



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

**April 30, 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**

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide supplemental comments to the Federal Trade Commission's (FTC) notice and questions regarding "Examining Health Care Competition." 79 Fed. Reg. 10153 (2014). NACDS submitted initial comments on March 10, 2014.

NACDS offers the following comments to the FTC as it seeks to better understand the competitive dynamics of evolving healthcare product and service markets and the emerging role pharmacies and pharmacists are playing in increasing access, improving outcomes and reducing health costs.

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. Additionally, as the face of neighborhood healthcare, to more fully meet the healthcare needs of the patients they serve, certain NACDS members also have convenient care clinics located inside their drug stores. Convenient care clinics are staffed by board-certified Nurse Practitioners (NP) and Physicians Assistants (PA) and deliver high quality care in an accessible and affordable manner. Today, there are over 1,500 convenient care clinics in 40 states and Washington, DC; a majority of those clinics are located inside NACDS member drug stores. Pharmacies are evolving to become the first and most convenient healthcare destination to meet a wide variety of patient needs.

Pharmacies remain committed to their valuable role in providing medications, fostering medication safety and effectiveness, and providing health and wellness services. In addition, innovative pharmacy services and other healthcare services available in accessible retail settings can do even more to improve patient health and wellness, often in collaboration with primary care physicians, nurses and other professionals. NACDS supports efforts by the FTC to create a robust healthcare marketplace that advances patient choice and competition to improve the accessibility,

quality, and affordability of healthcare in America. To that end, NACDS asks FTC to support the removal of needless barriers to the effective functioning of innovative healthcare delivery for the patients we seek to serve; support fairer scope of practice, supervision and reimbursement laws across states to advance competition and patient choice; and support federal legislation that would designate pharmacists as healthcare providers under Medicare Part B, removing an unwarranted and harmful exclusionary, competition barrier.

**I. Background on Community Pharmacists & Scope of Practice Issues**

In the United States, primary care services are traditionally provided by primary care physicians, nurse practitioners, and physicians assistants. In recent years, however, the role of community pharmacists has grown to encompass health and wellness care and screenings, immunizations and medication management, among others. While these services vary by state and venue, pharmacy services are designed to provide patients convenient access to affordable, quality care, especially to the uninsured, underinsured, and medically underserved populations. Community pharmacists have extensive education and training, which is similar to the amount of education and training required of other non-physician practitioners (e.g., NPs and PAs). Entry-level pharmacists receive a minimum of six (6) years of advanced education as part of the Doctor of Pharmacy degree (PharmD). Pharmacists also must pass a national, comprehensive and standardized board exam (North American Pharmacist Licensure Examination (NAPLEX)), and are subject to state licensure requirements. The training of pharmacists emphasizes patient-centered care as a medication expert, which involves interpreting evidence, formulating patient assessments and recommendations, implementing, monitoring and adjusting patient care plans, and documenting activities.<sup>1</sup>

	Entry-Level Degree	Licensing/Certification	Scope of Practice (varies by state)
Pharmacists	<p>Doctor of Pharmacy degree (minimum of 6 years)</p> <p>Doctorate degree accounts for 4 years of the six year training.</p> <p>Advanced pharmacy practice experiences are not less than 1440 hours during the last academic year; 300 hours of basic pharmacy practice.</p>	Pharmacists must pass the North American Pharmacist Licensure Examination.	<ul style="list-style-type: none"> <li>· Manage Medications</li> <li>· Provide Screenings, Immunizations,</li> <li>· Patient Assessment &amp; Diagnose Simple Ailments</li> <li>· Disease Prevention</li> </ul>

<sup>1</sup><http://www.aacp.org/resources/education/cape/Open%20Access%20Documents/CAPEoutcomes2013.pdf>

Nurse Practitioners <sup>2</sup>	Bachelor's degree in nursing followed by graduate level degree (Master's or Doctorate in Nursing Practice)	NPs are certified by the American Nurses Credentialing Center and the American Academy of Nurse Practitioners.	<ul style="list-style-type: none"> <li>· Patient Assessment</li> <li>· Diagnose Medical Conditions</li> <li>· Prescribe Medications</li> <li>· Disease Prevention</li> </ul>
Physician Assistants <sup>3</sup>	<p>Bachelor's degree followed by Master's degree in physician assistant studies, health or medical science.</p> <p>Clinical experience includes not less than 2,000 hours of clinical rotations with an emphasis in primary care.</p>	PAs are certified by the National Commission on Certification of Physician Assistants (NCCPA).	<ul style="list-style-type: none"> <li>· Patient Assessment</li> <li>· Diagnose Medical Conditions</li> <li>· Prescribe Medications</li> <li>· Disease Prevention</li> </ul>

In accordance with the 2011 Accreditation Council for Pharmacy Education (ACPE) guidelines (2016 update in progress), an entry-level pharmacist is trained to collaborate with patients, care givers, physicians, nurses, other healthcare providers, policy makers, members of the community, and administrative and support personnel to engender a patient-centered team care approach.<sup>4</sup> Pharmacists also are educated and trained to manage chronic disease, improve health and wellness, provide screenings, and patient assessments, coordinate care with other healthcare providers, and participate in population health management. In addition, their foundational didactic requirement includes a demonstration of an understanding of pathologic and pathophysiologic basis of diseases, therapeutic basis of drug treatment, immunology and genomics, biostatistics and population health, and other areas of pharmacy practice as it impacts clinical, social and behavioral health.

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 patient care, services and tests.<sup>5</sup> Specifically, a Centers for Disease Control and Prevention (CDC) review found that “pharmacist engagement in interdisciplinary health management with physicians and other providers significantly improved patients’ blood pressure, hemoglobin A1c” among other things, and those pharmacists’ “care services also reduced fragmentation of care, decreased health expenditures, and optimized health outcomes.”<sup>6</sup> Leading healthcare policymakers recently echoed this sentiment in highlighting the critical need to integrate pharmacists into collaborative and emerging care models, noting that the inclusion of all skilled clinicians in the team improves patient care experience and outcomes.<sup>7</sup> The patient-centered collaborative care team approach

<sup>2</sup> <http://www.nursecredentialing.org/RenewalRequirements.aspx>

<sup>3</sup> <http://www.aapa.org/landingquestion.aspx?id=290>

<sup>4</sup> Accreditation Council of Pharmacy Education. “Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree.” Updated February 2011. <https://www.acpe-accredit.org/pdf/FinalS2007Guidelines2.0.pdf>

<sup>5</sup> Giberson, S, Yoder, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec. 2011. Page 10.

<sup>6</sup> CDC “State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws” updated Dec. 2012. [http://www.cdc.gov/dhdsp/pubs/docs/Pharmacist\\_State\\_law.PDF](http://www.cdc.gov/dhdsp/pubs/docs/Pharmacist_State_law.PDF) at 1.

<sup>7</sup> Harvard Business Review: The Strategy that Will Fix Health Care; Oct. 2013; Harvard Business Review Blog: Redefining the Patient Experience with Collaborative, Sept. 2013. <http://hbr.org/2013/10/the-strategy-that-will-fix-health-care/ar/1>.

becomes increasingly relevant as the U.S. healthcare system continues on its transformational path, and as public health leaders continue to wrestle with challenging and positive environmental factors that include:

- An aging population that is expected to grow to 19% of the U.S. population by 2030;<sup>8</sup>
- A national primary care physician shortage which is expected to climb from 63,000 doctors in 2015 to 91,500 by 2020 and 130,000 by 2025, reflecting the aging population and insurance expansion;<sup>9</sup>
- Chronic disease that costs our nation \$1.7 trillion annually, accounting for seventy-five percent (75%) of the healthcare spend;
- Medications are the primary intervention to treat chronic disease, which are involved in 80% of all patient treatment regimens;<sup>10</sup>
- Almost 50% of Americans with chronic diseases fail to take their medications correctly;<sup>11</sup>
- 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;<sup>12</sup>

Community pharmacists have the education and training to address many of the noted healthcare challenges and stand ready to work with other healthcare providers to advance patient outcomes and population health.<sup>13</sup> Specifically, community pharmacists are trained and educated to provide comprehensive chronic medication management, health screenings, preventative care, pharmacogenomics counseling, 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, fill gaps in care, and other services offering innovative care services to reduce hospital readmissions and improve health outcomes in medical homes, and engage with high risk patients in emerging care models.

Regarding increasing access, there is strong evidence that patient health and public health improve when Americans have access to convenient, affordable, and quality care services. Thus, the issue of

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See also: NCQA. The Future of Patient-Centered Medical Homes. Foundation for a Better Health Care System.

[http://www.ncqa.org/Portals/0/Public%20Policy/2014%20Comment%20Letters/The\\_Future\\_of\\_PCMH.pdf](http://www.ncqa.org/Portals/0/Public%20Policy/2014%20Comment%20Letters/The_Future_of_PCMH.pdf)

And: Patient-Centered Primary Care Collaborative. "The Patient-Centered Medical Home: Integrating Comprehensive Medication

Management to Optimize Patient Outcomes." Updated June 2012. <http://www.pccpc.org/sites/default/files/media/medmanagement.pdf>

<sup>8</sup> [http://www.aoa.gov/aging\\_Statistocs/Profile/2011/4.aspx](http://www.aoa.gov/aging_Statistocs/Profile/2011/4.aspx) *Annals of Family Medicine – November/December 2012*: 52,000 additional primary care physicians by 2025 to account for population growth, aging population and insurance expansion; [Association of American Medical Colleges – April 2011](#) Estimated prior to ACA implementation a shortage of 63,000 doctors by 2015; and a shortage of 91,500 by 2020 and 130,000 by 2025.

<sup>9</sup> *Annals of Family Medicine – November/December 2012*: 52,000 additional primary care physicians by 2025 to account for population growth, aging population and insurance expansion; [Association of American Medical Colleges – April 2011](#) Estimated prior to ACA implementation a shortage of 63,000 doctors by 2015; and a shortage of 91,500 by 2020 and 130,000 by 2025

<sup>10</sup> Partnership to Fight Chronic Disease. 2009 Almanac of Chronic Disease at <http://www.fightchronicdisease.org/resurces/almanac-chronic-disease-0>.

<sup>11</sup> **Adherence to Long-Term Therapies: Evidence for Action.** *Eur J Cardiovasc Nurs* December 2003 2:323.

See also; National Priorities Partnership, in collaboration with NEHI. *Improving Patient Medication Adherence: A \$100+ Billion Opportunity*. Washington, DC: National Priorities Partnership, April 2011.

<sup>12</sup> <http://www.pccpc.org/sites/default/files/media/medmanagement.pdf>

<sup>13</sup> NACCHO Preparedness Brief "Leveraging Partnerships between Local Health Departments and Pharmacies: Bringing Rapid Diagnostic Testing to Community Pharmacies." Apr. 11, 2014.

access is extremely important, as the demand for healthcare will rise dramatically in the coming years. According to the American Association of Medical Colleges (AAMC):

A physician shortage was already expected before ACA was signed into law in March 2010, and now that gap could worsen. According to projections released last fall by the AAMC Center for Workforce Studies, there will be a shortage of about 63,000 doctors by 2015, with greater shortages on the horizon—91,500 and 130,600 for 2020 and 2025, respectively.<sup>14</sup>

Community pharmacists are uniquely positioned to increase access to care; 89% of all Americans live within 5 miles of a pharmacy, with a substantial number of consumers visiting pharmacies each week, including “off-clinic” hours such as weekends, evenings, and holidays. However, overly restrictive state regulatory and reimbursement policies limit the suite of care services that can be provided to consumers, and the conditions under which such care is permitted to be offered and/or reimbursed, providing a patchwork quilt of care options across the nation.

Lastly, perhaps instructive to U.S. healthcare policy makers, is the fact that Canada is struggling with similar healthcare challenges, including an increase in healthcare spend largely driven by an increase in prevalence of chronic disease.<sup>15</sup> The Canadian government is intent on improving access to primary care while reducing use of higher cost healthcare resources. One solution being implemented across Canada is the expansion of the pharmacy scope of practice so that Canadian pharmacists can play a larger role in the healthcare system.

Community pharmacists in Canada have the exact education and training requirements as pharmacists in the U.S. Under the expanded scope of practice, pharmacists across Canada “deliver a range of innovative services, including medication reviews, chronic disease management, immunization services and wellness programs;” supported by the authority to prescribe for minor ailments and conditions, order and interpret lab tests, renew and extend prescriptions, among other actions. Provincial governments are now in the process of aggressively implementing the expanded scope of pharmacy practice to provide enhanced, coordinated, innovative patient care and collaborative medication management.<sup>16</sup>

Given the recent creation of the 2011 Canada-United States Regulatory Cooperation Council (RCC), designed to better align the regulatory environment between the two countries, the scope of practice and the role of Canada’s community pharmacists in advancing patient care seems noteworthy.<sup>17</sup>

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<sup>14</sup> [https://www.aamc.org/newsroom/reporter/april11/184178/addressing\\_the\\_physician\\_shortage\\_under\\_reform.html](https://www.aamc.org/newsroom/reporter/april11/184178/addressing_the_physician_shortage_under_reform.html)

<sup>15</sup> Canadian Institute for Health Information “Seniors and the Health Care System: What is the Impact of Multiple Chronic Conditions?” Updated January 2011. [https://secure.cihi.ca/free\\_products/air-chronic\\_disease\\_aib\\_en.pdf](https://secure.cihi.ca/free_products/air-chronic_disease_aib_en.pdf)

<sup>16</sup> Canadian Pharmacists Association. “Pharmacists in Canada.” <http://www.pharmacists.ca/index.cfm/pharmacy-in-canada/pharmacists-in-canada/>

<sup>17</sup> On February 4, 2011, Prime Minister Stephen Harper and President Barack Obama announced the creation of the Canada-United States Regulatory Cooperation Council (RCC) to increase regulatory transparency and coordination between the two countries. The RCC will undertake efforts to better align the regulatory environment between Canada and the United States through a variety of tools such as enhanced technical collaboration, mutual recognition of standards and joint work sharing.

**SUMMARY OF PHARMACISTS' EXPANDED SCOPE OF PRACTICE ACROSS CANADA**

IMPLEMENTATION PROGRESS. SEE APPENDIX C: FOR CODES

Y Implemented in jurisdiction P Pending legislation or regulation or policy X Not implemented		Province/Territory												
		BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	NWT	YT	NU
Pharmacist Scope of Practice	Initiate prescription drug therapy	X	Y	Y	Y	Y	6 P	Y	Y	X	X	X	X	X
	Prescribe for minor ailments and conditions	X	Y	Y	Y <sup>3</sup>	Y	P	Y	Y	Y	X	X	X	X
	Order and interpret lab test	X	Y	X	Y	Y	6 P	Y	Y	Y	X	X	X	X
	Make therapeutic substitutions	Y	Y	Y	X	X	6 P	Y	Y	Y	Y <sup>1</sup>	X	X	X
	Renew and extend prescriptions	Y	Y	Y	Y		6 P	P	Y	X	Y	Y	X	X
	Change dose and formulation and provide emergency prescription refills	Y	Y	Y <sup>2</sup>	Y	Y	6 P	Y <sup>9</sup>	Y	X	Y	X	X	X
	Administer a drug by injections	Y	Y	X	Y	P	7 P	Y	Y	X	X	X	X	X
	Provide emergency prescription refills	Y	Y	Y	Y	Y <sup>5</sup>	6 P	Y	Y	P	P	Y	X	X

**State Regulations: Scope of Practice**

Community pharmacists are the most accessible healthcare professionals in the United States (U.S.) and are one of the most trusted professions.<sup>18</sup> Community pharmacies seek to provide consumers with additional access to and choice of innovative, affordable, and evidence-based care services and to improve public health. In so doing, pharmacies seek to work with physicians, NPs, PAs, and others to broaden the range of affordable care delivery options to Americans across this country while facilitating care coordination.

