2015

Inserting Pharmacists in Primary Care Roles in an Ambulatory Care Setting

Keith Yoshizuka  
*Touro University California*, keith.yoshizuka@tu.edu

Katherine K. Knapp  
*Touro University California, Touro College of Pharmacy (New York)*, katherine.knapp@tu.edu

Patricia A. Shane  
*Touro University California*, patricia.shane@tu.edu

Debbie H. Lu  
*Touro University California*, debbie.lu@tu.edu

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**Recommended Citation**  
Inserting Pharmacists in Primary Care
Roles in an Ambulatory Care Setting

KEITH YOSHIZUKA, PHARMD, MBA, JD, FCSHP, KATHERINE KNAPP, PHD
PATRICIA SHANE, PHD, MPH, DEBBIE LU, PHARMD, MPH

Rarely are health system administrators not concerned with finding adequate financial resources to provide quality care to the communities they serve. The Patient Protection and Affordable Care Act (PPACA) promises to bring more patients to hospital doors while, at the same time, reducing reimbursement for their hospitalization costs. The Center for Medicare and Medicaid Services (CMS) threatens reduced reimbursement for rehospitalization of patients within 30 days for similar diagnoses. To further exacerbate these financial pressures, the lack of primary care physicians forces hospitals into competition for physician services they can ill afford. What can be done?

In this report, we suggest how pharmacy personnel may be used to alleviate some of the pressures currently impacting health system administrators. We look back to the role(s) of the hospital pharmacy and the hospital pharmacist historically and outline changes that have occurred and how these changes may be helpful to address several problem areas in the ambulatory care venue.

The American College of Clinical Pharmacy defines clinical pharmacy as "a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention." 1 Clinical pharmacists assume responsibility and accountability for achieving therapeutic goals in all areas of pharmacy including critical care, anticoagulation, cardiology, geriatrics, immunization, infectious disease, nephrology, neurology, pediatrics and oncology. They serve as consulting pharmacists for long-term care facilities to ensure patients are receiving optimal medication therapy. They manage patient therapy in direct patient care settings working under protocol for conditions such as diabetes, anticoagulation management, immunization, and oncology/chemotherapy management.

Hospital pharmacies were historically sites for procuring medications and managing medication orders. Clinical pharmacy in hospitals was spawned by the expansion of new and expensive medications and the need for monitoring medications with possible serious side effects and/or very high costs. The clinical pharmacist often needed to be at the bedside thereby moving pharmacy for the first time out of the (usually) basement-based pharmacy and onto the hospital’s service units. The presence of pharmacists “on the floors” has gradually led to integration of pharmacists into the hospital healthcare team. A significant benefit of this shift is the presence in California of a larger cohort of pharmacists with clinical skills who can be mobilized to fill new roles that require clinical expertise.

Hospitals Utilization of Clinical Pharmacists: We now see smaller units, including hospitals, building clinics that offer other out-of-hospital services for high risk patients in order to make financially and clinically feasible strategies for sustained, successful operation. The role of pharmacists in these expanded operations is one factor to be considered as these models are rolled out. For example, in 2009 Jack et al pilot...
Clinical pharmacy in hospitals was spawned by the expansion of new and expensive medications and the need for monitoring medications with possible serious side effects and/or very high costs.

The historic successful co-existence of office-based physicians, medical groups and hospitals was based on the ability of each entity to succeed independently with relatively non-binding relationships with other entities. The emergence of health plans and changes in reimbursement structures forced hospitals to vertically integrate, adding services such as clinics for patients with chronic illnesses in order to retain a patient base. The emergence of clinics to provide care for patients with common, chronic medical conditions like diabetes began, not surprisingly, in organizations like the Veterans Administration and Kaiser Permanente where the organization had an obligation to care for a defined population on a fixed budget. These organizations were also the first to place pharmacists in clinic settings alongside physicians and nurses to help patients maintain health and avoid complications. These efforts were successful and have become a permanent feature of the care package. In a recent publication by Hill et al, for example, the authors described the comprehensive ambulatory clinical pharmacy services that are available at Kaiser Permanente Colorado (KPCO). KPCO has approximately 530,000 members and 150 clinical pharmacists who provide clinical pharmacy services. The primary roles of the clinical pharmacists in these settings were to assist providers in optimizing medication therapy to improve clinical outcomes while minimizing the total costs of care.

