they are still in their infancy. Pharmacists will more likely see these products become increasingly available to patients, especially those with chronic diseases requiring intensive adherence to prevent disease progression or symptoms. Pharmacy case managers in particular could benefit from the use of these tools to keep track of patients’ medication adherence and help with the reconciliation process between in- and outpatient management. The technology available may help keep better records that can inform community pharmacists and providers on what medications are being utilized and perhaps reduce medication errors leading to negative patient outcomes. The key factor will be the reimbursement models by insurance companies allowing patients to use such products; this will become more clear once results from ongoing studies results are published. Using sensors to track medication adherence is a factor that may help providers determine the best treatment regimen for the patient. Assessing adherence to treatment regimens would no longer solely rely on patient reporting. The data will show the exact date and time a medication was taken. It has the potential to save the healthcare system a significant amount of money while at the same time improving the patient’s quality of life by reducing unnecessary adverse effects and hospital visits due to nonadherence.

Digital Health Tools – Patient-Empowered Monitoring

Going beyond medication adherence, the use of digital health in practice may enable pharmacists to embrace more clinical responsibilities. There are currently many apps on the market directed for disease management and an increasingly developed market of smart devices for chronic disease assessment. For example, many apps exist to help with the management of diabetes, with key features of these apps typically including a blood glucose log, medication “pillbox,” weight chart, and diet log. These features can be very helpful, as typically this information can be exported and given to the healthcare provider responsible for the patient’s treatment. This also gives the patient more insight into their health, as they have a place to log their diet, medication/insulin usage, and blood sugar. The overall goal of recommending these apps is to put the patient in control of their own health, while also allowing patients to share their data in real time with their providers and caregivers. The provider can then
better assess the patient’s condition, medication adherence, and therapeutic efficacy. Changes to medication therapy could then be made depending on the patient’s results. Pharmacists have been actively involved in telehealth management for patients with diabetes and hypertension, and these apps and digital services could offer a potential way to access needed data for care.32,33

Pharmacists will also likely see an increasing number of digital health devices slowly enter the pharmacy in the near future. While wearable fitness devices (e.g., Fitbit) have seen a large uptake in society, other devices, are also gaining a large traction in the health industry. These include products by Withings (now owned by Nokia), which has created a line of smart Bluetooth-enabled devices, including blood pressure monitors, weight scales, and health trackers, that are being sold widely throughout the United States. Other devices, such as that by AliveCor, can be attached to the back of patients’ iPhones, turning them into EKGs and tracking their heart rhythms. This device is currently FDA approved and has been tested by pharmacists in Australia to identify patients with undocumented atrial fibrillation.34 Nonetheless, as these devices become more predominant in healthcare as a whole, they offer a significant opportunity for pharmacists to educate their patients on their use and integrate the data into patient care.

Considerations on the Future of Digital Health

Medication adherence and helping patients reach their health goals are two focuses seen across all pharmacy settings. With numerous digital health options available, ultimately the most ideal form of technology is dependent on the capabilities of each individual patient. There are many factors to consider when utilizing technology for patients, which could include financial barriers, technology literacy, age, physical disabilities, and simply the willingness to put extra effort into using the app or wearable device. Many of these apps and products can be expensive and out of a patient’s price range; one of the largest criticisms has been that patients who may benefit most from such services may not be able to afford them. The lynchpin of these services will be reimbursement for use by insurance companies or health agencies. Additionally, physical disabilities such as visual impairments could prevent a patient from using these apps and products. Age and technology literacy is an area where some research has been done. One study in a population of people aged 50 and older showed there was no benefit from utilizing a diabetes app, with the main problem being lack of ease of use.35

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<th>Table1: Sample Digital Health Devices and Services</th>
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<td><strong>Category</strong></td>
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<td>Medication Adherence</td>
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Many of the patients felt it was not worth the effort and found the app difficult to operate and read. On the other hand, another study performed on people aged 50 and older with chronic illnesses utilizing wearable activity tracking devices had different results.\textsuperscript{36} This population found the tracking devices very helpful, with the stipulation that someone was there to assist in setting up the device and helping interpret the data. Other studies have also demonstrated many patients are amenable to the integration of mobile devices and apps to help manage their medication therapies.\textsuperscript{37,38}