State-level regulations subject community pharmacies to various categories of regulation. State licensure regulations are for the most part similar across the country regarding entry qualifications and state licensure requirements. However, scope of practice laws and regulations that delineate the types of care that can be provided, and the conditions under which that care may be offered, differ extensively from state-to-state. NACDS submits that scope of practice laws and regulations across the country have wide-reaching negative implications on healthcare competition, and patient access and choice.

<sup>18</sup> Gallup, Inc. *Honesty/Ethics in Professions*. 2013. <http://www.gallup.com/poll/1654/honesty-ethics-professions.aspx>

For example, Washington State authorizes community pharmacists to provide patient assessments and diagnosis of simple ailments.<sup>19</sup> Some innovative state scope of practice laws provide community pharmacists with prescriptive authority to initiate, adjust, or discontinue treatment to manage a diagnosed disease/condition; order, interpret and monitor laboratory tests; perform patient assessments and other tests to monitor drug therapy.<sup>20</sup> A few other state scope of practice laws provide authorization for point of care testing and screenings, e.g., hemoglobin A1c, blood pressure, lipids, influenza, Strep throat, HIV, and tuberculosis.<sup>21</sup> Yet, most states require the delivery of such care and services subject under Collaborative Practice Agreements (CPAs) or Collaborative Drug Therapy Management (CDTM). Under CPAs and CDTMs, pharmacists work to manage patients' drug therapy according to specific guidelines established by the collaborating physician(s) to achieve desired therapeutic outcomes. The types of activities that pharmacists typically perform through collaborative practice agreements include: modification, continuation or discontinuation of drug therapy in accordance with written guidelines; conducting tests and screenings; and ordering lab work in accordance with written guidelines or protocols agreed to by the collaborating physician(s) and pharmacists.

Furthermore, in addition to the care services permitted, states vary as to the breadth and depth of CPAs and CDTMs -- a written agreement with a physician that defines pharmacy practice parameters.<sup>22</sup> Two (2) states, Michigan and Wisconsin, have permissive physician delegation, allowing pharmacists to perform delegated medical services similar to NPs and PAs.<sup>23</sup> Yet, on the other hand, two (2) states, Alabama and Tennessee, prohibit pharmacists from entering into agreements with physicians.<sup>24</sup> Thirty-six (36) states authorize physician-pharmacist CDTM for a wide array of health conditions, whereas Louisiana restricts CDTM to hyperlipidemia only. Five (5) states merely authorize pharmacists to provide CDTM vaccines and emergency contraception under protocol. Further, most states restrict CPAs to written agreements for individual patients, thus making it impossible for pharmacies to offer proactive, population-based health and wellness services. It is clear that regulatory state policies are inconsistent, and unnecessarily hamper the ability of pharmacists to provide innovative, quality, affordable care to consumers – care services

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<sup>19</sup> Washington State Department of Health. *Pharmacy Laws and Rules Book*. Updated March 2013.

<http://www.doh.wa.gov/portals/1/Documents/Pubs/690214.pdf>

<sup>20</sup> See: North Carolina Board of Pharmacy. *NC Pharmacy Laws*. Updated January 2014. <http://www.ncbop.org/LawsRules/Statutes.pdf>

Also: New Mexico: Regulation & Licensing Department. *Pharmacy Rules and Laws*. Updated June 2012.

[http://www.nmcpr.state.nm.us/nmac/\\_title16/T16C019.htm](http://www.nmcpr.state.nm.us/nmac/_title16/T16C019.htm)

<sup>21</sup> National Center for Chronic Disease Prevention and Health Promotion. Division for Heart Disease and Stroke Prevention. *Collaborative Practice Agreements and Pharmacists' Patient Care Services; A Resource For Pharmacists*. Publication date: 10.2013.

<sup>22</sup> CDC "State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws" updated Dec. 2012.

[http://www.cdc.gov/dhdsp/pubs/docs/Pharmacist\\_State\\_law.PDF](http://www.cdc.gov/dhdsp/pubs/docs/Pharmacist_State_law.PDF).

<sup>23</sup> See: State of Michigan Department of Licensing and Regulatory Affairs. *Michigan Public Health Code – Pharmacy Practice and Drug Control*. [http://www.legislature.mi.gov/\(S\(gvxjts451qyfv45i10dxc45\)\)/mileg.aspx?page=getObject&objectName=mcl-368-1978-15-177](http://www.legislature.mi.gov/(S(gvxjts451qyfv45i10dxc45))/mileg.aspx?page=getObject&objectName=mcl-368-1978-15-177). And: State of Wisconsin Department of Safety and Professional Services. *Wisconsin Statutes and Administrative Code Relating to the Practice of Pharmacy*. Updated February 2013.

<http://dsps.wi.gov/Documents/Board%20Services/Codebooks/Pharmacy%20Code%20Book.pdf>

<sup>24</sup> See: Alabama State Board of Pharmacy. *Practice of Pharmacy Act*. Updated December 2013. <http://www.albop.com/act205%20-%20DEC%202013.pdf> and Tennessee Department of Health Board of Pharmacy. *The Tennessee Board of Pharmacy Standards of Practice*. <http://tn.gov/sos/rules/1140/1140-03.20090207.pdf>

well within the scope of their education and training. Illustrating these points is a Case Study – State Policy: Pharmacists as Immunizers - see attached Appendix A.

A recent restrictive scope of practice example involves the state of California. Specifically, the state of California passed a new law last year that unduly imposes additional training and education requirements on community pharmacists<sup>25</sup> to render certain “advanced pharmacy care” services. However, 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.<sup>26</sup> In fact, forty-six (46) states allow pharmacists to enter into Collaborative Practice Agreements (CPAs) to provide “advanced pharmacy care” services.<sup>27</sup> Yet, these states do so without imposing additional educational requirements, including residencies or certification, as a condition to provide services. Furthermore, the services can be currently conducted in hospital pharmacies in California under a protocol, without similar training requirements.

In sum, pharmacists are “remarkably underutilized in the U.S. healthcare delivery system given their level of education, training, and access to the community.”<sup>28</sup> When neighborhood primary care services are needlessly restricted, the competitive benefits in the primary care space fail to materialize, potentially harming consumers, patients, payors, and taxpayers. Consistent with the growing body of evidence, community pharmacists are well trained to provide many of the same services and procedures provided by physicians, NPs, and PAs. Community pharmacists seek to deliver care at the top of their education and training, which is synergistic and coordinated with the care of other professionals. Importantly, state scope of practice policies hamper innovative care delivery and drive professional staffing decisions, impeding healthcare competition, patient choice, and access to affordable, quality care for patients, especially for the medically underserved population.

## II. INNOVATION IN HEALTHCARE DELIVERY

**A. PHARMACY CARE – COMPONENT OF NEIGHBORHOOD CARE:** 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, interoperability, and access to timely, affordable care. Success of these

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<sup>25</sup> See CA SB 493 enacted in 2013. Also, CA health system pharmacists are may already provide certain services under protocol. [http://leginfo.ca.gov/faces/billTextClient.xhtml?bill\\_id=201320140SB493](http://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201320140SB493)

<sup>26</sup> 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.

<sup>27</sup> Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011.

<sup>28</sup> See surgeon general report at 10.



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.

Poor medication adherence alone costs the nation approximately \$290 billion annually – 13% of total healthcare expenditures – and results in avoidable and costly health complications.<sup>29</sup> With this fact in mind, improved care coordination, chronic disease and medication management should be cornerstones of any delivery care model. Thus far, however, chronic disease and medication management services are poorly integrated into existing healthcare systems, including Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes (PCMHs).

Just recently, the National Committee for Quality Assurance (NCQA), an organization that has accredited more than 7,000 Patient-Centered Medical Homes (PCMHs) nationwide, recognized the role of pharmacy services in improving consumer access and patient outcomes. Specifically, in its 2014 issue brief on “The Future of Patient-Centered Medical Homes”, NCQA noted:

Pharmacies also are taking on new roles with immunizations, health and wellness screenings, adherence and other medication management services. As these options gain in popularity and scope, it becomes increasingly important to share information between them and PCMHs.<sup>30</sup>

NCQA also highlighted that medications are involved in 80 percent of all treatments, yet lack of coordination across providers leads to poor outcomes. NCQA has now stated that improving medication management can be a critical element of both PCMHs and ACOs. As such, NCQA increased the weighting for measures related to medication management by 33% in its 2014 standards update.

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, community 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.

One way in which pharmacists promote cost savings and improve quality is by promoting medication adherence through MTM services. As noted above, the costs of poor adherence are staggering, costing the U.S. approximately \$290 billion annually, 13% of total healthcare costs.<sup>31</sup>

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<sup>29</sup> [http://www.nehi.net/bendthecurve/sup/documents/Medication\\_Adherence\\_Brief.pdf](http://www.nehi.net/bendthecurve/sup/documents/Medication_Adherence_Brief.pdf)

<sup>30</sup> See NCQA at 7.

<sup>31</sup> New England Healthcare Institute, 2009.

These unnecessary costs fall disproportionately on government programs such as Medicare and Medicaid, which cover approximately 30 percent of all prescription drugs dispensed in this country. The experiences of Part D beneficiaries, as well as public and private studies, have confirmed the effectiveness of pharmacist-provided MTM:

- A 2013 report from the Centers for Medicare and Medicaid Services (CMS) found that Part D MTM programs consistently and substantially improved medication adherence and quality of prescribing medications for beneficiaries with congestive heart failure, COPD, and diabetes. 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 program as well, showing that the best performing plan reduced Part D costs for diabetes patients by an average of \$45 per patient.
- A study published in the January 2012 edition of *Health Affairs* identified the key role retail pharmacies play in providing MTM services. The study found that a pharmacy-based intervention program increased adherence for patients with diabetes and that the benefits were greater for those who received counseling in a retail, face-to-face setting, as opposed to a phone call from a mail order pharmacist. The study suggested that interventions such as in-person, face-to-face interaction between the retail pharmacist and the patient contributed to improved behavior with a return on investment of 3 to 1.
- The Congressional Budget Office (CBO) has also acknowledged that medication use reduces healthcare costs in other parts of the Medicare program. The CBO recently revised its methodology for scoring proposals related to Medicare Part D and found that for each one percent increase in the number of prescriptions filled by beneficiaries there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population this translates to a savings of \$1.7 billion in overall healthcare costs, or a savings of \$5.76 for every person in the U.S. for every one percent increase in the number of prescriptions filled.

Recent systematic reviews have also highlighted the beneficial role of the aforementioned pharmacy based services in team-based care.<sup>32</sup> Yet, experts have noted the lack of integration, to date, of community pharmacy services into emerging models of care such as ACOs.<sup>33</sup> 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

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<sup>32</sup> [http://www.accp.com/docs/positions/misc/improving\\_patient\\_and\\_health\\_system\\_outcomes.pdf](http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf)

<sup>33</sup> <http://content.healthaffairs.org/content/32/11/1963.full>

health professionals who are called on to mitigate the projected primary care provider shortage.<sup>7</sup>

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.<sup>34</sup> Eliminating the loss of adherence 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.

Considering the compelling evidence demonstrating that pharmacists are uniquely positioned to help patients improve medication adherence and to provide related care, the role that community pharmacies play in the transformation of the health system should be thoroughly assessed to identify significant impediments and challenges. However, one obvious challenge is the lack of pharmacy integration into these emerging models of care due to the lack of pharmacist provider status in the Medicare program as will be discussed in greater detail below. Another is the lack of consistent professional scope of practice regulations, impeding nationwide scale-up as discussed previously. NACDS submits that federal and state impediments and overly restrictive state professional and reimbursement regulations impede our endeavor to integrate innovative pharmacy care services into emerging care models to improve quality, patient outcomes and reduce system costs.

**B. HEALTHCARE DESTINATION -- COMPONENT OF NEIGHBORHOOD CARE:** Ninety-two percent of Americans live within five miles of a community pharmacy, making pharmacies among the most accessible healthcare providers. As the face of neighborhood healthcare, community pharmacies and pharmacists not only provide access to prescription medications and over-the-counter products, but have also become a healthcare destination for cost-effective health services such as immunizations, MTM, and disease screenings. Through personal interactions with patients, face-to-face consultations and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow—in partnership with other healthcare providers.

Additionally, convenient care clinics have been delivering innovative healthcare for nearly a decade, frequently inside NACDS member drug stores. By offering affordable, quality healthcare where people live and work, convenient care clinics improve health outcomes and connect patients with the greater healthcare community. Care is delivered by board-certified NPs and PAs who are licensed and trained to listen to patient's needs, consider their medical history and give appropriate diagnoses and recommendations. NPs and PAs diagnose and treat acute illnesses, chronic conditions such as asthma and diabetes and provide vaccinations and physicals. Convenient care clinics managed by NACDS members use nationally recognized, evidence based clinical-guidelines

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<sup>34</sup> <http://content.healthaffairs.org/content/31/8/1836.abstract>

for treatment. In addition, NPs and PAs collaborate with local physicians and often pharmacists as well when treating patients. In many instances, patients seeking healthcare at convenient care clinics do not have an established primary-care physician relationship; when this occurs the NP or PA treating that patient will help the patient connect with a local physician accepting new patients. Onerous practice barriers prevent convenient care clinics from offering the full scope of services NPs and PAs are allowed to provide. Likewise, NACDS submits that states should remove unnecessary burdens on NP and PA collaboration with physicians in order to give patients increased access to innovative, accessible healthcare in convenient settings.

### **C. IMPACT OF 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.

#### **i. FEDERAL LEVEL**

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. The Social Security Act contains an extensive listing of the types of services and practitioners eligible under Medicare.<sup>35</sup> Eligible providers range from clinical social workers to physical therapists, to NPs and registered dietitians. However, this list does not designate pharmacists – medication, public health, wellness, and preventative care professionals – as providers.

As a result, the lack of “provider status” under the Social Security Act precludes community pharmacists from being paid for clinical care services rendered to Medicare and Medicaid beneficiaries. It also impedes their ability to offer services they are well-trained to render.<sup>36</sup> For instance, 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 providers 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.

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<sup>35</sup> 42 U.S.C.A. § 1395x(s) Eligible provider types include: Physician; Physical therapist; Occupational therapist; Qualified speech-language pathologist; Qualified audiologist; Physician assistant (incident to a physician’s services); Nurse practitioner (incident to a physician’s services); Clinical nurse specialist (incident to a physician’s services); Certified nurse-midwife; Clinical social worker; Certified registered nurse anesthetist; Clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)); A registered dietitian or nutrition professional; Speech language pathologist.

<sup>36</sup> Pharmacists can be paid as mass immunizers and diabetes suppliers if they meet certain criteria.

To illustrate the negative impact of this arbitrary policy on public health and consumers, consider health and wellness screenings, such as CLIA-waived tests.<sup>37</sup> 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, the Medicare Part B Program provides many of these tests at no out-of-pocket cost to the beneficiaries, and pays the healthcare 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 populations.<sup>38,39,40</sup> 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 choice.

**Pharmacists: Health Testing Providers:** 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. The National Association of County and City 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.

In fact, NACCHO recently issued a public health brief calling for partnerships between local health departments and pharmacies focusing on rapid diagnostic testing.<sup>41</sup> Furthermore, published reports have also documented that pharmacies increased access to screenings for cardiovascular disease<sup>42</sup>, diabetes<sup>43</sup>, HIV<sup>44</sup>, Hepatitis C<sup>45</sup>, Strep throat<sup>46</sup>, osteoporosis<sup>47</sup>, and many other conditions.

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<sup>37</sup> 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.