Clinical pharmacists at Kaiser Permanente work in a wide variety of service areas including asthma/allergy, behavioral health, gastroenterology, infectious disease, inpatient, nephrology, cardiology, diabetes/endocrinology, dementia care, and emerging area of continuing care. A 2011 Report to the Surgeon General provided extensive documentation of the value produced by pharmacists working in clinic settings. Oncology is an area where pharmacists have started their services in the inpatient setting and transitioned into the ambulatory care setting. As oncology treatment migrated from hospitals to infusion centers and other ambulatory care settings, pharmacists were hired into these outpatient settings to prepare medications, dose, and manage symptoms related to chemotherapy. Today there are over 1,600 pharmacists who are Board certified in oncology.
Safety Net Clinics
One of the factors limiting the incorporation of clinical pharmacists into the multi-disciplinary care team in the clinic setting is the financial burden, as pharmacists are not reimbursed for their services by third party payers. Recognizing the important role that clinical pharmacists play in patients' health, particularly underserved populations with complex medical conditions, many colleges of pharmacy have developed partnerships with community medical clinics to enhance the pharmaceutical care in these populations. Examples of this include community partnerships between the University of Southern California School of Pharmacy and the Los Angeles County community clinics, Touro University and San Francisco General Hospital and Trauma Center, LifeLong Medical Care, and Clinic Ole in Napa. The pharmacists in these clinics provide clinical services including, but not limited to, a review of the patient's medication experience, updating medication allergies and adverse reactions, reviewing medication history and current medication record for indication for use, product, dose, duration, and how the medication is actually being taken. Pharmacists also review active drug therapy problem lists and therapeutic treatment plans for appropriateness, effectiveness, safety, and medication adherence for vulnerable population in safety net clinics.

Considerations for Placing Pharmacists in Ambulatory Care (am care) Clinics
Available evidence cited above suggests that when a hospital decides to initiate or expand ambulatory care clinics as part of its service package, it is logical to consider a role for pharmacists. The principal issues to be considered when moving in this direction are 1) financial considerations and 2) establishing a plan for introducing pharmacists into a clinic model. Median 2012 annual salaries before benefits as reported by the Bureau of Labor Statistics (BLS) are: physicians ($187,200), registered nurses ($65,470) and pharmacists ($116,670). The relatively high pharmacist salaries and reimbursement issues (discussed in other sections) have caused hospital administrators and others to demand financial justification for adding pharmacists to clinics. While there is abundant evidence of both financial and clinical value of clinical roles for pharmacists in clinics; much of the evidence comes from governmental or managed care organizations. Different business models and circumstances often make this justification a required step prior to adding pharmacists. Their justification is generally based on demonstrating reduced overall patient utilization of expensive services (hospital and emergency department use) and savings on expensive medication use. Experimenting with pharmacist roles is often an initial step. Many organizations experiment with new roles for pharmacists by adding a pharmacy resident(s). The resident's salary cost is less (approximately $46,000-$48,000 annual salary) and residency training is highly oriented to experimentation and data collection. Pharmacy residencies generally last one year—sufficient time to integrate into a service and observe the impact. There are many examples where data-driven, successful residencies result in converting the residency position to a staff position. (Residency training programs are described below).

Generally, adding pharmacists to clinics occurs in the setting of existing clinics run by physicians overseeing nurses who work directly with patients (case management). Pharmacists are often introduced into this traditional model by initially working as a consultant to the nurses for patients with complex medication regimens. Gradually, the pharmacist establishes an integrated
role that is best described as a referral role where both physicians and nurses refer those cases where the pharmacist’s expertise in medication management is likely to improve patient outcomes.

Pharmacists have identified a niche in managing chronic diseases treated primarily with medication, diet, and exercise (such as hypertension, diabetes, and hypercholesterolemia); and managing anticoagulant drug therapy.

Pharmacists have also played an important role in oncology through managing chemotherapy, symptom management support, pain management, assessment of response and toxicities, and management of nausea and vomiting through antiemetic therapy. This is contrasted with the roles of nurse practitioners and physician assistants who play major roles in urgent care clinics, physical assessment screenings, emergency departments, and working with orthopedic surgeons.