Overall, the breadth of research in the digital health field is in its nascent stage, with much speculation about its overall impact. There are multiple studies currently in process that will help determine what tools and services may ultimately benefit patients. Nonetheless, recent research is demonstrating the limitations of digital health tools. For one, there are multiple “bad” apps available on the market that could prove negative in patient care. For instance, recent publications in JAMA Internal Medicine identified apps that did not function as advertised, namely a blood pressure app that purported to calculate blood pressure from the smartphone camera, and a minireview demonstrated that many diabetes apps are not securing patient information.\textsuperscript{39-42} Another study, the BEAT-HF study, demonstrated the use of digital health tools did not help reduce the readmission rates in patients with a recent heart failure exacerbation.\textsuperscript{43} Nonetheless, there are a number of studies that have shown the benefits of digital health, such as the CHAMPION study where a remote patient monitoring system using an implantable microelectromechanical pulmonary artery pressure monitoring system was utilized to help manage heart failure patients and reduce hospitalization.\textsuperscript{3,44} While some of these interventions may be more invasive in their current form (e.g., implantation), digital health strives to make technology easier for patients and clinicians to utilize, and is demonstrative of its potential impact on high-risk diseases. These studies have demonstrated the initial flaws and successes of digital health interventions, and they may help future researchers and developers recognize more appropriate interventions to make and help the design process.

### Conclusion

The idea of digital health apps, wearable device utilization, and incorporation of dosage sensors in medication has the potential to revolutionize the way we practice pharmacy. They help bridge the gap between adherence, access, wellness, and chronic disease management. For these reasons, the incorporation of digital health into the curriculum for future pharmacists, as well as continuing education for current pharmacists, should be considered. While integrating technology into pharmacy, it is important to keep in mind that patients come from different technology literacy levels. With technology being such a key component of our lives, it is clear to see that many would benefit. More technology aimed at combating the lack of medication adherence is emerging, trying to provide user-friendly devices and applications centered around the patient. As we move forward, these technologies will become more financially feasible for the average consumer. The development of new technology with fewer limitations is becoming increasingly more important and will play a bigger role in how pharmacy is practiced.

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### References


Background
Asian immigrants are exposed to different lifestyles in the United States (U.S.) and may have different osteoporosis risk factors. This study investigated relationships between known risk factors for osteoporosis in general U.S. populations and heel bone mineral density (BMD) in Asian populations in San Diego County. A secondary aim was to correlate observed heel BMD T-scores with the Osteoporosis Self-Assessment Tool for Asians (OSTA).

Methods
This was a cross-sectional study of 150 Asians aged 50 years and older in San Diego County in 2014. An osteoporosis risk factor survey was administered, OSTA indices were calculated, and heel BMD T-scores were obtained using a portable GE Achilles bone densitometer.

Results
Participants aged 50 to 64 years (n=77, mean T-score: -0.62) had lower osteoporosis risk compared to participants 65 years and older (n=73, mean T-score: -0.90) (p-value=0.036). Body weight was higher in normal participants (median weight: 57.1 kg) than participants with osteopenia risk (median weight: 56.7 kg) or osteoporosis risk (median weight: 48.4 kg) (p-value=0.0059). Osteoporosis risk was not associated with female sex (n=109, p-value=0.218), previous osteoporotic fracture or family history of osteoporotic fracture (n=22, p-value=0.260), or early menopause or oophorectomy (n=31, p-value=0.536). The OSTA showed a weak correlation with T-scores (p-value=0.0029, r=0.24) and had moderate sensitivity (66%) and specificity (51%).

Conclusion
Older and lower-weight participants had higher osteoporosis risk by heel BMD T-scores. Other risk factors were not associated with osteoporosis risk. The OSTA showed a weak correlation with heel BMD T-scores and had moderate sensitivity and specificity in predicting the T-score classifications.

Background
Osteoporosis is a progressive bone disease that affects men and women of all races but is more prevalent in postmenopausal women and older adults. Osteoporosis is typically a silent disease until a bone fracture occurs. Therefore, it is important to know a patient’s osteoporosis risk factors to provide early intervention. Known risk factors for osteoporosis include being Caucasian or Asian, female sex, increased age, low body weight, nontraumatic fracture after age 50 or family history of osteoporotic fracture, and

early menopause or surgical removal of the ovaries. Asian immigrants are exposed to different dietary and lifestyle habits when living in the United States (U.S.) compared to in their countries of origin and may have different osteoporosis risk factors than the general U.S. population.3

