

# Patient Access to Pharmacists' Care Coalition (PAPCC)

April 30, 2014

Federal Trade Commission  
Office of the Secretary  
Room H-113 (Annex X)  
600 Pennsylvania Avenue NW.  
Washington, D.C. 20580

**RE: Health Care Workshop  
Project No. P13-1207**

Dear Sir or Madam:

We appreciate the opportunity to comment on the competitive implications of professional regulation in health care, particularly as they affect pharmacists. We submit these comments on behalf of the Patient Access to Pharmacists' Care Coalition (PAPCC or the Coalition).

A number of factors will combine to create excess demand and a shortage of primary health care providers in the near future. The factors include an aging population, a rise in chronic conditions, and policy changes such as those associated with the Affordable Care Act. Patient demand and the resulting problems associated with a lack of access to care are particularly acute in medically underserved areas. To address this increase in demand, all providers in the health care system should practice to the fullest extent allowed by their license.

We believe that the Social Security Act creates a barrier to pharmacists practicing to the fullest extent of their education, skills and training. H.R. 4190 has been introduced to the U.S. House of Representatives to address this issue. The bill would amend the Social Security Act and provide Medicare Part B payment for pharmacists' services. It promotes increased access to care for patients who are otherwise medically underserved.

Past experience has shown that quality of care is actually improved when pharmacists practice to the fullest extent of their education and training. According to a report issued by the U.S. Public Health Service in 2011, pharmacists involved in the delivery of patient care services with appropriate privileges across many practice settings have been successful in improving patient outcomes. Expanded pharmacists' services improve evidence-based quality metrics and health outcomes. For instance, pharmacist involvement in care has resulted in significant reductions of hemoglobin A1C levels in diabetic patients, significantly reduced systolic blood pressure in hypertension patients, and a reduced rate of inpatient admissions among heart failure patients.<sup>1</sup>

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<sup>1</sup> U.S. Public Health Service, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General 2011*, Office of the Chief Pharmacist, <http://www.usphs.gov/corpslinks/pharmacy/documents/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf>

## **Demand for Health Care Services is Increasing**

Millions of Americans lack adequate and timely access to primary health care and this is only expected to get worse as demand increases. Over the next two decades, due to an aging population, the number of Medicare enrollees is expected to grow from roughly 50 million to over 80 million.<sup>2</sup> In addition, the need for services is increasing. Approximately 45% of Americans have at least one chronic condition, and 27% have multiple chronic conditions, rates that are expected to continue to rise.<sup>3</sup> Further, the Congressional Budget Office estimates that an additional 25 million individuals will potentially be gaining health coverage under the Patient Protection and Affordable Care Act (PPACA). Factoring all of this in, the Association of American Medical Colleges projects that, by 2020, there will be more than 91,000 fewer doctors than needed to meet demand, and the impact will be most severe on underserved populations.

The lack of access to care will be particularly acute in medically underserved communities.<sup>4</sup> By definition, these areas already suffer from a lack of access to primary care services. And a disproportionate number of patients in certain racial and socioeconomic populations suffer from chronic conditions. For example, according to the Centers for Disease Control (CDC), non-Hispanic black adults are at least 50% more likely to die of heart disease or stroke prematurely than their non-Hispanic white counterparts. And the prevalence of adult diabetes is almost twice as great among poor adults than high income adults.

Given the increase in demand and the anticipated shortage of providers, it is critical that all providers in the health care system practice to the fullest extent of their skills, education and training.

## **States Define a Pharmacists' Scope of Practice**

Pharmacists stand ready to assist with the increase in demand for services. With their training and education, they are qualified to perform many patient care services such as immunizations, health testing and chronic care management that are needed by patients, particularly those with chronic conditions.

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<sup>2</sup> U.S. Congressional Research Service. *Medicare Financing* (R41436; September 19, 2013), by Patricia A. Davis.

<sup>3</sup> Wu S, Green A. *Projection of Chronic Illness Prevalence and Cost Inflation*. RAND Corporation, October 2000; *see also* Anderson G. *Chronic care: making the case for ongoing care*. Robert Wood Johnson Foundation: Princeton (NJ); 2010.

<sup>4</sup> The Department of Health & Human Services' Health Resources and Services Administration (HRSA) designates communities with unmet health care need as Medically Underserved Areas (MUAs), Medically Underserved Populations (MUPs), and Health Professional Shortage Areas (HPSAs), based on a number of factors. A description of each follows:

- Medically Underserved Areas identify geographic areas that have too few primary care providers, high infant mortality, high poverty, and a high elderly population.
- Medically Underserved Populations are identified by taking into account the same factors used to identify MUAs, but focus on specific population groups with the same characteristics.
- Health Professional Shortage Areas are areas with shortages of primary medical care, dental or mental health providers.