Availability of Appropriately Trained Personnel: Can You Find the Right People?

There are approximately 35,000 licensed pharmacists in California about 25% of whom practice in hospitals (<9,000).11,12 The number of pharmacists already working in clinics is unknown but likely less than 3,000. California law requires that in order to work in a clinic setting, a pharmacist must have either successfully completed a pharmacy residency or have demonstrated clinical experience in direct patient care delivery. Many pharmacists who have worked in an acute care setting in California have this clinical experience through the protocols of the hospital in managing the dosing of various antibiotics, parenteral nutrition, and anticoagulation therapies.

Residency-trained Pharmacists and Certification in Specialty Areas

Nationally, there has been rapid growth in pharmacy residencies. Based upon 2013 data, available through the Pharmacy Online Residency Centralized Application System (PhORCAS), there were over 1,600 residency programs that collectively offered over 3,000 positions. Despite the expansion of pharmacy residencies there continues to be unmet need, as evidenced by the volume of individual PGY1 and PGY2 applications (n=5,808) received that year. Pharmacy residencies are defined as an organized, directed, postgraduate training program in a defined area of pharmacy practice.13 The majority of pharmacy residencies are pursued immediately after graduation from pharmacy school and last one year. These residencies are identified as Post-Graduate Year 1 (PGY1) residencies.

The American Society of Health-System Pharmacists (ASHP) is the main accrediting body for accrediting health-system pharmacy residencies. Pharmacists who complete an ASHP-accredited PGY1 residency or a residency with Candidate status with ASHP are eligible to take a Board of Pharmaceutical Specialties (BPS) examination in Pharmacotherapy that, if passed, identifies them as BPS-certified in Pharmacotherapy.14 The Board-certified designation is helpful to hospitals for internal credentialing, credibility and comfort with assigning clinical roles.

Specialty residencies—referred to as PGY2 programs—offer additional postgraduate training in areas such as ambulatory care, critical care, psychiatry, nutrition support, oncology and infectious disease. Pharmacists who complete PGY2 residencies are eligible to take BPS examinations in specialty areas. Current areas of specialization include ambulatory care, nuclear pharmacy, nutrition support, oncology and psychiatric
pharmacy. Pediatrics and critical care have recently been added as BPS specialties with certification examinations to begin in Fall 2015.13 Passing the examination(s) qualifies the pharmacist as BPS-certified in a specialty area. The Board-certified specialty designation is again helpful to hospitals for credentialing, credibility and comfort with assigning clinical roles.

Residency programs can apply for accreditation through the American Society of Health-System Pharmacists (ASHP). Accreditation implies that the program has met ASHP standards for residency training. Continued accreditation requires periodic re-application and site visits. A listing of ASHP-accredited programs is available on the ASHP website (http://accred.ashp.org/aps/pages/directory/residency-ProgramSearch.aspx). Many residency programs do not apply for ASHP accreditation for a variety of reasons. There is no reliable listing of non-accredited programs but it is estimated that ASHP-accredited programs account for about two-thirds of residencies.

Hospitals wishing to explore or start residency programs can find help. ASHP offers specific information about starting residency programs.16 Many hospitals will find willing partners in schools or colleges of pharmacy. Pharmacy schools make good partners for the research projects that residents are required to complete and pharmacy schools prefer to have their students train in hospitals where residency training is concurrent. Professional meetings of ASHP, CSHP and the American College of Clinical Pharmacists (ACCP) almost always include programming about starting and managing residencies.

Whether PGY1 or PGY2, residents are required to complete a research project. These projects often present opportunities for hospitals to assess internal processes regarding the use of medications and to experiment with new services, processes and procedures. An example would be the initiation of a new ambulatory clinic with pharmacists participating on a medical team. California residents are required to present their projects at the Western States Residency Conference (www.western-states-rx.org) which is held annually in May. At the conference, hospitals and clinics with residency programs have the opportunity to identify "talent" in specialized or general clinical areas.