While a spine and hip dual-energy X-ray absorptiometry (DXA) scan is the gold standard for evaluating bone mineral density (BMD) and is used for the diagnosis of osteoporosis, many people in the Asian community in San Diego may not have easy or affordable access to BMD screening. Heel BMD T-scores can be used as the reference value in lieu of central DXA T-scores, as the latter is not portable. Another easier and low-cost method to predict the risk of osteoporosis would be helpful. The Osteoporosis Self-Assessment Tool for Asians (OSTA) is a simple tool that calculates the risk of osteoporosis based on age and weight [(Weight in kg - Age) x 0.2 and removing the decimal]. This tool has been validated in a number of Asian populations.4 The World Health Organization (WHO) diagnostic classification uses BMD by central DXA at the spine and hip to calculate T-scores in determining diagnosis of osteopenia or osteoporosis.5 A patient has normal BMD if T-score is ≥ -1, low bone mass or osteopenia if T-score is between -1 and -2.5, and osteoporosis if T-score is ≤ -2.5. Similarly, OSTA indices classify osteoporosis risks as low risk if OSTA index is > -1, intermediate risk if OSTA index is between -1 and -4, and high risk if OSTA index is < -4.4

Objectives
This study aimed to investigate relationships between known risk factors for osteoporosis in the general U.S. population and heel BMD, reported as T-scores, in Asian populations in San Diego County. The secondary aim was to correlate observed heel BMD T-scores with OSTA indices to determine the effectiveness of the OSTA tool in these populations.

Methods
This was a cross-sectional study of Asian men and women aged 50 years and older in San Diego County, California. Participants were recruited at health fairs between June and October 2014. All individuals interested in their bone health were screened. Exclusion criteria included those aged 49 and younger, non-Asians, people who were unable to understand the survey or consent forms, and people who failed to follow the instructions of the study personnel. Informed Consent, HIPAA and Bill of Rights forms were provided in English, Vietnamese, and Chinese (Mandarin). A risk factor survey was administered that included gender, age, body weight, previous osteoporotic fracture or family history of osteoporotic fracture, and menopause before age 45 or oophorectomy. Each participant’s heel BMD T-score was measured with a portable GE Achilles bone densitometer. For purposes of this study, participants were classified as normal, at risk for osteopenia, or at risk for osteoporosis based on heel BMD T-scores.

For the primary endpoint (relationships between heel BMD T-score and risk factors), chi-squared tests were performed for gender, age, previous osteoporotic fracture or family history of osteoporotic fracture, and early menopause or oophorectomy. The median body weights of each risk group were compared to one another by the Kruskall-Wallis rank test. For the secondary endpoint, a linear regression was performed to find correlation between heel BMD T-scores and OSTA indices. Sensitivity and specificity of the OSTA were also calculated. Data were analyzed with STATA statistical software (Revision October 22, 2012. StataCorp LP, College Station, Texas).

The study was approved by the university’s Human Research Protections Program.

Results
A total of 228 subjects were seen at nine health fairs between June and October 2014. One hundred and fifty subjects met the inclusion criteria. The study population included 110 Vietnamese (73%), 38 Chinese (25%), 1 Korean (1%), and 1 Filipino (1%). One hundred and nine
participants (73%) were female, and 41 (27%) were male. Ages ranged from 50 to 87 years old (Figure 1).

Participants aged 50 to 64 years had lower osteoporosis risk compared to participants 65 years or older (Table 1). Body weight was higher in normal participants (n=88; median weight: 57.1 kg [42.9 kg - 92.5 kg]) compared to participants at risk for osteopenia (n=52; median weight: 56.7 kg [35.4 kg - 75.7 kg]) or osteoporosis (n=10; median weight: 48.4 kg [36.7 kg - 63.5 kg]) (p=0.0059; Figure 2). Osteoporosis risk was not significantly associated with being female, having a history of fracture, early menopause, or oophorectomy (Table 1).

The OSTA showed a weak correlation (r=0.24) with heel BMD T-scores and moderate sensitivity (66%) and specificity (51%) in predicting normal bone density versus at risk for osteopenia or osteoporosis as measured by heel BMD T-scores (Figure 3).

**Discussion**

Five known risk factors for osteoporosis in the general U.S. population were evaluated in this study. As body weight decreased or as age increased, risk for osteoporosis measured by heel BMD T-scores increased as expected. However, being female, having a history of osteoporotic fracture or family history of osteoporosis, and having early menopause or oophorectomy were not associated with osteoporosis risk, possibly because the study was under-powered to detect these differences. A PubMed literature search revealed limited studies in Asian immigrant populations related to osteoporosis in bivariate analyses, and lower acculturation was significantly related to higher likelihood of osteoporosis among postmenopausal women. A separate study conducted in our study population assessed relationships between current calcium and vitamin D intake (dietary or supplements) and exercise with heel BMD T-scores. No significant associations were found.