This allows for efficient and cost-effective use of limited resources and allows primary care medical providers the ability to resolve complex patient cases and see more patients.

### Pharmacists Can Provide a Variety of Patient Care Services

While pharmacists remain committed to assisting patients with access and information related to their prescription medications, pharmacists today are providing a broad spectrum of services, within their scope of practice, including conducting health and wellness testing, managing chronic diseases and performing medication management, administering immunizations, and working in and partnering with hospitals and health systems to advance health and wellness and helping to reduce hospital readmissions. The provision of these services is guided by the same guidelines and standards adopted by the CDC and other recognized medical organizations, and followed by all health care providers.

In 47 states and the District of Columbia, pharmacists are authorized to enter into collaborative practice agreements with a physician or another prescriber, further expanding the services they are able to provide. Depending on the particular state, collaborative practice agreements enable pharmacists to provide a range of services such as initiation, monitoring, and modification of a patient's drug therapy. This is particularly effective with patients who have single or multiple chronic conditions. In 31 states pharmacists are also allowed to order and interpret lab tests. This collaborative approach, using pharmacists for the management of chronic conditions, has been utilized by the Indian Health Service for 40 years, as well as the Department of Veterans' Affairs and the Department of Defense.

There is broad commonality among states regarding a pharmacist's ability to deliver preventive services. Such services, many of which were mandated under the Patient Protection and Affordable Care Act (PPACA) for certain populations, include the following: blood pressure screening, cholesterol screening, diabetes (type 2) screening, diet counseling, immunizations (type, doses, age and population requirements vary), obesity screening and counseling, and tobacco use screening.

### State Regulations Differ on a Pharmacist's Scope of Practice

Although there is broad commonality in the types of patient care services that pharmacists can provide in each state, there are differences on the scope of practice for pharmacists on a state-by-state basis. In addition to coursework in biology, chemistry, pharmacology, pharmacotherapy, patient assessments, and medical ethics, students also receive structured experiential education where they gain experience delivering multiple services such as immunizations, medication management, HIV-specialized services, etc. This high level of education and training provides today's pharmacists with more education related to medication use and management than any other health care professional.

#### *Immunizations*

There is a large variation in state scope of practice laws with respect to immunizations. Some states only allow pharmacists to administer a few immunizations, and some states place age limits on the patients who can receive immunizations from a pharmacist.

Pharmacies have emerged as leading partners with public health officials, including the Center for Disease Control and Prevention (CDC), with respect to immunizations.<sup>5</sup> As it stands today, community pharmacies are leading providers of adult vaccinations in the United States, with nearly 1 in 4 adults receiving a vaccination in a community pharmacy in the past year. There are more than 230,000 pharmacists who have been trained to administer vaccines, in accordance with CDC and medical standards and guidelines, to patients across the lifespan. This training has been reviewed and recognized by CDC and other immunization experts for its content and quality. CDC has sought ways to engage with community pharmacist for over two decades, with the value of this partnership and collaboration being recognized after the 2009 influenza pandemic.<sup>6</sup> The convenience and accessibility of community pharmacists have helped enhance public health vaccination rates over the years by expanding the points of access and choice in communities.

### **Federal Law Limits Access to Care**

Even if the state-specific scope of practice obstacles were reduced, access to care may still be impacted by a lack of federal reimbursement for such services. As noted above, Medicare reimbursement for pharmacists' services beyond the dispensing role is limited. H.R. 4190 was recently introduced in the U.S. House of Representatives. The bill would amend the Social Security Act and provide Medicare Part B payment for pharmacists' services. It promotes increased access to care for patients who are otherwise medically underserved. Specifically, the legislation focuses on care for underserved beneficiaries in MUAs, MUPs, and HPSAs, as designated by HRSA. As the shortage of primary care physicians increases, so too will the challenges that patients in underserved communities face, especially those related to access. This legislation can help address provider shortages and access issues in underserved communities.

It is important to note that the bill seeks to increase access and improve quality by enabling pharmacists to provide patient care services consistent with their education, training and license. However, the federal legislation would not expand the types of services that pharmacists are permitted to provide which is governed by state scope of practice laws.

Furthermore, the bill promotes cost-effective health care by increasing access to care and opportunities for early intervention at cost-effective settings so as to minimize long-term health care costs such as those associated with preventable higher-cost conditions. Consistent with precedent established in the Social Security Act for nurse practitioners and physicians' assistants, pharmacist services would be reimbursed at 85% of the physician fee schedule, unless they are operating under the direct supervision of a physician, in which case they would be reimbursed at 100% of the physician fee schedule.