California has always been a leading state in providing residency-trained pharmacists. In 2014, California had approximately 121 accredited PGY1 programs and 33 accredited PGY2 programs. PGY2 specialty areas include administration, ambulatory care, cardiology, critical care, drug information, emergency medicine, infectious diseases, oncology, pain management and palliative care, pediatrics, pharmacy informatics, psychiatry and solid organ transplantation (data provided by ASHP, 2014). Many residency programs—PGY1 programs in particular—support more than one resident.17 The University of Southern California, for example, has 4 PGY1 and 2 PGY2 residency programs with over 40 residents annually. For the 2013-14 year (July 1 to June 30), there were about 314 pharmacists who completed either PGY1 or PGY2 residencies in California (data provided by the California Society of Health-System Pharmacists, 2014). Anecdotally, we observe that the majority of California-trained pharmacists seek to remain in California to practice.

**Legislative Issues**

As is often the case, the changes in practice preceded changes in the law to allow them to happen. This is not to say that these pharmacists were operating
outside of the law; only that the law was silent on the matter because the existing laws were developed before anyone had envisioned such services. The California legislature recognized this and promulgated legislation to keep up with the changing environment.

In California, a pharmacist in a medical clinic who has successfully completed clinical residency training or demonstrated clinical experience in direct patient care delivery has been able to legally adjust a patient's drug regimen per clinic approved protocol since 1996 (AB 2802 Granlund). In 1999, the law was expanded such that a pharmacist could adjust a patient's drug regimen pursuant to a protocol as part of the care of a single physician (not necessarily restricted to a clinic setting) (AB 261 Lempert). In 2001, that scope was expanded to include initiating a drug regimen, not restricted to adjusting a drug regimen that had already been commenced (AB 826 Cohn). In 2006, the section of the Business & Professions Code identifying this scope for a pharmacist in a clinic setting was renumbered to B&P §4052.2 (AB 2408 Negrete-McLeod).

Examining the requirements for the application of B&P §4052.2 dealing with a pharmacist's scope of practice in a clinic setting, all of the procedures logically involve patients on drug therapy or who will receive drug therapy. Specifically, a pharmacist may assess the drug therapy, including ordering laboratory tests, administer drugs and biologicals, and initiate and adjust drug regimens pursuant to an approved protocol. The protocol must be developed by a multidisciplinary team that includes both physicians and direct care registered nurses, who shall determine the breadth and limitations of such protocol. The protocol must require that the patient must first have been seen by a physician before referral to a pharmacist, and that the scope of procedures performed by the pharmacist must relate to the condition for which the patient was first seen by the physician. The protocol shall require that the patient's medical record be accessible to both the pharmacist and the physician, and that any change, adjustment, or modification of an approved pre-existing treatment or drug therapy be provided in writing to the treating or supervising physician within 24 hours.

In order for a pharmacist to be qualified to perform these functions in a clinic setting under B&P §4052.2, the pharmacist must have either successfully completed a clinical residency training program, or have demonstrated clinical experience in direct patient care delivery. Many of the pharmacists who have worked in an acute care setting in California have this clinical experience through the protocols of the hospital in managing the dosing of various antibiotics, parenteral nutrition, and anticoagulation therapies as described above.

In 2013, SB 493 (Hernandez) was approved by the California legislature to expand the scope of every pharmacist in California to furnish hormonal-based contraceptives, emergency contraception, travel medications for international travel, immunizations on the Centers for Disease Control (CDC)-recommended schedule, and nicotine-based smoking cessation aids, pursuant to state approved protocols and subject to specified training. In addition, the bill created a new category of licensed pharmacist known as an Advance Practice Pharmacist (APP), who would not necessarily be restricted to practice within a hospital or clinic. In order to qualify for licensure as an Advance Practice Pharmacist, the pharmacist must have completed two of the three following criteria:

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4210(a) (2) (A): Earn board certification,

4210(a) (2) (B): Complete a post-graduate clinical residency, and/or

4210(a) (2) (C): Have at least one year of experience practicing as a clinical pharmacist.

Under current law, there is no requirement for a pharmacist working in a clinic under B&P 4052.1 or 4052.2 to be licensed as an Advanced Practice Pharmacist.