The accuracy of the OSTA tool has been validated in a number of Asian populations. The accuracy of the OSTA tool has been validated in a number of Asian populations. Our study showed a weak correlation of OSTA with heel BMD T-scores. Also, it showed moderate sensitivity (66%) and specificity (51%) in predicting the heel BMD T-score classifications for normal versus low heel BMD. In our study, the risk category was defined as heel BMD T-score ≤ -1.0 and OSTA index ≤ -1 due to a small number of participants with heel BMD T-score ≤ -2.5. A study of Nepalese women used the same risk category as ours, and the sensitivity and specificity of

<table>
<thead>
<tr>
<th>Table 1: Heel BMD T-scores by Risk Factor Groups</th>
</tr>
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<tbody>
<tr>
<td>Categories</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>50 - 64 years old</td>
</tr>
<tr>
<td>65 years or older</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>History of fracture</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Early menopause or oophorectomy</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

*Significant at p-value < 0.05
the OSTA compared to heel BMD were 85.2% and 89.1%, respectively.\textsuperscript{9} In a study of Taiwanese women, the sensitivity and specificity were 84% and 61%, respectively, when the risk category was defined as heel BMD T-score \(\leq -2.5\) and OSTA index \(\leq -1.\textsuperscript{10}

**Limitations**

Data collection for history of osteoporotic fracture or family history of osteoporosis relied on self-reports. While body weight was obtained, body mass index was not recorded for participants, as it was not a required measurement for the OSTA tool. Smaller subgroup sample sizes for comparisons of gender, history of fracture, and early menopause or oophorectomy may have decreased the power to detect real differences. In addition, heel BMD T-scores were used as a reference group, as DXA T-scores of the spine or hip were not feasible in a community screening setting. Although a DXA scan is used as a diagnostic tool, heel BMD screening can be a useful prescreening tool for assessing risk of osteoporosis.\textsuperscript{11} Another limitation of our study was that we did not collect the age at immigration to the U.S. of each participant. Since immigrants could have arrived as children or as adults, this may have impacted the applicability of our findings. Participants’ general health was not asked in our survey, but all participants were ambulatory and presented themselves for the health fairs. We also did not ask about medication usage in our survey, as many of the participants spoke little English and may not be familiar with the names of medications they may be taking. A pilot study that we had conducted prior to this study showed that very few of our Asian patient population at our health fairs were smokers or alcohol users. In an effort to keep survey questions brief, we excluded questions related to tobacco or alcohol use. Lastly, our survey did not collect information about milk consumption during adolescence.

**Conclusion**

In Asian populations in San Diego County, California, participants aged over 65 or over 50 with low body weight should be screened for osteoporosis to evaluate the need for earlier intervention. The OSTA may be a moderately effective tool to identify patients at high risk for osteoporosis in these populations when peripheral heel BMD testing is not available.

**About the Authors**

Esther Park, PharmD, the corresponding author, was a PharmD candidate, class of 2016, at the University of California, San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences at the time she completed this project. She has no bias to report.

Binh Tran, MS, PharmD, MBA, is an assistant clinical professor at the University of California, San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences, and executive director at Asian Pacific Health Foundation, San Diego, with 15 years of experience in community screening.
work. She has no bias to report.

Brookie M. Best, PharmD, MAS, is a professor of clinical pharmacy and pediatrics at the University of California, San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences and Pediatrics Department, School of Medicine, with over 15 years of experience in clinical research study design, conduct, and analysis. She has no bias to report.

Renu Singh, PharmD, BCACP, CDE, is a clinical professor at the University of California, San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences. Dr. Singh has over 20 years of experience in adult ambulatory care practice and provides lectures in the area of osteoporosis. She has no bias to report.

References
8. Moshtael M, Tran B, Best BM, Singh RF. Early Detection of Osteoporosis in Asian Populations in San Diego County: Use of Calcium, Vitamin D and Exercise. Summer Research Training Program Poster Presentations. UC San Diego School of Medicine and Skaggs School of Pharmacy and Pharmaceuti-
Osteoporosis Screening & Educational Program
Subject Survey Form

Name: ___________________________________

Last              First               Middle

Date of birth: ____ ___ _____      Age: _____      Phone: __________________

Please answer the following questions:

1- Gender:         □ M           □ F

2- Race:          □ Vietnamese
                  □ Chinese
                  □ Indian
                  □ Korean
                  □ Filipino
                  □ Other (please specify): _______________________

3- Previous osteoporotic fracture in you or family history of osteoporotic fracture
   □ Yes   □ No

4- For women only.
   Early menopause (before age 45) or surgical removal of the ovaries
   □ Yes   □ No

5- Taking calcium supplement      □ Yes      □ No

   If yes,
   What kind?         □ Calcium supplement
                      □ Multivitamins
                      □ I don't know
                      □ Others (please specify): _______________________