<sup>38</sup> Carter M. Hepatitis C testing rate low and knowledge of the infection poor in the US "baby boomer" generation. May 18, 2012. Retrieved from: <http://www.aidsmap.com/Hepatitis-C-testing-rate-low-and-knowledge-of-the-infection-poor-in-the-US-baby-boomer-generation/page/2357610/>

<sup>39</sup> Smith M. Youth HIV Rate High, Testing Low. November 27, 2012. Retrieved from: <http://abcnews.go.com/Health/AIDS/youth-hiv-rate-high-testing-low/story?id=17821912>

<sup>40</sup> Associated Press. Study: High-risk groups not screened for diabetes. May 30, 2011. Retrieved from: <http://www.rrstar.com/updates/x724655842/Study-High-risk-groups-not-screened-for-diabetes>

<sup>41</sup> NACCHO Preparedness Brief "Leveraging Partnerships between Local Health Departments and Pharmacies: Bringing Rapid Diagnostic Testing to Community Pharmacies." Apr. 11, 2014.

<sup>42</sup> Snella KA. Pharmacy- and Community-Based Screenings for Diabetes and Cardiovascular Conditions in High-Risk Individuals. JAPhA. 2006;46:307-7.

<sup>43</sup> Fera T, et al. The Diabetes Ten City Challenge: Interim clinical and humanistic outcomes of a multisite pharmacy diabetes care program. JAPhA. 48:2. 2008.

<sup>44</sup> Calderon Y, et al. Counselor-Based Rapid HIV Testing in Community Pharmacies. AIDS Patient Care and STDs. August 2013. Retrieved from: <http://online.liebertpub.com/doi/abs/10.1089/apc.2013.0076>

<sup>45</sup> The Hepatitis C Trust. Pharmacy-based testing for hepatitis B and hepatitis C. Retrieved from: <http://www.hepctrust.org.uk/Resources/HepC%20New/Hep%20C%20Resources/Education%20and%20Training/Pharmacy%20Testing%20Overview%20-%20Oct%202011.pdf>

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-healthcare settings.<sup>48</sup>

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.<sup>49</sup> Another national pharmacy chain engaged its more than 26,000 health professionals to provide free blood pressure screenings. As 89% 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.* 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.<sup>50</sup> 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.<sup>51</sup> 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.<sup>52</sup> Increasing competition through further expansion of pharmacy-based testing may also generate significant system and consumer savings.

*Impact on Consumer Choice.* Patients have reported high rates of satisfaction with health testing in community pharmacies<sup>53</sup> and that testing in pharmacies was preferable to getting tested in physician settings.<sup>54</sup> 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. Yet, despite the high levels of patient-reported satisfaction, and demonstrated impact on consumer

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<sup>46</sup> MacLean et al, 2013. 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)

<sup>47</sup> Goode JV, et al. Regional osteoporosis screening, referral, and monitoring program in community pharmacies. JAPhA. 2004;44:152-60.

<sup>48</sup> Snella KA. Pharmacy- and Community-Based Screenings for Diabetes and Cardiovascular Conditions in High-Risk Individuals. JAPhA. 2006;46:307-7.

<sup>49</sup> Giberson S. Million Hearts: Pharmacist-Delivered Care to Improve Cardiovascular Health. Public Health Reports. January-February 2013.

<sup>50</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)

<sup>51</sup> Klepser D, et al. Cost-Effectiveness of Pharmacist-Provided Treatment of Adult Pharyngitis. Am J Manag Care. 2012 April 1;18(4):145-54.

<sup>52</sup> Department of Health and Human Services. Office of Inspector General. Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings. June 2013. Retrieved from: <http://oig.hhs.gov/oei/reports/oei-07-11-00010.pdf>

<sup>53</sup> Caldreon Y, et al. Counselor-Based Rapid HIV Testing in Community Pharmacies. AIDS Patients Care and STDs. Retrieved from:

<http://online.liebertpub.com/doi/abs/10.1089/apc.2013.0076>

<sup>54</sup> Hepatitis C Trust. Pharmacy-based testing for hepatitis B and hepatitis C. Retrieved from:

<http://www.hepctrust.org.uk/Resources/HepC%20New/Hep%20C%20Resources/Education%20and%20Training/Pharmacy%20Testing%20Overview%20-%20Oct%202011.pdf>

access and cost, physician groups have continued to actively oppose pharmacy services, such as health screenings, which are well within the pharmacists' education and training.<sup>55</sup>

**Pharmacy Care Reimbursed As “Incident to Physician.”** In recognizing that community pharmacists are providing valuable patient care, the American Academy of Family Physicians (AAFP) submitted a letter to CMS on January 22<sup>nd</sup> of this year.<sup>56</sup> In so doing, AAFP emphasized the increasing role of team-based care and the establishment of medical homes, and noted that family medicine practices are employing pharmacists as part of the team. AAFP further noted that these pharmacists are engaged in face to face delivery of patient care pursuant to a written physician protocol and incidental to services provided by the physician.

AAFP further explained that these services now provided by pharmacists are identical to those services coded and traditionally billed by physicians as “evaluation and management services,” and asked CMS to confirm that pharmacists are considered among the “auxiliary personnel” as defined in sections 60(A) and 60.1(B) of the Medicare Benefit Policy Manual so that “physicians may bill Medicare for a Part B covered service provided by a pharmacist in the practice as long as all the incident to rules are otherwise met.”<sup>57</sup> In response to the AAFP letter, CMS confirmed AAFP’s interpretation that a physician may bill for services provided by a pharmacist as incident to services; noting that the agency modified the definition of auxiliary personnel and the provision of services and supplies to state that all applicable state laws also must be observed.<sup>58</sup>

As a result of CMS’ confirmation, a CLIA-waived test for a patient with diabetes provided by a pharmacist may be billed as incident to physician services assuming all applicable requirements are met. However, the pharmacist who provided the services is prohibited from billing Medicare Part B for the same service.

Hence, the value of care services provided by pharmacists has been recognized by family medicine practitioners and CMS and may be billed and reimbursed incident to physician services if applicable requirements are met. Yet, such care services are limited by physician supervision and state scope of practice laws, having a profound impact on access to affordable, patient care in medically underserved areas. It is well documented that the physician shortage is more pronounced “in communities with high proportions of minority and low-income residents with greater health needs.”<sup>59</sup> As a result, stringent state supervision policies and federal “incident to physician”

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<sup>55</sup> For example, see Resolution 67-14 of the Michigan Academy of Family Physicians (MAFP), entitled “Oppose Rapid Diagnostic Testing (RDT) Program in Michigan Pharmacies” introduced by Barb Saul, DO, for the MAFP. See Appendix F for a copy of the Resolution.

<sup>56</sup> Jan. 22, 2014 Letter to CMS Administrator Marilyn Tavenner. <http://www.aafp.org/news/practice-professional-issues/20140416incidenttoltr.html>.

<sup>57</sup> American Academy of Family Physicians. *AAFP, CMS Clarify ‘Incident to’ Rules Relating to Pharmacists’ Services*. April 16, 2014. <http://www.aafp.org/news/practice-professional-issues/20140416incidenttoltr.html>

<sup>58</sup> In confirming care services provided by a pharmacist may be billed by a physician as incident to services, CMS also pointed out that regarding medication therapy management services, as described by CPT codes 99605 to 99607 – are not subject to incident to billing requirements since such codes are excluded from Part B coverage and are reimbursed under Medicare Part D. Cite CMS Ltr; or AAFP website.

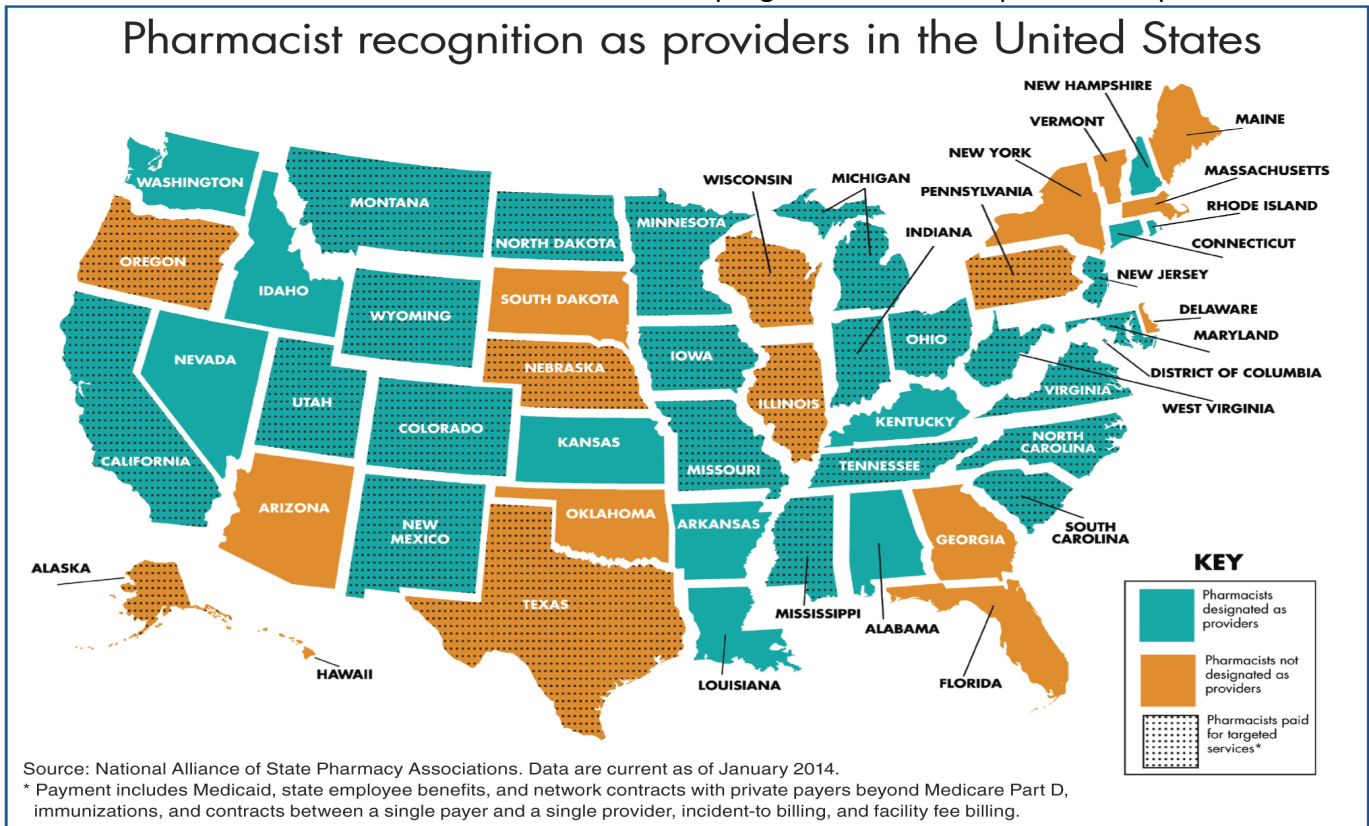
<sup>59</sup> Robert wood Johnson Foundation., Research Synthesis Report No. 22: Primary Care Health Workforce in the United States, at 7 (2011); Kaiser Foundation, Improving Access to Adult Primary Care in Medicaid; Exploring the Potential Role of Nurse Practitioners and Physician Assistants (Mar. 2011); <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8167.pdf>; <https://www.aamc.org/download/100598/data>.

requirements can have a dramatic impact on access to care services provided in medically underserved and rural areas.<sup>60</sup>

**Solution: Federal Legislation.** Federal legislation has recently been introduced to authorize Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services, subject to state scope of practice laws.<sup>61</sup> Private estimates of this legislative change reflect costs in the single-digit billion dollar range over ten years. However, this important legislation would lead not only to reduced overall healthcare costs, but also to increased access to healthcare services and improved healthcare quality and outcomes for a very vulnerable population. Accordingly, we encourage the FTC to support federal efforts to create a level playing field for trained and qualified health providers, thereby increasing competition and consumer choice.

ii. STATE LEVEL

According to a recent analysis conducted by the National Alliance of State Pharmacy Associations (NASPA), thirty-four (34) states recognized pharmacists as providers or practitioners in at least one section of their state statute or in their state Medicaid program. See NASPA provider map below.



<sup>60</sup> "Patient-Centered Medical Homes," *Health Affairs*, September 14, 2010.

<sup>61</sup> H.R. 4190 - To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services. 113th Congress (2013-2014). <http://beta.congress.gov/bill/113th-congress/house-bill/4190>



While recognition as a healthcare provider is certainly a positive development, a key point is that the provider designation at the state level, in and of itself, does not equate with reimbursement for services rendered. In fact, state reimbursement is inconsistent and limited at the state level. In assessing reimbursement policies, NASPA reported that only ten (10) states provide for reimbursement for MTM services through Medicaid programs. Likewise, only seven (7) states provide for pharmacy care reimbursement for these services through their state employee programs, while fifteen (15) states provided for reimbursement for certain Medicaid healthcare services.<sup>62</sup> Four states, Colorado, Iowa, Minnesota, and Wisconsin, are the most progressive states, providing reimbursement means for both Medicaid medication management and certain other services. Of the total reimbursing states, pharmacists are not formally recognized as providers in six (6) “state’s statute or Medicaid provider manuals, but are compensated for providing targeted patient care services.”<sup>63</sup> See following Reimbursement Table.

Current state reimbursement policies therefore hamper the delivery of innovative care and provide significant business uncertainty. As such, significant consideration should be given to state reimbursement policies for innovative care delivery and emerging care models, especially within the medically underserved population to enhance healthcare capacity and strengthen community partnerships to offset provider shortages and the surge in individuals with healthcare coverage.<sup>64</sup>

**STATE PAYMENT MEANS FOR PHARMACISTS**

Certain Medicaid Service	Medicaid MTM	State Employee MTM
Alaska, Colorado, Indiana, Iowa, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Mexico, North Dakota, Oregon, Texas, Utah, Wisconsin	Colorado, Iowa, Minnesota, Mississippi, Missouri, New Mexico, Oregon, Texas, Wisconsin	Kentucky, Maryland, Minnesota, North Dakota, West Virginia, Virginia

**III. ADVANCEMENTS IN HEALTHCARE DELIVERY & TECHNOLOGY**

The passage of the Affordable Care Act (ACA) established the Center for Medicare and Medicaid Innovation. The Center was appropriated \$10 billion to develop, implement and test a host of new payment models that aim to fundamentally change the way providers are reimbursed. The new models target providers along the entire continuum of care, with preference to models that improve the coordination, quality, and efficiency of healthcare services.<sup>65</sup>

<sup>62</sup> American Pharmacists Association 2014 Annual Meeting and Exposition. “Everything you ever wanted to know about Provider Status but didn’t have time to ask.” Presented March 29, 2014. Orlando, FL.

<sup>63</sup> *PharmacyToday* • FEBRUARY 2014; “NASPA finds state-level provider status is widespread, but not necessarily linked to payment”

<sup>64</sup> The medically underserved population includes seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others.

<sup>65</sup> Centers for Medicare and Medicaid Services. *About the CMS Innovation Center.* <http://innovation.cms.gov/about/index.html>

ACOs and PCMHs are central to the new structure for payment reform at the health system level. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services, reducing variability and waste, and preventing medical errors. Likewise, commercial payers increasingly are restructuring their payment models with providers to align incentives with improving quality and reducing the total cost of care. Many are experimenting with ACOs, PCMHs, and hospital bundling. In each of the value-based purchasing models, the fundamental change is simply to realign financial incentives, and create a business context for improvement, which builds upon the supposition that better care coordination and chronic disease management in the primary care setting can lead to higher quality care and lower inpatient utilization and lower total cost of care.

There is no question that improved medication management is central to better treatment of chronic disease. Efforts to improve care coordination and patient outcomes will be thwarted if patients with chronic disease do not appropriately take their medications as prescribed and get the requisite monitoring and care they need. As previously noted, there is compelling evidence demonstrating that pharmacists are uniquely positioned to improve patient outcomes and reduce overall healthcare costs. However, key IT operational and business challenges exist in the pursuit of care coordination and interoperability.