To date, the proliferation of clinical pharmacists in the ambulatory care (clinic) setting has occurred largely in managed care organizations such as Kaiser Permanente and the Veterans Administration, since fee-for-service reimbursement is not an issue in these environments. A limiting factor outside managed care is that pharmacists are not yet recognized as providers under Medicare Part B for reimbursement, so services rendered by pharmacists in the clinic are not reimbursable under Medicare. HR 4190 was introduced into the House of Representatives in Washington, DC in March 2014 by Representatives Bret Guthrie (R-Ky), G.K. Butterfield (D-N.C.), and Todd Young (R-Ind), a bill to amend the Social Security Act to provide for coverage under the Medicare program of pharmacist clinical services.2 This bill would have allowed pharmacists in the clinics to bill for their services through Medicare Part B. A recent letter from the Administrator of CMS affirming that incident-to Part B Medicare billing by physicians for pharmacist-provided services is lawful under specified conditions suggests the CMS would not be opposed to such legislation.24 Unfortunately, the term of the 113th Congress ended before the bill could be passed. Now that a new session of Congress is underway, bills have been introduced on both sides of Congress to allow pharmacists to bill for services under Medicare Part B in the Senate under S 31425 and in the House of Representatives under HR 59226. This is encouraging since bills have been introduced in both the Senate and the House of Representatives, and both appear to have bipartisan support.

Implications of Healthcare Law Changes for Hospitals

Healthcare law changes in 2013-2014 have the potential to trigger changes in affordable care and spur development of models that allow hospitals to utilize staff more efficiently. Furthermore, forecasts for meeting the demand for primary care predict that primary care physician shortages will increase dramatically by 2025, and there is growing evidence that primary care shortages are shifting the debate on expanding scope-of-practice laws.27 Given the current mismatch with patient needs, emergency room use for primary care problems is on the rise in several regions, and health care leaders in those markets believe that is due to a shortage of primary care physicians. The use of emergency departments by Medicaid patients for primary care services is a problem for insurers who cover that population, but it’s also an indication of what may be ahead for privately insured patients, who cannot get timely appointments with primary care providers. Hospitals in California are typically located where people are located. The geographic distribution indicates that hospitals are primarily distributed in proportion to the number of people, rather than income. However, a recent analysis of hospitals by population income in LA County suggests that people who have the least amount of money, may have relatively easy geographic access to hospitals but limited access to primary care.28 Low income areas in California may be surrounded by hospitals, but lack primary care resources.

How pharmacists get reimbursed directly affects the workforce and scope
of practice. Payment policies have an immediate effect that produces change in the volume and type of care delivered. Historically, health plans have been slow to change the way they reimburse for care. Increasingly, there is an impetus to find reimbursement and workforce mechanisms to prevent a diabetic from requiring an amputation, rather than a reimbursement schema that rewards an orthopedic surgeon for the amputation. In the absence of creating new efficiencies to address physician shortages, systemically, we could inadvertently develop greater inefficiencies, such as increases in emergency department use, longer waiting times for appointments, higher costs for imaging services and pharmaceuticals, and utilization of specialty care lacking coordination, magnified by health reform driven improved access to and demand for needed health care.

Health Care Reform & Physician Shortages in California
The shortages in primary care physicians are evident when mapped and indicate that these short falls are a geographic issue. Only 16 out of 56 California counties have enough primary care physicians.\(^{29}\) Effectively, when applied to the resident population of the state, less than one third of Californians live in a place where access to primary care physicians meets the needs of the population.\(^{30}\) With increased demand for health care services and a shortage of physicians, the potential gaps in direct patient care are likely to widen unless alternatives are brought into play.

In California a “Bridging the Provider Gap” campaign was initiated through the coalition Californians for Accessible Healthcare (comprised of the California Association for Health System Pharmacists, the California Society of Health System Pharmacists, the California Optometric Association, and the California Pharmacists Association). Effects of changes in health system management hold the promise of achieving efficiencies in staffing and producing improvements in outcomes.

Almost 20 percent of Americans, 56 million people, have inadequate or no access to primary care physicians because of a shortage of providers, and a majority of them are insured, according to a report issued by the National Association of Community Health Centers and the American Academy of Family Physicians.\(^{31}\) Multiple 2014 studies and surveys indicate that the number of uninsured fell as a result of expanded Medicaid eligibility and health insurance exchanges established through PPACA. Overall, RAND’s Health Reform Opinion Study (HROS) in March 2014 estimated that 9.3 million more people had health care coverage. The increase was driven by enrollment in health insurance marketplace plans and by increases in employer-sponsored insurance and Medicaid enrollment increases. Data from August 2014 showed that 7.3 million people had enrolled through the marketplace and paid their premiums.\(^{32}\)