   How much?          □ 200 mg tablets
                      □ 1000 mg tablets
                      □ I don’t know
                      □ Others (please specify): _______________________

6- Taking vitamin D?      □ Yes      □ No

   If yes,
   What kind?         □ Vitamin D supplement
                      □ In combination with calcium
                      □ I don’t know
                      □ Others (please specify): _______________________

(form continued on next page)
Osteoporosis Screening & Educational Program Subject Survey Form, Continued

<table>
<thead>
<tr>
<th>How much?</th>
<th>□ 400 IU</th>
<th>□ 800 IU</th>
<th>□ 1000 IU</th>
<th>□ more than 1000 IU</th>
<th>□ I don’t know</th>
<th>□ Others (please specify): ____________________</th>
</tr>
</thead>
</table>

7- Calcium-rich foods that you eat are
Serving size: 1 cup, 2 cups, etc.
How often: once a day, more than once a day, once a week, etc.

<table>
<thead>
<tr>
<th>Food Type</th>
<th>Serving Size</th>
<th>How Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheese</td>
<td></td>
<td></td>
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<tr>
<td>Yogurt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sardines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soybeans</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dark leafy greens (such as spinach, kale, turnips, collard greens)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dried figs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fortified cereal (such as Total, Raisin Bran, Corn Flakes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fortified soy milk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Others (please specify): ________________________________

8- Regular exercise 2.5 hours per week: □ Yes  □ No
IF yes,
What kind of exercise?

<table>
<thead>
<tr>
<th>Exercise</th>
<th>hours/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td></td>
</tr>
<tr>
<td>Running</td>
<td></td>
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<tr>
<td>Swimming</td>
<td></td>
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<tr>
<td>Hiking</td>
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<tr>
<td>Weight lifting</td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td></td>
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<tr>
<td>Tai chi</td>
<td></td>
</tr>
<tr>
<td>Dancing</td>
<td></td>
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<tr>
<td>Aerobics</td>
<td></td>
</tr>
<tr>
<td>Golf</td>
<td></td>
</tr>
<tr>
<td>Tennis</td>
<td></td>
</tr>
</tbody>
</table>

Others (please specify): ____________________________________________

(form continued on next page)
### Osteoporosis Screening & Educational Program Subject Survey Form, Continued

<table>
<thead>
<tr>
<th>Subject’s weight: ______ kg</th>
<th>OSTA index: ______</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index &gt; -1: Low risk</td>
<td>Index -1 to -4: Intermediate risk</td>
</tr>
<tr>
<td>Index &lt; -4: High risk</td>
<td></td>
</tr>
</tbody>
</table>

**Subject’s bone densitometry results:** T-score: ______

| T score ≥ -1: Normal | T score -1 to -2.5: Risk for osteopenia | T score < -2.5: Risk for osteoporosis |

**Consent:**

I hereby authorize all medical procedures. I agree to be tested by a physician, or all medical personnel under the supervision of a physician.

Signature: _________________________________ Today’s Date: ______________

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### University Reports

#### California Health Sciences University

**By Leticia Ordonez, CPhA Board of Directors Representative**

**CHSU CPhA- Pharmsgiving**

On Wednesday November 9, the CHSU Pharmily was invited to CPHA-ASP’s Pharmsgiving featuring Bella Pasta for dinner and board games for fun. It was a successful event as we all celebrated all that we are thankful for. A special appreciation was given to the CVPhA Board Members (our local chapter) for their continuous support and sponsorships.

**CPhA Leadership Summit**

On the weekend of November 12-13th, a couple of CHSU students treated themselves to CPhA’s Leadership Summit in Newport Beach. The leadership training was established to help emerging leaders become the best they could become. Students who attended had only positive things to say!

**CPhA Toy Drive**

Throughout the month of November and the beginning of December we collected new toys. The toys were donated to a children’s hospital where we were able to give these kids an unexpected surprise during the holidays.

**CPhA Candy Cane Grams**

CPhA sold holiday candy grams with hand written well-wishes and message(s) which faculty/staff/students were able to send to each other. We distributed them the week before finals. It was a very simple, but thoughtful way to wish each other happy holidays and luck on finals.
California Northstate University
By Angel Paia Lor, CPhA Board of Directors Representative

Policy on Tap
CNU hosted a Policy On Tap event and had the honor of having CPhA’s Policy and Advocacy Manager, Megan Maddox, discuss the Death with Dignity legislation. Students were able to hear about the procedures health care providers and the patient must follow in order to comply with the legislation and how the legislation will impact pharmacists. The student attendees were extremely engaged and enjoyed learning about the new policies that will shape their careers.