While some progress has been made with adoption and utilization of EHRs, issues with access and interoperability standards still exist, especially for community pharmacies. Without access to EHR data, pharmacy is essentially locked out from robust care coordination and the ability to identify gaps in care, avoid redundant care services, and secure access to full patient medical information, including medical diagnosis and important laboratory data. However, integrated healthcare teams benefit from bi-directional and interoperable systems in improving patients' quality of care and patient outcomes as well as providing system efficiencies.

The importance of interoperability and care coordination cannot be overstated. For example, interoperability of healthcare systems, and enhanced care coordination, would benefit Medicare beneficiaries with multiple chronic illnesses, who, as noted above, 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.<sup>66</sup> The lack of effective access and interoperability today continue to underpin the concerns of the potential monopolization of health IT, which occurs as a result of exclusionary proprietary standards and data ownership matters. As such, NACDS encourages FTC to assess access and interoperability issues in the healthcare IT space, and support efforts to remove barriers and obstacles that hinder holistic approaches to patient care, care coordination, and the advancement of public health.

#### **IV. MEASURING & ASSESSING QUALITY OF HEALTHCARE**

NACDS and its members recognize the importance of developing and implementing a meaningful quality measuring and rating systems (QRS) for federal programs, Qualified Health Plans (QHPs) offered through health insurance exchanges, as well as within standards for emerging care models,

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<sup>66</sup> <http://www.pccpc.org/sites/default/files/media/medmanagement.pdf>

such as ACOs and PCMHs. The overarching goal of QRS systems is to provide transparent, actionable ratings to consumers based on healthcare quality and outcomes, consumer experience, and cost. NACDS supports QRS systems that:

- Demonstrate sound, reliable, and meaningful information on the performance that is useful and pertinent to consumers to support informed decision-making;
- Align with priority measures currently implemented in federal, state, and private sector programs; and
- Include measures that are actionable to encourage delivery of high quality healthcare services, and improve patient health outcomes.

A central focus of the Medicare 5-Star rating system for medications for MA-PD and PDP Plans is on safe, consistent, and appropriate medication use. CMS has stated that “[o]ne of the most important ways you can manage your health is by taking your medication as directed.”<sup>67</sup> In 2012, CMS launched five (5) medication-related adherence measures as part of the Medicare 5-Star Part D program, which are now publicly reported for the Medicare Advantage program and the Part D program.

Moreover, a recent study conducted in conjunction with the Center for Medicare and Medicaid Innovation (“CMMI MTM study”)<sup>68</sup> found that individuals enrolled in Medication Therapy Management (MTM) programs -

particularly those who received annual CMRs – experienced *significant improvements in drug therapy outcomes* when compared to beneficiaries who did not receive any MTM services, thus supporting the hypothesis that the annual CMR may be one of the more crucial elements of MTM. *Significant cost savings associated with all-cause hospitalizations at the overall PDP and MA-PD levels were found, which may be due to MTM’s comprehensive rather than disease-specific approach.*<sup>69</sup>

CMS studies have found that high-performing MTM programs “not only improved drug therapy outcomes but also maintained or lowered rates of hospitalizations, ER visits, and associated costs.”<sup>70</sup> Specifically, MTM services decreased hospital utilization and costs in diabetes and congestive heart failure patients receiving CMRs, leading to significant cost savings in per-patient hospitalization costs of \$526 and \$329, respectively.<sup>71</sup>

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<sup>67</sup> <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2013-Part-C-and-D-Preview-2-Technical-Notes-v090612-.pdf>. at 62.

<sup>68</sup> <http://innovation.cms.gov/Files/reports/MTM-Interim-Report-01-2013.pdf>.

<sup>69</sup> See Proposed Part D Rule expanding eligibility for MTM care. <http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf>

<sup>70</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-31497.pdf>.

<sup>71</sup> [http://innovation.cms.gov/Files/reports/MTM\\_Final\\_Report.pdf](http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf).

Importantly, a recent research study has also shown a positive association between CMS 5-Star Medicare Part D quality ratings and beneficiary enrollment.<sup>72</sup> From the study findings, the authors noted that not only did ***this information assist consumers with enrollment decisions***, but also may provide:

- Firms with additional incentive to cultivate higher quality,
- CMS with justification to continue to advance public reporting, and
- Policy makers with a rationale to pursue quality reporting in other health insurance markets.<sup>73</sup>

Accordingly, patient outcomes and system costs are significantly influenced by medication management and related care quality metrics. Additionally, because of the transparent and accessible quality ratings of Medicare programs and because of quality bonus program payments, commercial payors have an increased interest in working with community pharmacies to help drive medication adherence public quality reporting, specifically with the Medicare Stars program.

NACDS therefore submits that transparent and meaningful quality measures significantly improve patient care,<sup>74</sup> and protect consumers by providing relevant and meaningful quality rating information on medications. We also submit that lack of alignment on quality standards, such as medication management metrics, undermines consumer education efforts, and diminishes the ability of individuals (both consumers and providers) to have a consistent understanding of the federal and state quality and performance measures with respect to safe, consistent, and appropriate medication use.

## V. PRICE COMPETITION OF HEALTHCARE SERVICES

NACDS is concerned that overly strict application of certain federal and state laws hampers the ability of pharmacies to compete on price for customers who are covered by Medicare, Medicaid, and other government programs. As a result, these customers have lost access to lower cost medications and other services, which negatively impacts their health.

One way that retail community pharmacies compete is by offering price reduction programs that reduce consumers' costs for prescription drugs and other products and services. For example, many pharmacies offer discount cards or loyalty programs that enable customers to pay lower prices for many healthcare and non-healthcare products and services. Similarly, pharmacy coupons offer consumers cost savings off prescription drugs, over the counter medications, and other products or services. These discount programs encourage price competition among pharmacies and help consumers by lowering costs.

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<sup>72</sup> Reid, R, et al. Association Between Medicare Advantage Plan Star Ratings and Enrollment. *JAMA*. 2013;309(3):267-274.

<sup>73</sup> *Id* at 273 emphasis added.

<sup>74</sup> Harvard Business Review: The Strategy that Will Fix Health Care; Oct. 2013; Harvard Business Review Blog: Redefining the Patient Experience with Collaborative, Sept. 2013. <http://hbr.org/2013/10/the-strategy-that-will-fix-health-care/ar/1>

However, the vast majority of consumers enrolled in Medicare, Medicaid, and other government healthcare programs are not allowed to receive the benefits of lower costs by participating in many pharmacy discount programs. As a result of strict interpretations of the federal civil monetary penalties law<sup>75</sup> and the federal anti-kickback law,<sup>76</sup> as well as parallel state laws, these consumers are routinely unable to enjoy the benefits of pharmacy discount programs.

NACDS understands that a principal rationale for these laws is to protect against overutilization of items and services that are paid for by government healthcare programs.<sup>77</sup> However, this rationale does not normally apply in the context of retail pharmacies, because pharmacies do not control utilization of prescription medications or medical equipment. Instead, utilization of covered items and services is controlled by physicians and others who issue prescriptions for covered drugs and medical equipment. Therefore, the underlying basis for applying these laws to pharmacies is questionable at best.

Statutory exceptions to the civil monetary penalties law were enacted in 2010 to enable pharmacies to offer discounts and other benefits to patients enrolled in government healthcare programs. For example, one provision that is specifically tailored to retail pharmacies allows pharmacies to offer “coupons, rebates, or other rewards” to Medicare and Medicaid patients as long as certain protections against fraud and abuse are implemented.<sup>78</sup> Unfortunately, thus far the HHS Office of Inspector General (OIG) has narrowly interpreted this exception to apply only in very limited circumstances.<sup>79</sup>

As a result, consumers enrolled in Medicare, Medicaid, and other government programs are still routinely excluded from accessing pharmacy price discounts, even though the same discounts are freely available to consumers enrolled in private insurance plans. This situation limits price competition among pharmacies for consumers enrolled in government programs, and denies those

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<sup>75</sup> Also known as the patient remuneration law, this statute makes it illegal for any person to offer or transfer “remuneration” to a beneficiary of a government healthcare program that is likely to influence the beneficiary’s selection of a reimbursable product (such as a prescription drug) or a provider (such as a retail pharmacy). 42 U.S.C. § 1320a-7a(a)(5). Remuneration “includes the waiver of coinsurance and deductible amounts (or any part thereof), and the transfer of items or services for free or for other than fair market value.” *Id.* at § 1320a-7a(i)(6); see also 42 C.F.R. § 1003.101. Remuneration essentially includes “anything of value.” OIG Special Advisory Bulletin, 67 Fed. Reg. 55855, 55856 (Aug. 30, 2002).

<sup>76</sup> The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items (such as prescription drugs) or services reimbursable by a federal health care program such as Medicare or Medicaid. 42 U.S.C. § 1320a-7b(b).

<sup>77</sup> See S. Becker, et al., *Health Care Law: A Practical Guide*, § 2.03[1][c] (2012).

<sup>78</sup> 42 U.S.C. § 1320a-7a(i)(6)(G). Other new exceptions to the definition of prohibited “remuneration” include discounts that promote access to care, unadvertised discounts related to medical care provided to consumers in financial need, and waiver of copays for generic drugs by plan sponsors. See *id.* at § 1320a-7a(i)(6)(F)-(I). OIG has also recognized an exception for items of “nominal value” but strict application of this exception (e.g., annual limits on the amount and restrictions on the types of benefits that may be offered) make it difficult or impossible for many pharmacy discount programs to satisfy this exception. See OIG Advisory Opinion 08-07 (Jul 7, 2008).

<sup>79</sup> See OIG Advisory Opinion No. 12-05 (May 1, 2012); OIG Advisory Opinion No. 12-14 (Oct 16, 2012). Both Advisory Opinions were limited to large supermarkets where consumers could earn discounts off the price of gasoline by purchasing many other types of non-healthcare items as well as prescription drugs.

consumers the important benefit of lower healthcare costs. Moreover, the inability of these consumers to access lower healthcare costs actually harms patient health by reducing the likelihood that patients will take their prescribed medications.<sup>80</sup> Failure to take prescription medications, in turn, actually increases overall healthcare costs paid by Medicare, Medicaid and other healthcare programs.<sup>81</sup>

In summary, strict application of these laws to pharmacies reduces competition among pharmacies, increases consumer costs, harms consumer health, and increases overall healthcare costs paid by taxpayer-funded programs. NACDS asks the FTC to work with OIG to advocate a balanced approach that protects against fraud and abuse while also protecting competition and helping consumers.

## VI. 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  
Senior Vice President, Pharmacy Care & Patient Advocacy



Don Bell  
Senior Vice President & General Counsel

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<sup>80</sup> A. Kulik et al., "Full Prescription Coverage Versus Usual Prescription Coverage After Coronary Artery Bypass Graft Surgery," *J. Am. Heart Assn* 128:S219-S225 (2013) ("the elimination of copays for secondary preventive therapies increased medication adherence and reduced patients' out-of-pocket spending for drugs, without increasing overall healthcare costs."), available at [http://scholar.harvard.edu/files/nkc/files/2013\\_mi\\_freee\\_cabg\\_subgroup\\_circulation.pdf](http://scholar.harvard.edu/files/nkc/files/2013_mi_freee_cabg_subgroup_circulation.pdf). See also N. Choudry et al., "Untangling the relationship between medication adherence and post-myocardial infarction outcomes: Medication adherence and clinical outcomes," \_\_\_\_\_ (in study with no patient copays, "patients randomized to full prescription drug coverage who achieved full adherence to their prescribed secondary prevention medications had significantly better event-free survival."), available at [http://scholar.harvard.edu/files/nkc/files/2014\\_adherence\\_outcome\\_relationship\\_ahj.pdf](http://scholar.harvard.edu/files/nkc/files/2014_adherence_outcome_relationship_ahj.pdf).

<sup>81</sup> See Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov 2012), retrieved from: <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>; Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication Adherence leads to lower health care use and costs despite increased drug spend. *Health Affairs*. 2011 Jan; 30(1):91-99; Jha AK, Aubert RE, Yao J, et al. Greater Adherence to Diabetes Drugs is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually. *Health Affairs*. 2012 Aug; 31(8):1836-46.

## **Appendix A**

### **Case Study -- State Policy: 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.<sup>82</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. 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.<sup>83</sup> 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:

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>84</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.

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

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<sup>82</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>83</sup> See Attachment 1: State Vaccination Overview.

<sup>84</sup> Department of Defense. Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of Retail Network Pharmacies as Authorized

TRICARE Providers for the Administration of TRICARE Covered Vaccines. Retrieved from: <http://www.gpo.gov/fdsys/pkg/FR-2011-07-13/html/2011-17516.htm>

be significantly lower than scheduled doctor's office visits and mass vaccination clinics (Table 1).<sup>85</sup>

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

Healthcare Setting	Mean Vaccination Cost
Pharmacy	\$11.57
Mass vaccination clinic	\$17.04
Doctor's office	\$28.67

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.<sup>86</sup> 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 healthcare service.

Patients consistently rate pharmacists as among the most accessible healthcare professionals; 89% 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: “[y]our collective efforts have made a tremendous contribution to raising awareness and increasing access to vaccines.”<sup>87</sup> CDC also highlighted the role pharmacists play in reaching difficult-to-reach patients for immunizations. State<sup>88</sup> and local<sup>89</sup> health officials, as well as the Institute of Medicine,<sup>90</sup> 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%.<sup>91</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 5 times more likely to be current on vaccines than patients receiving care from other providers.<sup>92</sup> Pharmacists have achieved similar increases in vaccination rates for

<sup>85</sup> Prosser LA, et al. Non-traditional settings for influenza vaccination of adults: costs and cost effectiveness. *Pharmacoeconomics*. 2008;26(2):163-78.

<sup>86</sup> Taitel M, et al. Pharmacists as Immunization Providers: Patient Attitudes and Perceptions. *Pharmacy Times*. Retrieved from: <http://www.pharmacytimes.com/publications/issue/2011/September2011/Pharmacists-as-Immunization-Providers-Patient-Attitudes-and-Perceptions/>

<sup>87</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>88</sup> ASTHO. Pharmacy Legal Toolkit. August 2013.

<sup>89</sup> NACCHO. Building and Sustaining Strong Partnerships between Pharmacies and Health Departments at State and Local Levels. March 2013. [http://www.citymatch.org/sites/default/files/documents/bookpages/NACCHO\\_reportMar2013.pdf](http://www.citymatch.org/sites/default/files/documents/bookpages/NACCHO_reportMar2013.pdf)

<sup>90</sup> Institute of Medicine. The 2009 H1N1 Influenza Vaccination Campaign: Summary of a Workshop Series. Retrieved from: <http://www.iom.edu/Reports/2010/The-2009-H1N1-Influenza-Vaccination-Campaign.aspx>

<sup>91</sup> Fera T, et al. The Diabetes Ten City 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>92</sup> Higginbotham S, et al. Impact of a pharmacist immunizer on adult immunization rates. *JAPhA*. 2012;52:367-71.



pneumococcal vaccine<sup>93</sup> and herpes zoster vaccine.<sup>94,95</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>96</sup>

**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.<sup>97</sup> 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:<sup>98</sup>

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**

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<sup>93</sup> Taitel M, et al. Pharmacists as providers: Targeting pneumococcal vaccinations to high risk populations. *Vaccine*. 29(2011)8073-6.

<sup>94</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>95</sup> Wang J, et al. The Effect of Pharmacist Intervention on Herpes Zoster Vaccination in Community Pharmacies. *J Am Pharm Assoc*. 2003. Retrieved from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3648883/>

<sup>96</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>

<sup>97</sup> NACDS. Statement of NACDS for U.S. House of Representatives Homeland Security Committee, Subcommittee on Emergency Preparedness, Response, and Communications. May 12, 2011.