Behind the Physician Shortages
The U.S., relative to other countries, has low physician to population ratios. The physician workforce is aging. The population is aging and doctor visits increase substantially for those over 65. Equally important, the supply of new primary care physicians is not sufficient. Estimates are that new U.S. educated physicians account for an increase each year of about 1 percent of the current primary care physician workforce. First year MD enrollment in relation to 100,000 population has been in steady decline since 1980. Limited residency slots are a contributing factor. “In 1997, the federal government essentially froze spending on residency slots, limiting the number to around 100,000 over
three-to-four years, and in turn freezing the number of newly licensed physicians available for hire each year to around 26,000.” While some increases have resulted from hospitals that have established new residency programs for primary care doctors, the volume is not sufficient, especially given the estimated 50 million person increase in the U.S. population during that time period. “The American Association of Medical Colleges estimates that the U.S. will face a shortage of 46,000 primary care doctors by 2020, equivalent to one-quarter of everyone practicing in that category today.”

**Workforce and Capacity Issues**

Around 2006, the concept of a U.S. shortage of primary care physicians was first publicized. Roles for advanced practice nurses and physician assistants were emphasized to “fill the gap.” Given the abundant research (see the Report to the Surgeon General) that has shown the value of pharmacists in ambulatory and primary care activities—both from an economical and from an outcomes perspective, pharmacists can contribute to “filling the gap” created by the primary care physician shortage.

With approximately 35,000 licensed pharmacists in California about 25% of whom practice in hospitals and of those who are hospital-based less than half qualifying as clinical pharmacists, there are less than 4,500 clinical pharmacists available for implementing or augmenting clinical services in hospital or clinics in California today.

Nationally, hospital-based pharmacists accounted for about 25% of total pharmacy positions. Some of these pharmacists typically have completed one or more years of pharmacy residency training which is focused on higher levels of clinical skills and experiences. Some hospitals separate clinical pharmacists based on their training and role from the rest of the pharmacy staff while other hospitals find it more practical to have pharmacists able to perform both traditional and newer clinical roles.

**Moving Forward**

Pharmacists are currently able to legally function as mid-level practitioners in an ambulatory care setting under approved protocols so long as they have either (1) successfully completed a clinical residency training program, or (2) have demonstrated clinical experience in direct patient care delivery. Hospitals and health systems looking to insert clinical pharmacists into a medical clinic setting may draw from their internal resources as well as recruiting new pharmacists with hospital experience, taking those pharmacists who have been functioning in the acute care setting practicing direct patient care delivery to those hospitalized patients and providing them with the opportunity to practice in the ambulatory care venue (the attraction of a Monday through Friday stable work schedule may be appealing). Even though the number of pharmacy residencies is increasing, only about half of those pharmacists who apply actually get accepted. One strategy to consider is for hospitals to develop their own pharmacy residencies with rotations in the clinic. Using this strategy, the facility gets a pharmacist (usually licensed within 90 days of starting) to train in both the hospital and the clinic for less than half of what it costs for a clinical pharmacist for a year, and the opportunity to recruit the resident when they complete the one year program. The proliferation of the use of pharmacists practicing in the ambulatory care environment has been hindered by the inability to capture reimbursement for these services; however the Affordable Care Act (ACA) is presenting some opportunities allowing pharmacists to qualify for “incident-to” billing just as much as other clinical team members, so long as such services are permitted under their state license and that “medication management services” (billing codes 99605-99607) are not covered under Medicare’s Part B program, but are instead billable under Medicare Advantage or Part D medication plan.

Another development is HR 4190 introduced in Congress earlier this year, which would allow pharmacists in the clinics to bill for their services through Medicare Part B. This bill has bipartisan support and is currently being heard in committee in the House of Representatives in Washington, DC. Given the current physician shortage, it would make sense to expand the use of pharmacists in primary care clinics as mid-level providers to manage chronic diseases such as diabetes, hypertension, hyperlipidemia, and other diseases managed primarily with medications.

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**Figure 1. ASHP Pharmacy Residency Program Growth**

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Figure 2. Distribution of Hospitals within California by Median Income

Distribution of Hospitals within California by Median Income

Figure 3. Medically Underserved Areas and Populations

Medically Underserved Areas and Populations

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