Pharmacist Month Resolutions
CNU contacted the City of Sacramento and City of Elk Grove to request that they proclaim October as Pharmacists Month. As a result, both the City of Sacramento and City of Elk Grove invited the CNU CPhA-ASP students to attend their City Council Meetings to accept the resolution and discuss the importance of the pharmacy profession. In doing so, we were able to further promote the pharmacy profession.

Pharmacist Appreciation Dinner
CNU hosted a dinner at the Sterling Hotel for pharmacists in order to honor their hard work and dedication to the profession. Furthermore, we wanted to thank them for taking the time to provide us with a wealth of knowledge as we continue our pharmacy education. Additionally, Sacramento Valley Pharmacist Association awarded David Mitchell the Pharmacist of the Year for his commitment to the organization and to pharmacy.

Angel Tree
CNU collaborated with the Salvation Army in their annual Angel Tree Gift Drive. Overall, we were able to provide over 60 gifts to children throughout the community.

Chapman University School of Pharmacy
By Melissa Sandoval, CPhA Board of Directors Representative

Senior Fitness Expo
Student pharmacists kicked off Pharmacists Month in October at the Rancho Senior Center for their Senior Fitness Expo! This educational event included exercise and fitness demonstrations, health vendors, and free health screenings. Our members helped perform BP measurements, BMI screenings, and healthy lifestyle education targeted for the seniors.

Making Strides
CUSP members walked with the Orange County Pharmacists Association (OCPhA) and Orange County Society of Health System Pharmacists (OCSHP) team this October at the Making Strides against Breast Cancer walk in Costa Mesa, CA. This inspiring event raised $255,000 for breast cancer research and awareness!

Legislative Week
CPhA-ASP Legislative Week 2016 was a joint effort from all California schools to host events that highlighted updates in pharmacy legislation and encouraged members to stay active! We had a great turnout at A Pizza Policy with Dr. Siu Fun Wong and Get the Scoop on Legislation with Dr. Tony Park.

Senator Janet Nguyen Health Clinic
To cap out Pharmacists Month, we had 16 Chapman pharmacy students volunteer to give flu shots at a local health clinic that provided free medical, dental, and vision care to the underserved residents in the Orange County area. We are so appreciative to Senator Janet Nguyen and her office to include Chapman students in this opportunity as well as show support for American Pharmacists Month by allowing one of our pharmacy students to immunize the Senator!de food and medical resources to those in need.
Keck Graduate Institute
By Natalia Ketoola, CPhA Board of Directors Representative

Parent Summit
KGI CPhA-ASP Chapter collaborated with KGI’s PharmCAMP to host a schoolwide health fair at Carter High School in Rialto Unified School District on Saturday, October 15th. The Parent Summit is an event aimed at fostering parent involvement in their children’s education by increasing awareness. Blood glucose and blood pressure screenings were provided in addition to health education for parents who attended the event. KGI’s involvement in the Parent Summit strives to inspire the pursuit of higher education in health care.

SGVPhA Annual Banquet
On Saturday, November 5th, we participated in SGVPhA’s Annual Banquet in Montebello by tabling for KGI to promote and provide information about the pharmacy program and future events that KGI CPhA-ASP Chapter will be hosting. On this big night, KGI was proud to be represented by Claudia Lekhac (P3), who won the Student of the Year Scholarship at the banquet.

Legislative Day
On Election Day, we hosted CPhA CEO, Mr. Jon Roth and Ms. Katie Dahl to discuss current relevant pharmacy propositions on the ballot. Student members learned about several propositions which included AB1114 (Medi-Cal Pharmacist Services) and Proposition 61 (State Prescription Drug Purchases).

Bowling Social
On October 14th, KGI CPhA-ASP Chapter hosted its very first bowling social to bring members together and excite them for upcoming events. This event was a success in getting acquainted with one another on a personal and professional level.

Loma Linda University
By David Downham, CPhA Board of Directors Representative

Health Fair
As a schoolwide community outreach the CPhA and APhA chapters of Loma Linda hosted a highly attended health fair at one of our local Walmarts. At this event our booth covered new pharmacist legislation and highlighted what pharmacists can do for the public as health care providers. This was a great opportunity for our new first year members to get into the community and work with patients.

Pizza and Policy
This event highlighted the new legislation in California. Here we provide students with an understanding of where the pharmacy field is going in the future.

PY1 Blood Pressure Training
As a near yearly tradition, our chapter helped run this year’s blood pressure reading training for our first year students. Many of our board members participate and help give hands-on training for our first year students. The PY1’s were able to work on how to interact with their patients, how to use each kind of blood pressure monitor, and how they should be properly counseling their patients.