<sup>98</sup> NACCHO. Building and Sustaining Strong Partnerships between Pharmacies and Health Departments at State and Local Levels. March 2013. [http://www.citymatch.org/sites/default/files/documents/bookpages/NACCHO\\_reportMar2013.pdf](http://www.citymatch.org/sites/default/files/documents/bookpages/NACCHO_reportMar2013.pdf) Emphasis added.

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.

**Appendix B**  
**Advanced Practice Designation Status**  
 Updated September 2013

State	Advanced Designation	Requirements	Practice Privileges
California	Advanced Practice Pharmacist  Business and Professions Code Sections 733, 4016.5, 4040, 4050, 4051, 4052, 4052.3, 4052.6, 4052.8, 4052.9, 4060, 4076, 4111, 4174, 4210, and 4233	<ol style="list-style-type: none"> <li>1. Hold an active license to practice pharmacy in California</li> <li>2. Satisfy any two of the following criteria:               <ol style="list-style-type: none"> <li>a. Earn certification in a relevant area of practice from an organization recognized by ACPE or another entity recognized by the board</li> <li>b. Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams</li> <li>c. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacy practicing collaborative drug therapy management, or health system.</li> </ol> </li> <li>3. Pay the applicable fee to the board (not to exceed \$300)</li> <li>4. Recognition must be renewed every two years</li> </ol>	<ol style="list-style-type: none"> <li>1. Perform patient assessments</li> <li>2. Order and interpret drug therapy-related tests</li> <li>3. Refer patients to other healthcare providers</li> <li>4. Participate in the evaluation and management of disease and health conditions</li> <li>5. Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2 (collaborative practice). A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record. Pharmacists must register with DEA prior to initiating or adjusting controlled substance therapy</li> </ol>

State	Advanced Designation	Requirements	Practice Privileges
		<p>5. Complete 10 hours of CE each renewal cycle in addition to the requirements of Section 4231 (CE requirements to maintain pharmacist license). The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice</p>	
<p>Montana</p>	<p>Clinical Pharmacist Practitioner</p> <p>ARM 24.174.524</p>	<p>Clinical Pharmacist Practitioner</p> <p>Qualifications (Montana Code 37-7-306)</p> <ol style="list-style-type: none"> <li>1. Is certified by the board, in concurrence with the board of medical examiners, to provide drug therapy management, including initiating, modifying, or discontinuing therapies, identifying and managing drug-related problems, or ordering tests under the direction or supervision of a prescriber;</li> <li>2. Has additional education, experience, or certification as required by the board in concurrence with the board of medical examiners; and</li> <li>3. Has in place a collaborative pharmacy practice agreement.</li> </ol> <p>Requirements (Rule Chapter 24.174.526)</p> <ol style="list-style-type: none"> <li>1. Submit an application on a form prescribed by the board;</li> <li>2. Pay a registration fee as prescribed by the board;</li> <li>3. Hold an active, unrestricted Montana pharmacist license;</li> <li>4. Have completed five years of clinical practice experience or have completed a pharmacy</li> </ol>	<p>Collaborative Practice Agreement</p> <ol style="list-style-type: none"> <li>1. Prior to initially engaging in collaborative practice, a pharmacist must provide the board with an executed written and electronic copy of the collaborative practice agreement.</li> <li>2. The collaborative practice agreement must include:             <ol style="list-style-type: none"> <li>a. The identification and signature of individual practitioner(s) authorized to prescribe drugs and responsible for the delegation of drug therapy management;                 <ol style="list-style-type: none"> <li>i. The practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana; and</li> <li>ii. The practitioner must be in active practice in the community in which the collaborating pharmacist practices. A request for an exception to this provision must be in writing and will be decided by the board.</li> </ol> </li> <li>b. The identification and signature of individual pharmacist(s) authorized to</li> </ol> </li> </ol>

State	Advanced Designation	Requirements	Practice Privileges
		<p>residency and two years clinical practice experience and hold one of the following active certifications:</p> <ul style="list-style-type: none"> <li>a. BPS certification; or</li> <li>b. Nationally recognized certification in an area of practice as approved by the board and Board of Medical Examiners (BME).</li> </ul> <p>5. Submit a signed collaborative practice agreement to the board that includes a description of the type of supervision the collaborating physician will exercise over the clinical pharmacist practitioner;</p> <p>6. Following approval of the board, submit the application and collaborative practice agreement to the BME for approval; and</p> <p>7. Appear before the board and/or BME if requested.</p>	<p>dispense drugs and engage in drug therapy management;</p> <ul style="list-style-type: none"> <li>c. The types of drug therapy management decisions that the pharmacist is allowed to make which may include: <ul style="list-style-type: none"> <li>i. A specific description of the types of diseases and drugs involved, and the type of drug therapy management allowed in each case; and</li> <li>ii. A specific description of the procedures and methods, decision criteria and plan the pharmacist is to follow.</li> </ul> </li> <li>d. A detailed description of the procedures and patient activities the pharmacist is to follow in the course of the protocol, including the method for documenting decisions made and a plan or mechanism for communication, feedback and reporting to the practitioner concerning specific decisions made. Documentation shall be recorded within 24 hours following each intervention and may be recorded on the patient medication record, patient medical chart, or a separate log book. Documentation of drug therapy management must be kept as part of the patient's permanent record and shall be considered confidential information;</li> <li>e. A method by which adverse</li> </ul>

State	Advanced Designation	Requirements	Practice Privileges
			<p>events shall be reported to the practitioner;</p> <ul style="list-style-type: none"> <li>f. A method for the practitioner to monitor clinical outcomes and intercede when necessary;</li> <li>g. A provision that allows the practitioner to override protocol agreements when necessary;</li> <li>h. A provision that allows either party to cancel the agreement by written notification;</li> <li>i. The effective date of the protocol. The duration of each protocol shall not exceed one year;</li> <li>j. The annual date by which review, renewal, and revision, if necessary, will be accomplished;</li> <li>k. The addresses where records of collaborative practice are maintained; and</li> <li>l. The process for obtaining the patient's written consent to the collaborative practice agreement.</li> </ul> <p>3. Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM 24.174.817.</p> <p>4. Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for inpatients are exempt.</p>
New Mexico	Pharmacist Clinician  Occupational and	<ol style="list-style-type: none"> <li>1. Complete application</li> <li>2. Pay fee set by the board</li> <li>3. Submit the following:               <ol style="list-style-type: none"> <li>a. Proof of completion of sixty (60) hour board</li> </ol> </li> </ol>	<p>Prescriptive authority, guidelines or protocol:</p> <ol style="list-style-type: none"> <li>1. Only a registered pharmacist clinician with current protocols, registered with the New Mexico</li> </ol>

State	Advanced Designation	Requirements	Practice Privileges
	<p>Professional Licensing: Pharmacists 16.19.4.17</p> <p>Pharmacist Prescriptive Authority 16.19.26</p>	<p>approved physical assessment course, followed by a 150 hour, 300 patient contact preceptorship supervised by a physician or other practitioner with prescriptive authority, with hours counted only during direct patient interaction</p> <p>b. Submit log of patient encounters</p> <p>c. Patient encounters must be initiated and completed within 2 years of application</p> <p>d. A pharmacist clinician requesting a controlled substance registration to prescribe controlled substances in Schedule II or III shall be trained in responsible opioid prescribing practices</p> <p>4. The board shall register each pharmacist certified as a pharmacist clinician</p> <p>5. Information must be added to a roster of pharmacist clinicians</p> <p>6. Biennial renewal of registration which must include:</p> <p>a. After January 1, 2013, documentation of CE hours, including proof of completion of 2.0 CEU twenty contact hours of live CPE or CME approved by CPA or AACME, beyond the</p>	<p>medical board or the New Mexico board of osteopathic medical examiners, may exercise prescriptive authority</p> <p>2. A pharmacist clinician seeking to exercise prescriptive authority shall submit an application to the board with the supervising physician's name and current license, protocol of collaborative practice and other information requested by the board</p> <p>3. The protocol will be established and approved by the supervising physician as set forth in these regulations and will be kept on file at each practice</p> <p>4. The protocol must include:</p> <p>a. Name of the physician(s) authorized to prescribe dangerous drugs and name of the pharmacist clinician</p> <p>b. Statement of the type of prescriptive authority decisions the pharmacist clinician is authorized to make, including, but not limited to:</p> <p>i. Types of disease, dangerous drug or dangerous drug categories involved and the type of prescriptive authority authorized in each case</p> <p>ii. Ordering lab tests and other tests appropriate for monitoring of drug therapy</p> <p>iii. Procedures, decision criteria or plan the pharmacist clinician is to follow when exercising prescriptive</p>

State	Advanced Designation	Requirements	Practice Privileges
		<p>required hours in 16.19.4.10 NMAC (CE required to be a licensed pharmacist), as required by the board</p> <ul style="list-style-type: none"> <li>b. Effective January 1, 2015, a pharmacist clinician with a controlled substance registration to prescribe controlled substances listed in Schedule II or II shall complete a minimum of 0.2 CEU per renewal period in the subject area of responsible opioid prescribing practices</li> <li>c. A current copy of collaborative practice (if prescriptive authority is sought)</li> <li>d. A current copy of pharmacist clinician registration (if prescriptive authority is sought)</li> <li>e. Additional information required by the board</li> </ul>	<p>authority</p> <ul style="list-style-type: none"> <li>c. Activities to be followed by the pharmacist clinician while exercising prescriptive authority, including documentation of feedback to the authorizing physician concerning specific decisions made; documentation may be made on the prescriptive record, patient profile, patient medical chart or in a separate log book</li> <li>d. Description of appropriate mechanisms for consulting with the supervising physician, including quality assurance program for review of medical services provided by the pharmacist clinician</li> <li>e. Description of the scope of practice of the pharmacist clinician</li> </ul> <p>5. Pharmacist clinicians shall not prescribe dangerous drugs including controlled substances for self-treatment or treatment of immediate family members, except under emergency situations. This does not apply to administered vaccines. Pharmacist clinicians shall not write a recommendation for the use of medical cannabis.</p> <p><b>Collaborative Professional Relationship</b></p> <ul style="list-style-type: none"> <li>1. The direction and supervision of pharmacist clinicians may be rendered by approved supervising physician/designated alternate supervising physician(s)</li> <li>2. The direction may be done by written protocol or by oral consultation. It is the responsibility of the supervising physician to assure that the appropriate</li> </ul>



State	Advanced Designation	Requirements	Practice Privileges
			<p>directions are given and understood</p> <p>3. The pharmacist clinician must have prompt access to consultation with the physician for advice and direction</p> <p>4. Any change to the supervising physician must be submitted to the board within ten working days</p> <p>Prescriptive Authority (all pharmacists that intend to exercise the authority to prescribe dangerous drugs based on written protocols approved by the Board)</p> <p>1. Vaccines</p> <p style="padding-left: 20px;">a. Protocol</p> <p style="padding-left: 40px;">i. Shall be exercised in accordance with the written protocol for vaccine prescriptive authority approved by the board</p> <p style="padding-left: 40px;">ii. Must maintain a copy of protocol</p> <p style="padding-left: 20px;">b. Education and Training</p> <p style="padding-left: 40px;">i. Pharmacist must successfully complete a training course, accredited by ACPE, provided by: the CDC, a similar health authority of professional body approved by the board</p> <p style="padding-left: 40px;">ii. Training must include study materials, hands-on training and techniques for administering vaccines, comply with current CDC guidelines, and provide instruction and experiential</p>

State	Advanced Designation	Requirements	Practice Privileges
			<p>training in the <a href="#">following content areas</a>.</p> <ul style="list-style-type: none"> <li>iii. Any pharmacist exercising prescriptive authority for vaccines shall complete a minimum of 0.2 CEU of live ACPE approved vaccine related CE every two years. Such CE shall be in addition to requirements in 16.19.4.10 NMAC (CE for licensed pharmacists)</li> <li>c. Authorized Drugs               <ul style="list-style-type: none"> <li>i. Limited to those drugs and vaccines delineated in the written protocol for vaccine prescriptive authority approved by the board</li> <li>ii. Other vaccines determined by the CDC, the advisory committee on immunization practices (ACIP) or New Mexico department of health that may be required to protect the public health and safety</li> </ul> </li> <li>d. Records               <ul style="list-style-type: none"> <li>i. Must generate written or electronic prescription</li> <li>ii. Informed consent must be documented in accordance with the written protocol</li> </ul> </li> </ul>

State	Advanced Designation	Requirements	Practice Privileges
			<p>for vaccine prescriptive authority approved by the board and must be maintained for at least three years</p> <p>e. Notification</p> <p>i. Upon signed consent of the patient or guardian the pharmacist must:</p> <ol style="list-style-type: none"> <li>1. Notify the New Mexico department of health immunization program and the patient's physician</li> <li>2. Update the New Mexico department of health immunization program's electronic database of any vaccine administered</li> </ol> <p>2. Emergency Contraception</p> <p>a. Protocol</p> <ol style="list-style-type: none"> <li>i. Shall be exercised in accordance with the written protocol for vaccine prescriptive authority approved by the board</li> <li>ii. Must maintain a copy of protocol</li> </ol> <p>b. Education and Training</p> <ol style="list-style-type: none"> <li>i. Pharmacist must successfully complete a training course, accredited by</li> </ol>

State	Advanced Designation	Requirements	Practice Privileges
			<p>ACPE, in the subject area of emergency contraception drug therapy provided by: the department of health, planned parenthood, or a similar health authority or professional body approved by the board</p> <p>ii. The training must include study materials and instruction in the <a href="#">following content areas</a>.</p> <p>iii. Any pharmacist exercising prescriptive authority for emergency contraception shall complete a minimum of 0.2 CEU of live ACPE approved emergency contraception CE every two years. Such CE shall be addition to requirements in 16.19.4.10 NMAC (CE for licensed pharmacists)</p> <p>c. Authorized Drugs</p> <p>i. Prescriptive authority is limited to emergency contraceptive drug therapy and shall exclude any device intended to prevent pregnancy after intercourse</p>

State	Advanced Designation	Requirements	Practice Privileges
			<ul style="list-style-type: none"> <li>ii. Prescriptive authority for emergency contraception drug therapy shall be limited to those drugs delineated in the written protocol approved by the board</li> <li>d. Records                             <ul style="list-style-type: none"> <li>i. Must generate written or electronic prescription</li> <li>ii. Informed consent must be documented in accordance with the written protocol for emergency contraceptive drug therapy prescribing authority approved by the board and must be maintained for at least three years</li> </ul> </li> <li>e. Notification                             <ul style="list-style-type: none"> <li>i. Upon signed consent of the patient or guardian, the pharmacist shall notify the patient's physician</li> </ul> </li> <li>3. Tobacco Cessation Drug Therapy                             <ul style="list-style-type: none"> <li>a. Protocol                                     <ul style="list-style-type: none"> <li>i. Shall be exercised in accordance with the written protocol for tobacco cessation therapy authority approved by the board</li> <li>ii. Must maintain a copy of protocol</li> </ul> </li> <li>b. Education and Training                                     <ul style="list-style-type: none"> <li>i. Pharmacist must</li> </ul> </li> </ul> </li> </ul>

State	Advanced Designation	Requirements	Practice Privileges
			<p>successfully complete a training course, accredited by ACPE, in the subject area of tobacco cessation drug therapy provided by: the department of health, health and human services, or a similar health authority or professional body approved by the board</p> <p>ii. The training must include study materials and instruction in the <a href="#">following content areas</a>.</p> <p>iii. Any pharmacist exercising prescriptive authority for tobacco cessation shall complete a minimum of 0.2 CEU of live ACPE approved tobacco cessation CE every two years. Such CE shall be addition to requirements in 16.19.4.10 NMAC (CE for licensed pharmacists)</p> <p>c. Authorized Drugs</p> <p>i. Prescriptive authority is limited to tobacco cessation therapy including prescription and non-prescription therapies</p> <p>ii. Prescriptive</p>

