March 10, 2014

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

Re: Health Care Workshop, Project No. P131207


NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS’ 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions annually, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

NACDS members are committed to and supportive of the goals of competition, consumer choice, and quality of care. Each and every day, NACDS members make important contributions to the health and wellbeing of Americans across this nation. As we know, efforts to transform healthcare are gaining momentum with broad support from both the public and private sectors. The federal government, major insurers and employers are driving the change towards patient-centered care, value-based payment system and alternative care delivery models. Key components of these approaches include care coordination across the broad medical neighborhood, patient performance metrics, quality care measures, and access to timely, affordable care. Success of these approaches depend upon, among other things, the ability to effectively and efficiently improve access to affordable, quality patient care across all sites of care in the medical community. Ongoing innovative emerging care initiatives underscore the importance of consumers having accessible, affordable, and quality neighborhood healthcare. Yet, our industry faces significant, unwarranted federal and state impediments and overly restricted state professional regulations in our endeavor to provide consumers with choices regarding enhanced and innovative, quality neighborhood care.

NACDS is submitting an overview on the topics outlined in the Federal Register notice, with the intention of providing a supplemental filing after the workshop to address the specific questions outlined in the notice on health care competition.
I. DISCUSSION

In this transformational healthcare landscape, community pharmacies seek to provide consumers with additional access to innovative, affordable, and evidence-based care services. In so doing, pharmacies seek to work collaboratively with others to provide care coordination as well as broaden the range of affordable care delivery options to Americans across this country. Community pharmacists are among the most trusted and accessible healthcare providers; pharmacists have a minimum of six years of extensive education and training, and pharmacies are located on average within 5 miles of consumers.

Community pharmacists are educated and trained to fill system care gaps, provide medication management services, order and interpret lab tests, initiate and modify medication regimens, provide rapid diagnostic testing (e.g. flu, strep and others), perform physical assessments, provide immunizations, health and wellness care and other services. Recent reviews by the U.S. Public Health Service (USPHS) and others have highlighted the improved clinical outcomes and healthcare savings that result when pharmacists provide these services and tests. With the current changing landscape, pharmacy is now deepening its commitment to chronic medication management, health screenings, preventative care, pharmacogenomics counseling, offering innovative care services to reduce hospital readmissions and health outcomes in medical homes, and engage with high risk patients in Accountable Care Organizations (ACOs). Yet, many overly restrictive and needless state regulations limit the suite of services that can be offered to consumers, providing a patch quilt of care options across the nation.
1. STATE-LEVEL SCOPE OF PRACTICE RESTRICTIONS

Some state-level professional regulations have wide-reaching negative implications on the scope of practice of community pharmacists. Just recently, a new law in California unduly imposes additional training and education requirements on community pharmacists\(^1\) to render certain “advanced pharmacy care” services. Yet, community pharmacists already provide these “advanced pharmacy care” services and similar care in neighboring states, within the United States Public Health Service (PHS) and in other states across the under country.\(^2\) In fact, forty-six (46) states allow pharmacists to enter into Collaborative Practice Agreements (CPAs) to provide such services. Yet, these states do so without imposing additional educational requirements, including residencies or certification, as a condition to provide services. While states unnecessarily restrict the ability of pharmacists in several practice areas, we will highlight the needless and unwarranted impediments by states that limit the ability of community pharmacists to serve as public health immunizers.

**Pharmacists as Immunizers.** Pharmacies have emerged as leading partners with public health officials, including the Center for Disease Control and Prevention (CDC), with respect to immunizations.\(^3\) 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. Starting in 2009, and every year since then, CDC seeks the partnership and collaboration of the community pharmacy industry in an effort to meet certain public health vaccination goals. The convenience and accessibility of community pharmacists have helped enhanced public health vaccination rates over the years by expanding the points of access and choice in communities.

The authority of pharmacists to administer vaccines is determined by each state’s laws and regulations governing pharmacy practice. However, despite the public health benefits, some states limit either: (1) the types of vaccinations pharmacists are allowed to administer; or/and (2) the age of patient populations that pharmacists can vaccinate. See Attachment 1: State Vaccination Overview. Unwarranted and needless state restrictions limit consumer access and choice to cost-effective vaccinations and impede major public health goals.

Published studies have demonstrated that pharmacies significantly increase competition and consumer choice, leading to more affordable vaccinations than 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:

\(^1\)See CA SB 493 enacted in 2013. Also, CA health system pharmacists are may already provide certain services under protocol.