Community Outreach: Telecu
Under the leadership of Thao Nguyen, our outreach coordinator, CPhA-LLU ran a successful event at a local retirement home including a medication review “brown bagging”, osteoporosis, and blood pressure monitoring event. Although finals were over and many were already in the winter break mindset, we had an amazing turnout of students. It was a phenomenal success and we look forward to the next opportunity to engage in patient care during upcoming quarter.
Touro University California

By Julian Aurigui, CPhA Board of Directors Representative

APhA / CPhA Collaborative Health Fair with UOP and CNU

October 2nd, 2016 In a combined effort, TUC, COP, and CNU promoted health awareness with blood pressure monitoring, glucose screening and influenza vaccinations.

Clinical Skills Workshop – Motivational Interviewing

P1 students were introduced to the art of motivational interviewing. Faculty began the workshop with introductory information. Students then broke into small groups with their mock patients. As they worked through their cases, they learned what it would be like to encounter non-compliance in the healthcare setting. Faculty and upperclassmen were able to share insight with P1s as the workshop progressed. Most P1s walked away from the event with a new found awareness towards potential interpersonal hurdles they may face in the near future and the beginning framework on how to work past that.

Legislative Week – Policy On Tap and Get The Scoop on policy

Participation in Legislative week took the form of a Policy On Tap event and a Get The Scoop On Policy event. Policy On Tap was an opportunity for students to share in the perspectives of faculty and local pharmacists on healthcare and potential future directions of the profession.

Get The Scoop On Policy was an opportunity for students to learn about policy and current hot topics in pharmacy from CPhA Policy and Advocacy Manager, Megan Maddox. Over ice cream, students were able to get the scoop on policy, including topics such as end of life care.

University of California, San Diego

By Sarah Graveline, CPhA Board of Directors Representative

Health Education Event

On October 7, chapter members participated in a health fair event for the employees of Vi Retirement Facility. Student pharmacists provided blood pressure, blood glucose, and cholesterol readings. Employees at the event were able to speak with student pharmacists regarding their readings and learn about lifestyle changes which can help to lower their blood pressure and blood sugar levels.

Generation Rx Event

As future pharmacists it is our responsibility to help our community safely use their medications and this includes preventing misuse of prescription medications in our youths. Student pharmacists spent the afternoon with a local Girl Scout troop to teach them about prescription medication safety. In this interactive session, the Girl Scouts learned about consequences of inappropriate prescription drug use and how to avoid situations which could lead to medication abuse.

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University of California, San Francisco
By Emmeline Academia, CPhA Board of Directors Representative

Amongst many health fairs, our students coordinated with the Peninsula Pharmacists’ Association to host Talk With a Pharmacist Day at Hillsdale Mall, with projects such as Project Health Heart, and Operation Diabetes, along with many other informational booths for patients. During American Pharmacists’ Month, students were encouraged to share their stories, and at Talk With A Pharmacist, students shared their purpose with health fair attendees. From promoting health to leveraging pharmaceutical and insurance knowledge, it was clear that students’ passion for service was of utmost importance!

October also brought about our second annual statewide Legislative Week. On November 4, 2016, we hosted Policy on Tap, bringing together a small group of students for a discussion on current propositions affecting pharmacy care services, drug take back initiatives, and advocacy in light of an ever-changing health-care landscape.

We rounded out our quarter with our Around the World Night, an annual event that brings students together with health systems pharmacists, professors, industry professionals, and clinicians of different specialties. With three rotations, students were afforded great opportunities to learn more about life after pharmacy school and career options that are available to them.

University of the Pacific
By Brandi Tacdol, CPhA Board of Directors Representative

Legislative Week
Our CPhA-ASP Chapter celebrated the end of American Pharmacists’ Month by hosting the 2nd Annual Legislative Week from October 31st to November 4th. On November 1st, Assemblymember Susan Eggman was invited to speak to students about her recently passed bill, AB1114, and how it expands the scope of the profession. Next, CPhA-ASP collaborated with the student Policy Advocacy Coalition (SPAC) to host our first Legislative Quiz Bowl, where students were able to engage in friendly competition while learning about important policies that have shaped the profession. Lastly, CPhA President Dr. Edlen Wong discussed his views on Prop 61 and AB1114 during our last Legislative Week event, Policy on Tap.