State	Advanced Designation	Requirements	Practice Privileges
			<p>authority for tobacco cessation drug therapy shall be limited to those drugs delineated in the written protocol approved by the board</p> <p>d. Records</p> <ul style="list-style-type: none"> <li>i. Must generate written or electronic prescription</li> <li>ii. Informed consent must be documented in accordance with the written protocol for tobacco cessation drug therapy prescribing authority approved by the board and must be maintained for at least three years</li> </ul> <p>e. Notification</p> <ul style="list-style-type: none"> <li>i. Upon signed consent of the patient or guardian, the pharmacist shall notify the patient's physician</li> </ul> <p>4. TB Testing</p> <ul style="list-style-type: none"> <li>a. Protocol <ul style="list-style-type: none"> <li>i. Prescriptive authority for TB testing shall be exercised in accordance with the written protocol for TB testing drug therapy approved by the board</li> <li>ii. Must maintain a copy of protocol</li> </ul> </li> <li>b. Education and Training <ul style="list-style-type: none"> <li>i. The pharmacist must successful complete</li> </ul> </li> </ul>

State	Advanced Designation	Requirements	Practice Privileges
			<ul style="list-style-type: none"> <li>ii. CE must be completed as specified by the CDC</li> <li>c. Authorized Agents                             <ul style="list-style-type: none"> <li>i. TB skin antigen serum</li> <li>ii. Prescriptive authority for TB testing shall be limited to those drugs delineated in the written protocol approved by the board</li> </ul> </li> <li>d. Records                             <ul style="list-style-type: none"> <li>i. Must generate written or electronic prescription</li> <li>ii. Informed consent must be documented in accordance with the written protocol for TB testing prescribing authority approved by the board and must be maintained for at least three years</li> </ul> </li> <li>e. Notification                             <ul style="list-style-type: none"> <li>i. Upon signed consent of the patient or guardian, the pharmacist shall notify the patient's physician and the department of health of any positive TB test</li> </ul> </li> </ul>
North Carolina	Clinical Pharmacist Practitioner (CPP)  21 NCAC	<ol style="list-style-type: none"> <li>1. Unrestricted or current license to practice as a pharmacist in North Carolina</li> <li>2. Meets one of the following qualifications:</li> </ol>	The written agreement shall: <ol style="list-style-type: none"> <li>1. Be approved and signed by both physician and the CPP</li> <li>2. Be specific in regard to the physician, the pharmacist, the patient and the disease</li> </ol>



State	Advanced Designation	Requirements	Practice Privileges
	46.3100	<p>a. Has earned Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Pharmacists as certified by the Commission for Certification in Geriatric Pharmacy or has completed an ASHP accredited residency program, which includes two years or clinical experiences approved by the Boards</p> <p>b. Has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the Boards and has completed the North Carolina Center for Pharmaceutical Care (NCCPC) or ACPE approved certificate program in the area of practice covered by the CPP agreement</p> <p>c. Has successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the Boards and has completed two NCCPC or ACPE approved</p>	<p>3. Specify the predetermined drug therapy which shall include the diagnosis and product selection by the patient's physician; any modifications permitted, dosage forms, dosage schedules and tests which may be ordered</p> <p>4. Prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed by the physician without first obtaining written consent of the physician</p> <p>5. Include pre-determined plan for emergency services</p> <p>6. Include a plan and schedule for weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician and CPP</p> <p>7. Require that the patient be notified of the collaborative relationship</p> <p>8. Be terminated when patient care is transferred to another physician and new orders shall be written by the succeeding physician</p>

State	Advanced Designation	Requirements	Practice Privileges
		<p>certificate programs with at least one program in the area of practice covered by the CPP agreement</p> <ol style="list-style-type: none"> <li>3. Submits application and fee (\$100) to the Medical Board</li> <li>4. Submits any information deemed necessary by the Medical Board</li> <li>5. Has a signed supervising physician agreement</li> <li>6. Renew annually (\$50)</li> <li>7. Earn 35 hours of practice relevant CE each year approved by the Pharmacy Board</li> </ol>	
Federal	Yes	<p>National Clinical Pharmacy Specialist (NCPS)          NCPS credentialing determined by IHS, adopted by IHS/PHS in 1997          Required credentials<sup>99</sup></p> <ol style="list-style-type: none"> <li>1. Two experiential components             <ol style="list-style-type: none"> <li>a. 2-4 years in IHS pharmacy practice</li> <li>b. &gt;1 year in clinical practice with requested disease state as <i>local</i> clinical pharmacy specialist</li> </ol> </li> <li>2. Attestation letters of clinical competence from physician</li> <li>3. Didactic credentials may be included (disease management certificate, BPS, additional CPE</li> </ol>	<p>“Patient care” may include:<sup>100</sup></p> <ul style="list-style-type: none"> <li>• patient interview</li> <li>• chart review</li> <li>• ordering and interpretation of laboratory tests</li> <li>• physical assessment</li> <li>• prescriptive authority</li> <li>• formulation of clinical assessments</li> <li>• development of therapeutic plans</li> <li>• patient education</li> <li>• patient follow-up</li> </ul> <p>Treatment and management are performed through a local CPA approved by local medical staff. If a pharmacist is a credentialed NCPS, they are able to perform patient care under the CPA – <i>if</i> the privileges are granted by local staff.</p>

<sup>99</sup> <http://www.usphs.gov/corpslinks/pharmacy/documents/ncps.ppt>

<sup>100</sup>

[https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=7&cad=rja&uact=8&ved=0CE8QFjAG&url=https%3A%2F%2Fs3.amazonaws.com%2Fpicsportal%2Fresources%2Fnlr%2Fslides%2FLeadership\\_Roundtable\\_Final\\_051911-\\_Giberson.ppt&ei=N8BWU9HPOMuysQSy11HoAg&usg=AFQjCNHC8SpwheuLB5w9tor84gsRGVv9ug](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=7&cad=rja&uact=8&ved=0CE8QFjAG&url=https%3A%2F%2Fs3.amazonaws.com%2Fpicsportal%2Fresources%2Fnlr%2Fslides%2FLeadership_Roundtable_Final_051911-_Giberson.ppt&ei=N8BWU9HPOMuysQSy11HoAg&usg=AFQjCNHC8SpwheuLB5w9tor84gsRGVv9ug)

State	Advanced Designation	Requirements	Practice Privileges
		<p>courses, etc.)</p> <ol style="list-style-type: none"> <li>4. Minimum patient contact hours each year</li> <li>5. NCPS committee approved CPA that contains all critical elements</li> </ol> <p>Recertification required every 3 years. Requires ongoing practice hours, credentials and CE</p>	<p>Disease states for which pharmacists can provide patient care</p> <ol style="list-style-type: none"> <li>1. Anticoagulation</li> <li>2. Nicotine dependence</li> <li>3. Diabetes</li> <li>4. Dyslipidemia</li> <li>5. Asthma</li> <li>6. Hypertension</li> <li>7. Pain Management</li> <li>8. HIV/AIDS</li> <li>9. Family practice</li> </ol> <p>Note: only a little more than 20% of IHS pharmacists, from 10 different states hold the designation after nearly 15 years in existence.</p>

## Appendix C

### SUMMARY OF PHARMACISTS' EXPANDED SCOPE OF PRACTICE ACROSS CANADA

Y Implemented in jurisdiction P Pending legislation or regulation or policy X Not implemented		Province/Territory												
		BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	NWT	YT	NU
Pharmacist Scope of Practice	Initiate prescription drug therapy	X	Y	Y	Y	Y	6 P	Y	Y	X	X	X	X	X
	Prescribe for minor ailments and conditions	X	Y	Y	Y <sup>3</sup>	Y	P	Y	Y	Y	X	X	X	X
	Order and interpret lab test	X	Y	X	Y	Y	6 P	Y	Y	Y	X	X	X	X
	Make therapeutic substitutions	Y	Y	Y	X	X	6 P	Y	Y	Y	Y <sup>1</sup>	X	X	X
	Renew and extend prescriptions	Y	Y	Y	Y	Y	6 P	P	Y	X	Y	Y	X	X
	Change dose and formulation and provide emergency prescription refills	Y	Y	Y <sup>2</sup>	Y	Y <sup>4</sup>	6 P	Y <sup>9</sup>	Y <sup>2</sup>	X	Y	X	X	X
	Administer a drug by injections	Y	Y	X	Y	P	7 P	Y	Y	X	X	X	X	X
	Provide emergency prescription refills	Y	Y	Y	Y	Y <sup>5</sup>	6 P	Y	Y	P	P	Y	X	X

<sup>1</sup> ©Canadian Pharmacists Association, January 2014

1. AB: pharmacists in Alberta who have "additional prescribing authority" can prescribe a Schedule I drug (prescription-only) for the treatment of minor ailments
2. SK & NS: only as part of assessment and prescribing for minor ailments
3. MB: as Continued Care Prescriptions under section 122 of the Regulations to the Pharmaceutical Act
4. ON: restricted to prescribing specified drug products for the purpose of smoking cessation
5. ON: administration of influenza vaccination to patients five years of age and older; administration of all other injections and inhalations for demonstration and educational purposes
6. QC: pending Orders in Council (activity enabled by passage of Bill 41, an Act to amend the Pharmacy Act, December 8, 2011; regulation for this activity was planned for September 3, 2013, however it was postponed by Orders in Council on August 22, 2013)
7. QC: when authorized by a physician by means of a "collective prescription" (i.e., collaborative practice agreement)
8. QC: for demonstration purposes only
9. NB: prescribing constitutes adapting, emergency prescribing or within a collaborative practice; independent prescribing or as part of minor ailments prescribing is pending
10. NL: limited to non-formulary generic substitution

**Appendix D**  
**State Collaborative Practice Agreement Chart**

State	DTM Authority	Restrictions
Alabama	No	N/A
Alaska	12 AAC 52.240; 12 AAC 40.983	<ul style="list-style-type: none"> <li>▪ Authority granted to pharmacist must be within the prescriber's scope of practice</li> <li>▪ Activities limited to protocol / agreement established by collaborating physician</li> <li>▪ Initial agreement between physician and pharmacist may not exceed 2 years</li> </ul>
Arizona	AZ Prac Act 32-1970; R4-23-110; R4-23-421	<ul style="list-style-type: none"> <li>▪ Only allowed in acute care hospitals, nursing care institutions, staff model HMOs or community health centers.</li> <li>▪ Pharmacist may implement, monitor, or modify a person's drug therapy and use as directed by prescribed protocols, as each protocol developed pursuant to the drug therapy agreement shall contain directions concerning the actions the pharmacist may perform for the patient\</li> <li>▪ The protocol shall specify the drug or drugs to be managed by the pharmacists, the conditions and events for which the pharmacists must notify the provider and the laboratory tests that may be ordered.</li> </ul>
Arkansas	AR Prac Act 17-92-101 (14)(A)(viii)  AR BReg 09-00-0004	<ul style="list-style-type: none"> <li>▪ (DTM) written protocol from in state physician</li> </ul>

State	DTM Authority	Restrictions
California	<p><b>NO</b></p> <p>– but community pharmacists may initiate emergency contraception</p> <p>CA Practice Act 4046, 4052 (only for pharmacists in institutional settings)</p>	<ul style="list-style-type: none"> <li>▪ Collaborative practice allowed in licensed healthcare facilities (which only includes pharmacies in institutional settings) pursuant to a protocol with a physician</li> <li>▪ Community pharmacists may only initiate emergency contraception (not able to enter into collaborative practice agreements)</li> </ul>
Colorado	<p>CO Prac Act 12-22-102 per definition of practice of pharmacy; 3 CCR 719-1 6.00.10 et. seq.</p>	<ul style="list-style-type: none"> <li>▪ May only be undertaken pursuant to initial diagnosis made by practitioner,</li> <li>▪ Require a valid order for DTM – DTM may only be conducted by a RPh upon the presentation of a valid order for a specific, individual patient, and must specify protocol to be used</li> <li>▪ Must have a written agreement delineating proper protocols to be used and type of interaction that must occur between RPh &amp; MD</li> </ul>
Connecticut	<p>Yes</p> <p>CT Statutes 20-631</p>	<ul style="list-style-type: none"> <li>▪ In hospitals, nursing homes and if under contract with a hospital only</li> </ul>
Delaware	<p>No</p>	<p>N/A</p>
Dist. of Col.	<p>No</p>	<p>N/A</p>
Florida	<p>FL Prac Act 465.186, .003(13)</p> <p>64 B16-27.830</p>	<ul style="list-style-type: none"> <li>▪ Formulary and procedures determined by BoP, Board of Medicine and Board of Osteopathic medicine</li> <li>▪ FL Prac Act 465.186</li> <li>▪ Pursuant to Prescriber Care Plan 64B16-27.830</li> </ul>
Georgia	<p>Yes</p> <p>Code 26-4-50; 43-34-26.2; Regs 480-35-.01 et. seq.</p> <p>(Effective 7/1/00)</p>	<ul style="list-style-type: none"> <li>▪ Pursuant to protocol agreement between appropriately certified pharmacist and physician (which identifies each patient for whom pharmacist is authorized to modify drug therapy)</li> <li>▪ Protocol agreement restricts types &amp; categories of meds allowed to be utilized and max/min dosage levels within each type / category of meds</li> </ul>

State	DTM Authority	Restrictions
Hawaii	HI Practice Act §461-1 (Per definition of practice of pharmacy); HAR §16-95-130	<ul style="list-style-type: none"> <li>▪ Pursuant to an order or authorization made by the patient’s licensed medical doctor and related to condition for which patient was seen by doctor</li> <li>▪ For EC, pharmacists may only dispense drugs approved by FDA for EC – Plan B is the preferred drug therapy, but other products may be dispensed under specific circumstances</li> </ul>
Idaho	ID BReg 165  IDAPA 27.01.01 Sec. 165	<ul style="list-style-type: none"> <li>▪ Pursuant to parameters established in the written; signed protocol agreement between one or more pharmacist and one or more practitioners-pharmacist may conduct DTM in accordance with their “scope of practice” as approved by the practitioner in the collaborative practice agreement.</li> <li>▪ Collaborative practice agreement must be coupled with a medical order from the practitioner to invite allowed activities for any particular patient.</li> <li>▪ reviewed annually</li> </ul>
Illinois	No	N/A
Indiana	Indiana Pharmacy Prac Act IC 25-26-16-3(a), 4	<ul style="list-style-type: none"> <li>▪ Hospital/Clinic</li> </ul>
Iowa	Iowa Code §155A.3(26); 657-8.34 (155A)	<ul style="list-style-type: none"> <li>▪ Pursuant to written community practice or hospital practice protocol with physician</li> <li>▪ Protocol identified by topic and submitted to BoP or BoP-authorized committee - written protocols must be submitted to the BoP until 6/30/07</li> <li>▪ Protocols must contain specific information detailed in 657-8.34(2) and may authorize therapeutic interchange, lab tests, physical exams and monitoring of certain patient activities.</li> </ul>
Kansas	HB 2146	<p>Such collaborative practice agreement shall contain certain specified conditions or limitations pursuant to the collaborating physician’s order, standing order, delegation or protocol. A collaborative practice agreement shall be: (A) Consistent with the normal and customary specialty, competence and lawful practice of the physician; and (B) appropriate to the pharmacist’s training and experience.</p> <p>K.S.A. 65-1626a</p>