\(^2\)Flexible CPAs in states, such as Washington, have allowed pharmacists to provide “advanced patient care” services such as ordering labs, initiate and modify drug therapy regimens, and chronic disease management.

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. 4

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.

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 (Table 1). 5

Table 1. Vaccination Cost Per Setting – Data from Harvard Medical School

<table>
<thead>
<tr>
<th>Healthcare Setting</th>
<th>Mean Vaccination Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td>$11.57</td>
</tr>
<tr>
<td>Mass vaccination clinic</td>
<td>$17.04</td>
</tr>
<tr>
<td>Doctor’s office</td>
<td>$28.67</td>
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</table>

In this study, patient surveys show a high level of satisfaction with vaccines provided at community pharmacies. The study indicated that when patients received a flu shot at a national pharmacy chain, 97% of patients reported satisfaction with their experience, and 95% were satisfied with the information they received. 6 Further, in a nationwide survey of consumers, 69% of respondents reported vaccinations should be allowed in community pharmacies, and 69% noted they would be likely to go to their pharmacy for this health care service.

Patients consistently rate pharmacists as among the most accessible healthcare professionals; 95% of all consumers live within 5 miles of a pharmacy. Public health officials have noted the significant role pharmacies play in increasing access to vaccination. The U.S. Department of Health and Human Services issued a letter to pharmacists, noting: “Your collective efforts have made a tremendous contribution to raising awareness and increasing access to vaccines.” 7 CDC also highlighted the role pharmacists play in reaching difficult-to-reach patients for immunizations.

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8 ASTHO. Pharmacy Legal Toolkit. August 2013.
local\textsuperscript{9} health officials, as well as the Institute of Medicine,\textsuperscript{10} have also lauded the role of pharmacists as immunizers in enhancing points of access for vaccinations in communities.

Peer-reviewed research reports further confirm the 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%.\textsuperscript{11} 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 5 times more likely to be current on vaccines than patients receiving care from other providers.\textsuperscript{12} Pharmacists have achieved similar increases in vaccination rates for pneumococcal vaccine\textsuperscript{13} and herpes zoster vaccine.\textsuperscript{14,15} 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.\textsuperscript{16}

**Pharmacist Restrictions Reduce Community Preparedness.** During the 2009 H1N1 pandemic, the CDC launched the H1N1 Vaccine Retail Initiative to supplement state and local public health vaccination efforts. Through this program, CDC partnered with community pharmacies and retail clinics to directly provide H1N1 vaccine. Ten community pharmacy chains participated, totaling 10,700 retail locations served. These pharmacies received over 5.4 million doses of 2009 H1N1 vaccine directly from CDC; many of these doses were provided during the Christmas holiday when other providers were closed.\textsuperscript{17} However, state laws and restrictions limited the total number of pharmacies that could participate. Some states imposed age restrictions on community pharmacies due to political problems from pediatricians; even though CDC prioritized children ages 6 months through 24 years of age for vaccination.

The National Association of City and County Health Officials (NACCHO) highlighted another example of the impact of state laws on public health preparedness:\textsuperscript{18}

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In January 2013, there was an increasingly shrinking vaccine inventory nationwide. While many pharmacies still had inventory, some states imposed age restrictions on the patient populations that pharmacists could immunize. As a result, some pharmacies were unable to maximally contribute to prevention efforts. To address this challenge in the state of New York, Governor Andrew Cuomo issued an emergency order waiving age restrictions imposed on pharmacies. While altering the age restrictions is a very important first step to allow for more immunizations, rapidly implementing this type of waiver during an actual event is difficult because pharmacies may have to revise standing orders, ensure they have sufficient vaccines and syringes, and take other steps that would require significant lead time.

Current State Legislation Addressing Pharmacist Vaccinations. Several states are currently considering legislation to increase consumer access. Two examples include:

- **Pennsylvania S.B. 819; Sponsor: Senator Edwin Erickson**
  This bill authorizes a pharmacist to administer injectable medications, biologicals, and immunizations to individuals seven years of age and older, provided that the pharmacist obtains parental consent for individuals under 18 and notifies the individual's primary care provider, if known, within 72 hours of administration.

- **Vermont S.B. 142; Sponsor: Senator Kevin Mullin**
  Enables pharmacists to administer immunizations recommended by the Centers for Disease Control and Prevention to individuals seven years of age and above. Provides that a pharmacist authorized to administer vaccines will be reimbursed by an individual or an individual’s health insurance plan for administering a vaccine at the same rate or amount as a physician licensed.