Assistant Surgeon General - Rear Admiral Pamela M. Schweitzer
During the month of November, UOP’s CPhA-ASP Chapter had the honor of inviting Rear Admiral (RADM) Pamela M. Schweitzer on campus to discuss her role as the United States Public Health Service (USPHS) first female Chief Professional Officer and the highest ranked pharmacist in the federal government. She discussed her career path and what steps she took to become the Assistant Surgeon General of the United States and what her role entails. She demonstrated to students that the future of the profession is changing and inspired them to consider non-traditional roles in pharmacy like hers to be the change.
University of Southern California
By Michelle Lee, CPhA Board of Directors Representative

American Pharmacists Month
To celebrate American Pharmacists Month, the American Pharmacy Student Alliance (APSA) provided whiteboards for students, pharmacists, faculty, and residents to share about what they think pharmacists can do. To share photos with family and friends, we uploaded photos to Facebook using hashtags #APhM, #APhA, #AmericanPharmacistsMonth, and #IAmAPharmacyBecause. This was also an opportunity to enter into APSA’s contest for a chance to win a $50 gift.

On October 7th, 2016, APSA held the annual Trojan Family Health Fair at USC University Park Campus in Los Angeles, CA. A total of 220 health screenings in diabetes, hypertension, and body fat analysis were done. Moreover, our student pharmacists, pharmacy residents, and preceptors also demonstrated to the USC Community what pharmacists can offer as healthcare providers by sharing their own stories on what pharmacists can do using: “I Am a Provider Because…” and “As a Pharmacist, I Can…” on our American Pharmacist Month Whiteboards.

During CPhA’s statewide legislative week, the USC School of Pharmacy organized the annual Legislative Day on November 4th, 2016, at the John Stauffer Pharmaceutical Sciences Center (PSC), where it focused on the impact of provider status in California with SB493, current pharmacy legislation, and expectations for the future of the pharmacy profession. Our speaker panel included Dr. Edlen Wong and Mr. Brian Warren on behalf of CPhA, Dr. Kethen So and Dr. Loriann DeMartini on behalf of CSHP, Dr. Naomi Florea, Dr. Carey Gore, Dr. Rebecca Cupp, Mr. Victor Law, Assembly-member Mike Eng, and Dr. Michael Hochmann, MD.

West Coast University
By Marc Salvatus, CPhA Board of Directors Representative

Legislative Week
CPhA Legislative Week 2016 was filled with policy discussion. On October 11th, Dr. Sarah McBane shared with us her professional background, her involvement in CPhA including her experience as its president, and provider status for pharmacists. On October 13th, at our Pizza Policy event, guest speaker Dr. Steven Gray delivered a presentation on pharmacy policy and legislation, as well as SB493. We were very honored to have both speakers join us in celebration of Legislative Week.

Student Outreach
Our chapter attended the Los Angeles City College Swap Meet on November 20th to give blood pressure screenings and cardiovascular education to patients. On October 13th and November 3rd, students attended the East Hollywood Certified Farmers’ Market. In addition to blood pressure screenings, students provided patients with blood glucose testing for the first time. Patients who wanted their blood glucose tested also requested for their blood pressure to be taken. We are eager to continue both of these services.

Executive Committee Meeting
With the Fall semester coming to a close, a committee meeting was held after finals to discuss both successes and improvements of our chapter. Other topics of discussion included planning of future fundraisers, outreach opportunities, and new initiatives.
Western University of Health Sciences

By Thu Nguyen, CPhA Board of Directors Representative

American Pharmacists Month

To commemorate October American Pharmacist’s Month, our International Policy Vice President initiated a Humans of APhA campaign on social media with members of our chapter and various faculty members. Our Communications Vice President tabled a lunch and took professional headshots of each participant for the event. Each headshot was uploaded on Facebook with a short biography about why everyone chose to be in pharmacy. The intent of this campaign was to bring knowledge about what pharmacists could do and our presence in the community. We were able to include 28 participants and represent pharmacy across our social media platforms.

Health Fairs

We participated in various health fairs within the Pomona Community, including the Crystal Cathedral Church Flu Clinic on October 9th, the Pomona Health Fair on October 15th, and the Annual Cultural Festival Health Fair on October 22nd.

Legislative Week Policy on Tap

For CPhA Legislative Week, our chapter put on Policy on Tap at Sactum Brewing Company in Claremont. We invited students to come talk to our guest speakers about policy while enjoying a cold brew. Our guest speakers included Dr. Ethan Huynh, Robert Torres, and Daniel Martinez. Daniel Martinez is a representative for Congresswoman Norma Torres and Robert Torres is a representative for Assemblyman Freddie Rodriguez from District 52. These speakers spoke to students about the importance of political advocacy and the process to make significant change in healthcare.

ERRATA, continued from page 5.

Corrected Figure 3: Third model of interprofessional collaboration: Network of preferred pharmacies and dental clinics.

Jennifer Jurado, P1, and incoming Finance Vice President for APhA-CPhA/ASP Executive Board 2017 posing for our campaign.
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