State	DTM Authority	Restrictions
Kentucky	KY Practice Act 315.010(4)	<ul style="list-style-type: none"> <li>▪ May perform activities outlined in written, collaborative agreement w/physician for each individual patient</li> </ul>
Louisiana	LA B Reg 909; LAC 46 §523  (Very in depth rule; refer to specific language for more details)	<ul style="list-style-type: none"> <li>▪ Must be approved by both Boards of Medicine and Pharmacy under written protocol that _____ to established guidelines</li> <li>▪ Any pharmacist engaged in CDTM in Louisiana must be registered with the BoP.</li> <li>▪ CDTM is limited to monitoring and modifying a disease specific drug therapy; collecting and reviewing patient history; obtaining and reviewing vital signs, including pulse, temperature, blood pressure, and respiration; ordering, evaluating, and applying the results of laboratory tests directly related to the disease specific drug therapy being managed under written protocol, provided such tests do not require the pharmacist to interpret such testing or formulate a diagnosis</li> <li>▪ For a specific patient ,treatment and prevention of arterial and venous clot propagation and disease, i.e., anti-coagulant therapy; treatment and prevention of diabetes; adjustment of medication administered by inhalant for treatment of asthma; treatment and prevention of dyslipidemia; smoking cessation therapy; administration of disease specific vaccines to patients 16 years of age or older; and such other drugs, diseases or conditions as may be subsequently recommended by the advisory committee and approved by the Board.</li> <li>▪ Appropriately registered pharmacist may engage in CDTM to the extent authorized by CDTM agreement filed with and approved by Board and in accordance with a patient specific, drug specific, disease specific written protocol.</li> <li>▪ A separate protocol must be written for each patient, and a copy of each written protocol must be provided to physician and pharmacist, made part of the patient’s pharmacy record, and appended by the pharmacist to the CDTM agreement and maintained in a separate file at the pharmacist’s practice site listed on the pharmacist’s registration on file with the Board</li> <li>▪ CDTM must be in conformity with generally accepted standards of care for treatment of a patient’s specific disease or condition.</li> </ul>



State	DTM Authority	Restrictions
Maine	<p>32 MRSA 13821 et. seq.</p> <p>L.D. 1134</p>	<ul style="list-style-type: none"> <li>▪ EC only</li> <li>▪ Pursuant to written protocol with physician</li> <li>▪ Pharmacist must complete required board approved training program / course</li> </ul> <p>A pharmacist engaging in collaborative drug therapy management pursuant to subsection 1 is entitled to adequate access to a patient's history, disease status, drug therapy and laboratory and procedure results and may:</p> <ul style="list-style-type: none"> <li>• Collect and review a patient's history;</li> <li>• Obtain and check vital signs;</li> <li>• Order and evaluate the results of laboratory tests directly related to drug therapy under the supervision of, or in direct consultation with, a practitioner and in accordance with approved protocols applicable to the practice setting and when the evaluation does not include a diagnostic component; and</li> <li>• Initiate, monitor, modify and discontinue drug therapy for a particular patient pursuant to the collaborative practice agreement with a practitioner who is treating the patient, as long as the action is reported to the practitioner in a timely manner as determined by rules adopted pursuant to section 13846.</li> </ul>

State	DTM Authority	Restrictions
Maryland	Yes  12-6A-01  et. seq.; COMAR 10.34-29 et. seq.	<ul style="list-style-type: none"> <li>▪ Pharmacist must have a doctor of pharmacy degree or equivalent training as established by the board</li> <li>▪ Protocol may not authorize acts that exceed the scope of practice of the parties to the therapy management contract</li> </ul>

State	DTM Authority	Restrictions
Massachusetts	<p>Board policy 2006-01 based on M.G.L. c. 94C, § 19A allows dispensing of EC even though not discussed in CDTM law</p> <p>M.G.L.A. 94C, § 7 allows CDTM</p>	<p>EC only pursuant to written standardized procedure or protocol</p> <p>Pursuant to CDTM agreement and mutually agreed upon guidelines in some instances, RPh may issue prescriptions</p> <p>In retail settings:</p> <ul style="list-style-type: none"> <li>-patient 18 or older</li> <li>- may only extend 30 days of drug therapy prescribed by a physician</li> <li>- allow administration of vaccines or modification of dosages of medications prescribed by supervising pharmacist for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS, osteoporosis and co-morbidities identified by the supervising for the individual patient along with primary diagnosis. The collaborative practice agreement shall specifically reference each disease state being co-managed.</li> <li>-No prescribing of CII-IV in retail setting</li> </ul> <p><i>M.G.L.A. 94C § 7 subsection (g)</i></p> <p>-No collaborative practice agreement in the retail drug business setting may permit the prescribing of schedule II through V controlled substances. <i>M.G.L.A. 94C § 3</i></p>

State	DTM Authority	Restrictions
Michigan	Michigan Public Health Code §333.16215,  MI Prac Act §333.17708	See comments
Minnesota	MN Prac Act 151.01 Subdivision 27	<ul style="list-style-type: none"> <li>▪ Pursuant to a written protocol between the specific pharmacist and the individual dentist, optometrist, physician, podiatrist, or veterinarian who is responsible for the patient's care and authorized to independently prescribe drugs</li> <li>▪ Any significant changes in drug therapy must be reported by the pharmacist to the patient's medical record</li> </ul>
Mississippi  <b><u>*Please refer to Board website*</u></b>	MS Practice Act 73.21.73; MS B Regs Articles XXIX, XXXVI	<ul style="list-style-type: none"> <li>▪ Community pharmacy – a specific protocol agreement shall be signed on each patient for whom a practitioner delegates any authority to initiate or modify drug therapy MS B reg XXXVI</li> </ul>
Missouri	Sections 338.010  (Note - MO BoP is working on new rules and regulations that must be implemented before pharmacists can begin practicing under the new guidelines.)	<ul style="list-style-type: none"> <li>▪ Pharmacists may design/initiate/implement/monitor medication therapeutic plan <u>defined by prescription order where prescription order is specific to each patient.</u></li> <li>▪ Pharmacists accepting Rx. order for medication therapeutic plan must have written protocol from physician referring patient for medication therapy services.</li> <li>▪ Written therapeutic plan and/or order may come from physician only (not nurse engaged in collaborate practice arrangements w/physician.</li> <li>▪ Therapeutic substitution of a pharmaceutical prescribed by a physician allowed only if authorized by the written protocol or the physician's prescription order.</li> <li>▪ Participating pharmacist must have BoP issued certificate of medication therapeutic plan authority.</li> <li>▪ Pharmacist may not diagnose or independently prescribe pharmaceuticals.</li> </ul>

State	DTM Authority	Restrictions
Montana	MCA 37-7-101; ARM 24.174.524	<ul style="list-style-type: none"> <li>▪ Types of drug management decisions that pharmacist may make restricted to those listed in protocol</li> <li>▪ Agreement to specify the types of diseases and drugs involved, and the type of DTM allowed in each case and</li> <li>▪ Agreement to specify procedures and methods, decision criteria and plan the pharmacist must follow</li> <li>▪ practitioner must be in active practice in community where collaborating pharmacist practices – requests exceptions to this requirement will considered by BoP</li> </ul>
Nebraska	NE B Reg 128-013	<ul style="list-style-type: none"> <li>▪ Pursuant to written protocol detailed in collaborative agreement with physician</li> </ul>
Nevada	Nevada Revised Statutes §639.0124	Registered pharmacist, pursuant to a collaborative practice agreement entered into with a physician and approved by the State Board of Pharmacy, to implement, monitor and modify the drug therapy of a patient at a facility other than a licensed medical facility or an extension of a licensed medical facility although the extended may not be independently licensed as specified.

State	DTM Authority	Restrictions
New Hampshire	NH RSA 318:1; NH RSA 318: 4-5; NH RSA 318:47 ; N.H. Code Admin. R. Ph 1001.01 et. seq.	<p><b><u>Collaborative Practice</u></b></p> <ul style="list-style-type: none"> <li>▪ Pursuant to written protocol; collaborating pharmacist(s) may perform medication therapy management authorized by attending practitioner(s) under specified conditions / limitations</li> <li>▪ Patient must grant his / her informed consent as part of the collaborative agreement</li> <li>▪ Pharmacist must hold unrestricted and current license to practice in NH</li> <li>▪ Pharmacist must have at least \$1,000,000 of professional liability insurance coverage</li> <li>▪ Pharmacist must have earned a Pharm.D. degree or completed 3 years of institutional clinical experience as a licensed pharmacist</li> <li>▪ Allowed only in hospitals, long-term care facilities, licensed inpatient / outpatient hospice settings, and ambulatory care clinics</li> </ul> <p><b><u>EC</u></b></p> <ul style="list-style-type: none"> <li>▪ Pharmacist may initiate EC in accordance with standardized procedures or protocols developed by the board and an authorized prescriber acting within scope of practice</li> <li>▪ Only a pharmacist who has completed the required training may initiate EC therapy</li> <li>▪ Since Plan B requires a prescription for people ages 17 years and under, Plan B may be dispensed to patients under 18 pursuant to collaborative agreement; however, for patients over 18 years of age, Plan B may be dispensed per FDA guidelines. (1/2007 BoP Newsletter)</li> </ul>
New Hampshire (continued)	See above	See EC restrictions above
New Jersey	NJ Prac Act 45:14-41	<ul style="list-style-type: none"> <li>▪ Pursuant to written protocol with physician with patient's consent</li> <li>▪ Interpretation of clinical or lab tests under a written protocol may only be performed by a pharmacist in direct consultation with a physician</li> <li>▪ Each pharmacist who is permitted to participate in CDTM must be identified by name and title in the protocol</li> <li>▪ Pharmacists may only perform functions identified in protocol</li> </ul>

State	DTM Authority	Restrictions
New Mexico	NM Practice Act 61-11B-1, B-3; 61-11-2 NMAC 16.19.26.9; 16.10.11.9 NMAC; 16.10.11.7 NMAC	Board certified “Pharmacist Clinician” under protocol filed with the board  NM B Reg 18.3 --- 18.7  <ul style="list-style-type: none"> <li>▪ Prescriptive authority limited to emergency contraception drug therapy (and shall exclude any device intended to prevent pregnancy after intercourse), vaccinations (see vaccinations chart), and tobacco cessation;</li> <li>▪ Pharmacists may dispense emergency contraceptives pursuant to written protocol for EC drug therapy approved by Board;</li> <li>▪ Prescriptive authority also limited to those drugs delineated in the written protocol for EC drug therapy approved by the Board</li> <li>▪ Pharmacist who have registered with the Board of Medical Examiners may enter into collaborative agreements with a physician</li> <li>▪ Pharmacists who have entered into collaborative agreements with a supervisory physician may have limited prescriptive authority pursuant to protocol agreement within the pharmacist clinician’s scope of practice. Such pharmacist may prescribe drugs listed in the Board of Medical Examiners protocol.</li> <li>▪ Board allows for there to be “alternative supervising physicians” (written Protocol must include a statement that describes provisions for immediate communication or consultation between the pharmacist clinician and the supervision physician or alternate supervising physician.)</li> </ul>

State	DTM Authority	Restrictions
New York	McKinney's Education Law 6801	<p>Pharmacist who meets the requirements and who is employed by or otherwise affiliated with a facility shall be permitted to enter into a written agreement or protocol with a physician authorizing collaborative therapy management, subject to certain limitations and within the scope of employment or affiliation.</p> <p>Physician who's party to a written agreement or protocol authorizing collaborative drug therapy management shall be employed in the same facility which the pharmacist is also employed or affiliated.</p> <p>Existence of a written agreement or protocol on collaborative drug therapy management an the patient's right to choose not to participate in collaborative drug therapy management shall be disclosed to any patient who's eligible to receive collaborative drug therapy management. CDTM shall not be utilized unless the patient or the patient's authorized representative consents, in writing to such management. If the patient or patient's authorized representative consents it shall be noted in medical record and shall be disclosed to primary physician or any other healthcare provider.</p> <p>Participation in a written agreement or protocol authorizing DTM shall be voluntary, and no patient, physician, pharmacist, or facility shall be required to participate.</p>



State	DTM Authority	Restrictions
North Carolina	NC PracAct 90-18.4  21 NCAC 46.3101	<ul style="list-style-type: none"> <li>▪ Prohibits substitution of a chemically dissimilar drug product without physician consent.</li> <li>▪ CPPs restricted from supervising no more than 3 pharmacies.</li> </ul>
North Dakota	ND Practice Act 43-15-31.4  ND B Reg 61-04-08-02	<ul style="list-style-type: none"> <li>▪ Institutional only</li> <li>▪ (However, pharmacists may enter into agreements with physicians or nurse practitioners to administer vaccines in facilities as detailed in protocol/agreement – see Drug administration chart for detail. 61-04-11-01)</li> </ul>
Ohio	OH Prac Act 4729.01; OH Prac Act 4729.39; OH B Reg 4729-5-30	<ul style="list-style-type: none"> <li>▪ Pursuant to protocol / written treatment guidelines;</li> <li>▪ Pharmacist who modifies DTM must personally transmit the fax/oral order to another pharmacist if the drug is not dispensed by the pharmacist who modified the drug order; can only dispense drug prescribed by physician.</li> </ul>
Oklahoma	No	N/A

<b>State</b>	<b>DTM Authority</b>	<b>Restrictions</b>
Oregon	OR B Reg 855-006-0010 and 855-041-0400	<ul style="list-style-type: none"><li>▪ written protocol includes dosage frequency, duration and route of administration</li><li>▪ initiate upon prescription order for individual patient</li><li>▪ protocol filed with BoP</li></ul>

State	DTM Authority	Restrictions
<p>Pennsylvania</p>	<p>PA Prac Act Sec. 2 (11 &amp; 14) (In definition of pharmacy practice</p> <p>Collaborative Practice Authority</p> <p>63 PS §390.2 (11) (14)</p> <p>63 PS §390.9.3</p>	<ul style="list-style-type: none"> <li>▪ Institution only – see PA Regs Title 49 § 27.1, § 27.301 &amp; § 27.311 for restrictions, ed requirements, liability insurance, etc.</li> <li>▪ May engage in “management drug therapy” pursuant to written protocol which includes: adjusting drug regimen; strength; frequency of administration or route; administration of drugs; ordering lab tests and ordering and performing other diagnostic test necessary in MDT.</li> <li>▪ Pharmacist may be employed by a physician for the purposed of MDT and receive appropriate compensation for such employment, but not engage in retail dispensing while in healthcare practice within the context of such employment.</li> <li>▪ Management of drug therapy pursuant to a collaborative agreement shall be initiated by a written referral from licensed physician to pharmacist. Written referral shall include the frequency in which pharmacist must conduct management of drug therapy in person.</li> <li>▪ Licensed physician who is party to collaborative agreement authorizing the management of drug therapy shall hold an active license in good standing and in accordance w/ terms of collaborative agreement shall be within scope of the licensed physician’s current practice.</li> <li>▪ Collaborative agreement must specify the terms under which pharmacist providing management of drug therapy is permitted to adjust drug regimen or adjust drug strength, frequency of administration or route w/out prior written or oral consent by the collaborating physician.</li> </ul>

State	DTM Authority	Restrictions
Rhode Island	5-19.1-1 et. seq.	<ul style="list-style-type: none"> <li>▪ Pharmacist must have post-graduate education training including (but not limited to) residency training, board certification, certification from an accredited professional organization educational institution (or any other CE provider approved by Director of Health) relevant to proposed scope of practice agreement</li> <li>▪ May engage in collaborative practice pursuant to written protocols and scope of practice</li> </ul>
South Carolina	SC PracAct 40-43-30	N/A
South Dakota	SD Practice Act 36-11-19.1	<ul style="list-style-type: none"> <li>▪ Institution only</li> </ul>
Tennessee	TN B Reg 1140-3-.01	
Texas	TX Practice Act Section 5 (38), Regs §295.13 22 TAC 193.7  OCCUPATIONS CODE CHAPTER 157.101 (b-1) and 554.017, 55.057	<ul style="list-style-type: none"> <li>▪ Physician written protocol, notification to the board, CE requirements</li> <li>▪ Does not include selection of drug products not prescribed by the physician unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from a standard protocol.</li> <li>▪ Properly trained and qualified pharmacist working in a hospital, hospital-based clinic, or academic healthcare institution delegated by a physician may; pursuant to protocol agreement; an Rx for dangerous drugs, if the delegation follows a diagnosis, initial patient assessment, and drug therapy order by the physician.</li> </ul>
Utah	58-17b-102; R156-17b-611	<ul style="list-style-type: none"> <li>• Pursuant to protocol as outlined in collaborative agreement</li> </ul>