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<sup>5</sup> U.S. Department of Health and Human Services. CDC, HHS urge more vaccination coverage. July 22, 2013. Retrieved from <http://www.pharmacist.com/cdc-hhs-urge-more-vaccination-coverage>

<sup>6</sup> See, eg., *Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine*, Retrieved from: [http://www.astho.org/Programs/Infectious-Disease/H1N1/OpFramework\\_Pharmacies\\_STHOs\\_FINAL/](http://www.astho.org/Programs/Infectious-Disease/H1N1/OpFramework_Pharmacies_STHOs_FINAL/)

## **Greater Use of Pharmacists Promotes Access to Care, Lower Cost and Higher Quality**

Greater integration of pharmacists into the health care system as a whole can increase access to care, lower overall cost, and improve quality outcomes. These attributes are somewhat inter-related. Because 95% of all U.S. residents live within five miles of a community pharmacy, patients have tremendous access to often multiple pharmacists within minutes of their homes. In some remote areas, the pharmacist is the only health care provider for miles.<sup>7</sup> And wait times to see pharmacists are almost non-existent compared to a wait time of over a month for a new patient to see a family physician in some places.<sup>8</sup> Accessibility to pharmacists allows for more frequent contact with patients which can positively affect medication adherence, increase patient health, and reduce cost to the health care system. Geographic access to providers, along with timely access to services, are important parameters to consider in determining provider and network adequacy.

Peer-reviewed research reports support the valuable and effective role pharmacists play as accessible immunization providers. In one study, community pharmacies increased influenza vaccination rates in a high-risk population from 43% to 61%.<sup>9</sup> Another study found that patients receiving immunizations from pharmacists were 18 times more likely to be current on their vaccines than a control group, and five times more likely to be current on vaccines than patients receiving care from other providers.<sup>10</sup> Pharmacists have achieved similar increases in vaccination rates for pneumococcal vaccine<sup>11</sup> and herpes zoster vaccine.<sup>12</sup> In addition, expanded consumer access to vaccinations maybe a driving force for increasing vaccination rates. Specifically, one study noted that 31.7% of the administered vaccines provided in community pharmacies occurred during “off-clinic” hours, including weekends, evenings, and holidays.<sup>13</sup>

As with immunizations, needed health care tests are increased through pharmacist involvement. In a 2013 nationwide survey of U.S. adults, one in five adults reported having a health test performed at a

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<sup>7</sup> Hessler, Peter, *Dr. Don, The Life of a Small Town Druggist*, The New Yorker, September 26, 2011 (some patients drive 80 miles to visit the pharmacy).

<sup>8</sup> See 2013 MMS Patient Access to Care Study, Retrieved at: <http://www.massmed.org/News-and-Publications/Research-and-Studies/2013-MMS-Patient-Access-to-Care-Study/> (average wait time for new patients to see a family practice physician is 39 days).

<sup>9</sup> Fera T, et al. *The Diabetes Ten Chity Challenge: Interim clinical and humanistic outcomes of a multisite pharmacy diabetes care program*. JAPhA. 48:2. 2008. Retrieved from: <http://www.diabetestencitychallenge.com/pdf/DTCCInterimReport.pdf>

<sup>10</sup> Higginbotham S, et al. *Impact of a pharmacist immunizer on adult immunization rates*. JAPhA. 2012;52:367-71.

<sup>11</sup> Taitel M, et al. *Pharmacists as providers: Targeting pneumococcal vaccinations to high risk populations*. Vaccine. 29(2011)8073-6.

<sup>12</sup> Otsuka S, et al. *Improving Herpes Zoster Vaccination Rates Through Use of a Clinical Pharmacist and a Personal Health Record*. American Journal of Medicine. September 2013;832.

<sup>13</sup> Cannon A, et al. *Vaccinations Administered During off-Clinic Hours At a National Community Pharmacy: Implications for Increasing Patient Access and Convenience*. March 26, 2012. Retrieved from: <https://cdc.confex.com/cdc/nic2012/webprogram/Paper30288.html>

pharmacy in the previous year. The National Association of City and County Health Officials (NACCHO) has also noted the role pharmacies play in increasing access to health testing:

Given the accessibility of pharmacies and their reach into diverse communities, pharmacies can improve...compliance with screenings recommended by the U.S. Preventive Services Task Force. As healthcare providers, pharmacists offer an important contribution to preventive health services and the broader public health system. Health departments traditionally have a strong reach into diverse populations, so coordinated efforts with pharmacies can ensure improved preventive services within communities.<sup>14</sup>

Greater access to pharmacist services not only increases the chances of a patient obtaining a medically necessary health test, but at least one study found that health tests in community pharmacy settings improved follow-up rates with physicians compared with tests conducted in non-health care settings.<sup>15</sup> For many preventive services, such as immunizations, timely access is an important factor that supports achievement of healthcare quality metrics. Providing the service at the time when a patient has decided to receive it is an important determinant for success.