Both bills make great strides towards enhancing consumer access and highlight the need to remove unwarranted impediments to patient care. Given the negative impact on improving consumer access and choice of affordable care, we urge FTC to explore this matter further, and support efforts to increase the enhanced consumer access to pharmacy-based immunizations.

**B. IMPACT OF MEDICARE PAYMENT POLICY: CONSUMER ACCESS & CHOICE**

As noted previously, pharmacists have played an increasingly important role in the delivery of healthcare services. However, the lack of pharmacist recognition as a “provider” by third party payers including Medicare has limited the number and types of services for which pharmacists may be paid. Obtaining pharmacist provider status in Medicare has been advocated by some groups for well over a decade, but few advancements have been made.
Current law confers “provider status” on certain providers and facility types. A majority of the listed provider types have been listed since the implementation of Medicare while only a few have been added to the list in recent years. Social Security Act contains an extensive listing of the types of services and practitioners eligible under Medicare. Eligible provider types include:

1. Physician
2. Physical therapist
3. Occupational therapist
4. Qualified speech-language pathologist
5. Qualified audiologist
6. Physician assistant (incident to a physician’s services)
7. Nurse practitioner (incident to a physician’s services)
8. Clinical nurse specialist (incident to a physician’s services)
9. Certified nurse-midwife
10. Clinical social worker
11. Certified registered nurse anesthetist
12. Clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)
13. A registered dietician or nutrition professional
14. Speech language pathologist

In other words, the lack of provider status precludes community pharmacists from being paid for clinical care services rendered to Medicare and Medicaid beneficiaries; and/or impedes their ability to offer services they are well-trained trained to render. For instance, the Medicare Part B currently pays for health and wellness screenings, immunizations, disease state management, and smoking cessation programs, among others – all are services that pharmacists can currently provide in accordance with the vast majority of state laws. The arbitrary omission of pharmacists as a provider within the Medicare program serves to limit consumer access and choice for services that pharmacists readily provide to other patient populations. The impact of this unwarranted and arbitrary policy is seen most in medically underserved populations.

To illustrate the negative impact of this arbitrary policy on public health and consumers, consider health and wellness screenings, such as CLIA-waived tests. Many CLIA-waived tests are used by physicians, nurse practitioners and others to assist with the early detection and monitoring the progression of disease. As we indicated previously, Medicare Part B Program provides many of these tests at no out-of-pocket cost to the beneficiaries, and pays health care providers listed above to render these services. Despite this wide authorization to provide free health screenings to beneficiaries, rates remain extremely low for many common conditions, particularly in rural and minority

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19 42 U.S.C.A. § 1395x(s)
20 Pharmacists can be paid as mass immunizers and diabetes suppliers if they meet certain criteria.
21 The Food and Drug Administration (FDA) defines a CLIA-waived test as one that has been cleared safe for home use, and employs methodologies that are simple and accurate or pose no reasonable risk of harm to the patient if the test is performed incorrectly.
populations. Many states permit pharmacists to order and interpret tests related to a patient’s medication regimen, and an increasing proportion of community pharmacists provide these services for their non-Medicare population. However, the lack of Medicare “provider” status prevents community pharmacists from billing for such tests and, thus, drastically limits consumer access.

**Pharmacists as Health Testing Providers: Impact on Access.** In a 2013 nationwide survey of U.S. adults, one in five adults reported having a health test performed at a pharmacy in the previous year. 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.

Published reports have also documented pharmacies increased access to screenings for cardiovascular disease, diabetes, HIV, Hepatitis C, Strep throat, osteoporosis, and many other conditions. In one study, pharmacists screened 888 participants for diabetes and cardiovascular conditions and 81% of these patients were referred for follow-up care due to the detection of an abnormality. Screenings in community pharmacy settings improved follow-up rates with physicians compared with screenings conducted in non-health care settings.

A report from the U.S. Public Health Service noted the capacity of community pharmacy in augmenting patient access; in 6 months, one nationwide pharmacy program provided

services such as blood pressure screenings to more than 42,000 patients. Another national pharmacy chain engaged its more than 26,000 health professionals to provide free blood pressure screenings. As 95% of all U.S. residents live within 5 miles of a community pharmacy, the unique reach and accessibility of pharmacies holds promise to increase competition and consumer screening choices. No evidence has been reported related to safety concerns with CLIA-waived tests being conducted at pharmacies.