In addition to savings realized because of healthier patients, delivery of certain services by pharmacists can result in a direct savings. Published studies have demonstrated that pharmacies significantly increase competition and consumer choice, leading to more affordable vaccinations than are available in other healthcare settings. Data from the Department of Defense's TRICARE program reported significant costs savings from a pharmacy-based vaccination pilot project. The agency noted:

For the first six months following publication of the interim final rule, 18,361 vaccines were administered under the pharmacy benefits program at a cost of \$298,513.19. Had those vaccines been administered under the medical benefit, the cost to TRICARE would have been \$1.8M.<sup>16</sup>

Based on the positive acceptance of pharmacy-based vaccinations along with substantial system cost savings of the pilot project, TRICARE expanded beneficiary access to vaccinations.

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<sup>14</sup> *Building and Sustaining Strong Partnerships between Pharmacies and Health Departments at State and Local Levels*, NACCHO Report (March 2013). Retrieved From: <http://preparednesssummit.org/wp-content/uploads/2014/03/NACCHO-Pharmacy-Report.pdf>

<sup>15</sup> Snella KA. *Pharmacy and Community-Based Screenings for Diabetes and Cardiovascular Conditions in High-Risk Individuals*. JAPhA. 2006;46:307-7.

<sup>16</sup> *Inclusion of Retail Network Pharmacies as Authorized TRICARE Providers for the Administration of TRICARE Covered Vaccines, Final Rule*, 76 Fed. Reg. 41063, 41064 (July 13, 2011).

Furthermore, Harvard Medical School published a report on the mean cost of vaccinations at a variety of healthcare settings. The mean cost of vaccines at community pharmacies was reported to be significantly lower than scheduled doctor's office visits and mass vaccination clinics<sup>17</sup>

Likewise, pharmacy-based tests are frequently less expensive when administered by pharmacists than in other health care settings. For example, one study showed rapid antigen detection testing services cost patients \$45 in pharmacies versus \$100 during a physician visit.<sup>18</sup>

Pharmacists have a proven record of cost savings in the Medicare program. The CBO recently estimated that a 1% increase in drug utilization causes Medicare's spending on medical services to fall by one-fifth of one percent. Arguably pharmacists' direct participation in the Medicare Part B program as a non-physician provider would likely magnify cost savings in the overall Medicare program, as well as produce savings across the entire healthcare system.

## **Conclusion**

Federal law limiting reimbursement for services that can be provided by pharmacists has an adverse impact on patient access to care. Greater access to providers such as pharmacists can increase immunizations, medically necessary health care tests, and chronic care management. Given the increase in chronic conditions, and the increase in demand for health care services as a whole in the near future, it is critical to fully engage all health care providers within the system and ensure that they practice to the fullest extent of their education and training.

## **About the PAPCC**

The PAPCC includes a number of national organizations representing pharmacists and pharmacies across the country including the American Pharmacists Association (APhA), the American Association of Colleges of Pharmacy (AACCP), the American Society of Health-System Pharmacists (ASHP), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), Walgreens, Rite Aid, and a number of other organizations listed on Attachment A.

Formed in 2013, the Coalition works with policy makers, regulators, and key patient and health care stakeholders to advance patient access to, and payment for, Medicare Part B services by state-licensed pharmacists in medically underserved communities. Through stakeholder education and the development and promotion of federal legislation that ensures fair payment of licensed pharmacists who provide Medicare Part B services in medically underserved communities, the Coalition seeks to improve medically underserved patient access to quality services provided by pharmacists.

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<sup>17</sup> Prosser LA, et al. *Non-traditional settings for influenza vaccination of adults: costs and cost effectiveness*. *Pharmacoeconomics*. 2008;26(2):163-78.

<sup>18</sup> Garrelts MacLean L. *Community Pharmacy Based Rapid Strep Testing with Prescriptive Authority*. Retrieved from: [http://www.communitypharmacyfoundation.org/resources/grant\\_docs/CPFGGrantDoc\\_12587.pdf](http://www.communitypharmacyfoundation.org/resources/grant_docs/CPFGGrantDoc_12587.pdf)

Thank you, again, for the opportunity to submit comments.

Sincerely,

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