Impact on Competition and Consumer Choice. Studies have shown that pharmacy-based tests are more affordable than those provided in other settings. One study showed rapid antigen detection testing services cost patients $45 in pharmacies versus a $100 physician visit. A separate study identified pharmacist-provided testing for pharyngitis to be the most cost-effective strategy as well as the cost-minimizing strategy for the diagnosis and treatment of pharyngitis in adults. A report by the HHS Office of Inspector General recently found that Medicare could have saved $1 billion in 2011 had it paid the lowest rate negotiated by private insurers for lab tests. Increasing competition through further expansion of pharmacy-based testing may also generate significant system and consumer savings.

Patients have reported high rates of satisfaction with health testing in community pharmacies and that testing in pharmacies was preferable to getting tested in physician settings. In a 2013 survey of U.S. adults, 69% of consumers reported they would be likely to receive diagnostic services such as blood pressure screenings at pharmacies, and 59% reported they would access diagnostic tests such as blood, urine, or strep testing at pharmacies if available.

Accordingly, we encourage the FTC to support efforts to create a level playing field for trained and qualified health providers, thereby increasing competition and consumer choice.

C. INNOVATIONS IN HEALTHCARE DELIVERY

Medications are the primary intervention to treat chronic disease, and are involved in 80% of all treatment regimens. Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76 percent of all hospital admissions, and are 100 times more likely to have a preventable hospitalization. Yet, medication management services are poorly

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38 http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
integrated into existing healthcare systems, including ACOs. Poor medication adherence alone costs the nation approximately $290 billion annually – 13% of total healthcare expenditures – and results in avoidable and costly health complications.\textsuperscript{39}

A growing body of evidence suggests that when physicians, nurses, pharmacists, and other healthcare professionals work collaboratively, better health outcomes are achieved. Pharmacies in particular provide access to highly-trained and highly-trusted health professionals. The unique reach and access points of pharmacy provide a means of continuous care and oversight between scheduled doctor visits. As such, pharmacies have increasingly provided a suite of medication management and related services, including Medication Therapy Management (MTM), disease-state monitoring and patient self-management, adherence interventions, medication synchronization, transitions of care, immunization programs, chronic care and wellness programs, and patient engagement, among others.

Experts have written about the beneficial role of pharmacists in Medical Homes and Accountable Care Organizations (ACOs).\textsuperscript{40,41} In so doing, these experts have noted the lack of integration of pharmacy services into emerging models of care such as ACOs.\textsuperscript{42} Specifically, Smith and colleagues noted:

Pharmacists can help meet the demand for some aspects of primary care and can contribute to the efficient and effective delivery of care. Thus, they should be included among the health professionals who are called on to mitigate the projected primary care provider shortage.

The potential benefits of integrating medication management services have been emerging in the last couple of years. For example:

- Jha and colleagues found that improved adherence to diabetes medication could avert 699,000 emergency department visits and 341,000 hospitalizations annually, for a saving of $4.7 billion.\textsuperscript{43} Eliminating the loss of would lead to another $3.6 billion in savings, for a combined potential savings of $8.3 billion. These benefits were particularly pronounced among poor and minority patients.

- CMS’ own report from 2013 found that Part D MTM programs consistently and substantially improved medication adherence and quality of prescribing for evidence-based medications for beneficiaries with congestive heart failure, COPD, and diabetes.\textsuperscript{44} The study also found significant reductions in hospital costs, particularly when a comprehensive medication review (CMR) was utilized. This included savings of nearly $400 to $525 in lower overall hospitalization costs for beneficiaries with diabetes and congestive heart failure. The report also found that MTM can lead to reduced costs in the Part D

\textsuperscript{39}http://www.nehi.net/bendthecurve/sup/documents/Medication_Adherence_Brief.pdf
\textsuperscript{40}http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
\textsuperscript{41}http://content.healthaffairs.org/content/29/5/906.abstract
\textsuperscript{42}http://content.healthaffairs.org/content/32/11/1963.full
\textsuperscript{43}http://content.healthaffairs.org/content/31/8/1836.abstract
\textsuperscript{44}http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf
program as well, showing that the best performing plan reduced Part D costs for diabetes patients by an average of $45 per patient.

One reason for the lack of integration of pharmacy services into these emerging models of care is the lack of pharmacist provider status in Medicare program as discussed previously. Another is the lack of consistent professional scope of practice regulations, impeding nationwide scale-up.

**Conclusion.**

We appreciate your engagement in this important area and the thoughtful approach in which you are soliciting views from stakeholders on these issues. We look forward to continuing to work with you, and other stakeholders, as you continue consideration of these and other important matters to advance competition and consumer choice.

Sincerely,

Kathleen Jaeger  
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Don Bell  
Senior Vice President & General Counsel