State	DTM Authority	Restrictions
Vermont	(NOTE- N/A to Chain Pharmacies)  Board Regs 4.512  VT B reg 2; 26 V.S.A. § 2077--2079	DTM (General): <ul style="list-style-type: none"> <li>▪ Dependent in Institutional - permits dosage adjustment under approved protocol</li> </ul> VT B Reg 4.512  EC (26 V.S.A. § 2077--2079): <ul style="list-style-type: none"> <li>▪ Pursuant to protocol detailed in collaborative agreement between appropriately trained RPh and physician or other prescriber;</li> <li>▪ Pharmacist to provide each patient with standardized fact sheet (includes indications &amp; appropriate methods for use, info on importance of follow-up care, sexual assault, risks of unprotected sexual intercourse, and referral to appropriate agencies and other appropriate information)</li> </ul>
Virginia	Yes  18 VAC 110-40-10 et. Seq.  (Effective 1/17/01)  H.B. 1501	<ul style="list-style-type: none"> <li>▪ A patient who does not wish to participate in a collaborative procedure must notify the prescriber of his decision.</li> <li>▪ A prescriber may elect to have a patient not participate in a collaborative agreement by contacting the pharmacist or his designated alternative pharmacist or by documenting his decision on the patient's prescription.</li> </ul>
Washington	RCW 18.64.011 (11)  Regs 246-863-100; 246-863-110	<ul style="list-style-type: none"> <li>▪ Protocol on file with board</li> <li>▪ Reviewed every 2 years</li> <li>▪ Pharmacist prescriptive authority restricted by drugs detailed collaborative agreement with physician;</li> </ul>

State	DTM Authority	Restrictions
West Virginia	WV Code §30-5-1b; §30-5-26; §30-5-27; §30-5-28	<ul style="list-style-type: none"> <li>▪ Collaborative practice agreements allowed only in hospital, nursing home, medical school, hospital community and ambulatory care clinic settings</li> <li>▪ Activities restricted to drug therapy management activities in the pharmacist's scope of practice as detailed in the collaborative pharmacy practice agreement and approved by the collaborating physician</li> <li>▪ Collaborative practice agreements may not include management of controlled substances</li> </ul>
Wisconsin	No	N/A
Wyoming	Board adopted reg Ch 2, Sec 4(z)-(cc); Ch 2, Sect. 32, appendix A  Adopted 1/27/00	<ul style="list-style-type: none"> <li>▪ May only perform functions authorized by physician under specified conditions or limitations detailed in protocol</li> </ul>

Prepared by the National Association of Chain Drug Stores – Revised April 2014

## Appendix E

### State Immunization Laws

State	Influenza	Pneumococcal	Shingles/herpes zoster /Zostavax <sup>101</sup>
<b>Alabama</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Alaska</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Arizona</b>	Yes	Yes	Yes
Rx Required	No	17 yrs and younger must have Rx;  Rx not required for 18 yrs and older	No
Age Limit	6 yrs or older	6 yrs or older	--
<b>Arkansas</b>	Yes	Yes	Yes
Rx Required	No	17 yrs and younger must have Rx;  Rx not required for 18 yrs and older	No
Age Limit	7 yrs or older	7 yrs or older	--

<sup>101</sup> The herpes zoster vaccine is labeled by FDA for administration to patients 50 years and older; however, CDC guidelines recommend administration to patients 60 years and older.

<b>State</b>	<b>Influenza</b>	<b>Pneumococcal</b>	<b>Shingles/herpes zoster /Zostavax<sup>101</sup></b>
<b>California</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Colorado</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Connecticut</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	18 yrs or older	18 yrs or older	--
<b>District of Columbia</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	11 yrs or younger must have "doctor referral"; otherwise, 12 yrs and older	11 yrs or younger must have "doctor referral"; otherwise, 12 yrs and older	--
<b>Delaware</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	18 yrs or older	18 yrs or older	
<b>Florida</b>	Yes	Yes	Yes
Rx Required	No	No	Yes
Age Limit	18 yrs or older	18 yrs or older	--
<b>Georgia</b>	Yes	No	No



<b>State</b>	<b>Influenza</b>	<b>Pneumococcal</b>	<b>Shingles/herpes zoster /Zostavax<sup>101</sup></b>
Rx Required	12 yrs and younger must have Rx;  Rx not required for 13 yrs and older	--	--
Age Limit	No	--	--
<b>Hawaii</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	14 years or older	18 yrs or older	--
<b>Idaho</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	12 yrs or older	12 yrs or older	--
<b>Illinois</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	14 yrs or older	14 yrs or older	--
<b>Indiana</b>	Yes	Yes	Yes
Rx Required	No	In some instances <sup>102</sup>	No
Age Limit	14 yrs old or older	65 yrs or older	--
<b>Iowa</b>	Yes	Yes	Yes
Rx Required	No	No	Yes
Age Limit	6 yrs or older	18 yrs or older	--
<b>Kansas</b>	Yes	Yes	Yes

<sup>102</sup> A group of individuals may receive that meet the appropriate criteria under a drug order, under a prescription, or according to a protocol approved by a physician.

State	Influenza	Pneumococcal	Shingles/herpes zoster /Zostavax <sup>101</sup>
Rx Required	No	No	No
Age Limit	6 yrs or older	18 yrs or older	--
<b>Kentucky</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	9 yrs or older	12 yrs or older	--
<b>Louisiana</b>	Yes	Yes	Yes
Rx Required	No	In some instances <sup>2</sup>	In some instances <sup>3</sup>
Age Limit	7 yrs or older	16-18 yrs or older <sup>4</sup>	50-60 years or older <sup>5</sup>
<b>Maine</b>	Yes	Yes	Yes
Rx Required	No	In some instances <sup>6</sup>	In some instances <sup>7</sup>
Age Limit	9 yrs or older	16-18 yrs or older	--
<b>Maryland</b>	Yes	Yes	Yes
Rx Required	No	Yes	Yes
Age Limit	9 yrs or older	18 yrs or older	18 yrs or older
<b>Massachusetts</b>	Yes	Yes	Yes
Rx Required	No	No	Y
Age Limit	18 yrs or older	18 yrs or older	18 yrs or older

<sup>2,3</sup> Prescriptions not required in parishes designated as a primary care health professional shortage area

<sup>4</sup> Individuals 16-17 years old may obtain pneumococcal vaccine from pharmacist in parishes designated as a primary care health professional shortage area; others must be 18 years or older

<sup>5</sup> Individuals 50 years or older may obtain pneumococcal vaccine from pharmacist in parishes designated as a primary care health professional shortage area; others must be 60 years or older

<sup>6,7</sup> When patient does not have existing relationship with a primary care physician or other practitioner, authorized pharmacist may administer according to a treatment protocol, and in such instances, a patients is not required to present a prescription. Otherwise, a prescription is required.

State	Influenza	Pneumococcal	Shingles/herpes zoster /Zostavax <sup>101</sup>
<b>Michigan</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Minnesota</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	10 yrs or older	18 yrs or older	--
<b>Mississippi</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	5 yrs or older	5 yrs or older	--
<b>Missouri</b>	Yes	Yes	Yes
Rx Required	No	No	Ages 50-59 require Rx
Age Limit	12 yrs or older	12 yrs or older	60 yrs or older
<b>Montana</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	12 yrs or older	18 yrs or older	--
<b>Nebraska</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Nevada</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--

State	Influenza	Pneumococcal	Shingles/herpes zoster /Zostavax <sup>101</sup>
<b>New Hampshire</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	18 yrs or older	--
<b>New Jersey</b>	Yes	Yes	Yes
Rx Required	No <sup>103</sup>	No	No
Age Limit	12 yrs or older	18 yrs or older	--
<b>New Mexico</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>New York</b>	Yes	Yes	Yes
Rx Required	No	No	Yes <sup>104</sup>
Age Limit	18 yrs or older	18 yrs or older	18 yrs or older
<b>North Carolina</b>	Yes	Yes	Yes
Rx Required	No	No <sup>8</sup>	No <sup>9</sup>
Age Limit	14 yrs or older	18 yrs or older	--
<b>North Dakota</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	5 yrs or older	11 yrs or older	--

<sup>103</sup> A patient under the age of 18 must receive parent's permission for an influenza vaccine; patients under 12 must have a valid prescription. A.B. 3251

<sup>104</sup> Patient specific order prescribed or ordered by a physician or certified nurse practitioner.

<sup>8,9</sup> Pharmacist must first consult with patient's primary care provider before administration. In the event patient does not have primary care provider, a pharmacist may not administer a vaccines for pneumoccal or herpes zoster.

<b>State</b>	<b>Influenza</b>	<b>Pneumococcal</b>	<b>Shingles/herpes zoster /Zostavax<sup>101</sup></b>
<b>Ohio</b>	Yes	Yes	Yes
Rx Required	No	No	Yes
Age Limit	14 yrs or older	14 yrs or older	--
<b>Oklahoma</b>	Yes	Yes	Yes
Rx Required	Yes	Yes	Yes
Age Limit	No	No	--
<b>Oregon</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	11 yrs or older	11 yrs or older	--
<b>Pennsylvania</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	18 yrs or older	18 yrs or older	--
<b>Rhode Island</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	9 yrs or older	18 yrs or older	--
<b>South Carolina</b>	Yes	Yes	Yes
Rx Required	No	Yes	Yes
Age Limit	18 yrs or older	No	--
<b>South Dakota</b>	Yes	Yes	Yes
Rx Required	No	Yes	Yes
Age Limit	18 yrs or older	18 yrs or older	--
<b>Tennessee</b>	Yes	Yes	Yes

<b>State</b>	<b>Influenza</b>	<b>Pneumococcal</b>	<b>Shingles/herpes zoster /Zostavax<sup>101</sup></b>
Rx Required	No	No	No
Age Limit	No	No	--
<b>Texas</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	7 yrs or older <sup>10</sup>	14 yrs or older	--
<b>Utah</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>Vermont</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	18 yrs or older	18 yrs or older	--
<b>Virginia</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	18 yrs or older	--
<b>Washington</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	No	No	--
<b>West Virginia</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	18 yrs or older	18 yrs or older	18 years or older

<sup>10</sup> Patients 7-13 yrs who have an established physician-patient relationship must be referred to pharmacist for flu vaccine. Patients 7-13 yrs without a physician-patient relationship may receive flu vaccine from physician without referral.

State	Influenza	Pneumococcal	Shingles/herpes zoster /Zostavax <sup>101</sup>
<b>Wisconsin</b>	Yes	Yes	Yes
Rx Required	No	No	No
Age Limit	6 yrs or older	6 yrs or older	--
<b>Wyoming</b>	Yes	Yes	Yes
Rx Required	In some instances <sup>11</sup>	In some instances <sup>12</sup>	In some instances <sup>13</sup>
Age Limit	7 yrs or older <sup>105</sup>	18 yrs or older <sup>106</sup>	18 years or older <sup>107</sup>

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<sup>11, 12, 13</sup> Individuals deemed “high risk” must have prescription from their physician. “High risk” individuals are those who may have an absolute or relative contraindication to receive immunizations.

<sup>105</sup> Vaccines may be administered to “healthy” individuals; for ages 7-17 pharmacists must receive parental consent.

<sup>6,7</sup> Vaccines may be administered to “healthy” individuals.

**Appendix F:**

**Copy of Resolution 67-14 of the Michigan Academy of Family Physicians (MAFP):  
“Oppose Rapid Diagnostic Testing (RDT) Program in Michigan Pharmacies, introduced  
by Barb Saul, DO, for the MAFP.**



1  
2  
3 **Title: Oppose Rapid Diagnostic Testing (RDT) Program in**  
4 **Michigan Pharmacies**

5  
6 **Introduced by: Barb Saul, DO, for the Michigan Academy of Family**  
7 **Physicians**

8  
9 **Original Author: Fred Van Alstine, MD**  
10

---

11  
12 **Whereas, the Michigan Academy of Family Physicians (MAFP) and the**  
13 **Michigan State Medical Society (MSMS) share a common mission of advocating**  
14 **for the safety, health and wellbeing of medical care patients and caring for the**  
15 **welfare of the citizens of Michigan, and**

16  
17 **Whereas, MAFP very recently learned that a new Rapid Diagnostic**  
18 **Testing (RDT) in the Community Pharmacy Program is being conducted in**  
19 **Michigan, which would allow a pharmacist to administer and interpret certain**  
20 **diagnostic tests, perform physical assessments, make a diagnosis and**  
21 **prescribe medication that are beyond a pharmacist's scope of practice and**  
22 **raise serious concerns about patient safety, and**

23  
24 **Whereas, a presentation offered through the Michigan Pharmacists**  
25 **Association (MPA) stated that the "physical assessment skills of many**  
26 **pharmacists/pharmacy students are not adequate for patient care activities,"**  
27 **and**

28  
29 **Whereas, it would appear that the RDT program sanctions the unlicensed**  
30 **practice of medicine and violates the delegation, supervision and prescriptive**  
31 **authority provisions of Michigan's Public Health Code, MCL 333.1101 (PHC),**  
32 **and**

33  
34 **Whereas, MSMS and MAFP recognize that pharmacists play a valuable**  
35 **role in the delivery of high quality health care, particularly medication therapy**  
36 **management (MTM) activities administered as part of an integrated, physician-**  
37 **led health care team, patient-centered medical home, or patient-centered**  
38 **medical neighborhood, so long as the activities fall within a pharmacist's scope**  
39 **of practice and do not sacrifice a patient's health, safety or welfare, and**

40  
41 **Whereas, a recent presentation conducted on behalf of MPA also**  
42 **acknowledged that "pharmacists' use of RDTs to collect patient information will**  
43 **increase dramatically over the next 5-10 years...[and] will become**  
44 **commonplace like pharmacy-based immunizations," and**

45  
46 **Whereas, the RDT program will not only put patients at risk but will**  
47 **further fragment health care delivery and create unaccountable silos of care,**  
48 **which is in direct opposition to ongoing systemic efforts to promote continuous**

49 whole-person care with improved health outcomes for both the individual and  
50 society; therefore be it

51

52 **RESOLVED:** That MSMS oppose the existing Rapid Diagnostic Testing  
53 (RDT) program in Michigan pharmacies, as well as any future expansion or  
54 creation of similar programs that may result in a diagnosis of illness or  
55 initiation of a prescription medication treatment plan by a pharmacist in the  
56 state of Michigan; and be it further

57

58 **RESOLVED:** That MSMS work with the Michigan Academy of Family  
59 Physicians and other partners to ensure the appropriate governmental agencies  
60 investigate activities which may promote the unlicensed practice of medicine  
61 without adequate delegation and supervision, like the Rapid Diagnostic Testing  
62 (RDT) program, and seek the discontinuance of any such programs deemed to  
63 exceed the limits of the Public Health Code or acceptable standards of  
64 prevailing practice; and be it further

65

66 **RESOLVED:** That MSMS work with the Michigan Academy of Family  
67 Physicians to educate physician members on what constitutes appropriate  
68 delegation authorities under the Public Health Code and acceptable and  
69 prevailing practice standards; and be it further

70

71 **RESOLVED:** That MSMS work with the Michigan Academy of Family  
72 Physicians to educate physician members on what constitutes meaningful  
73 supervision and/or oversight under the Public Health Code and acceptable and  
74 prevailing practice standards; and be it further

75

76 **RESOLVED:** That MSMS work with the Michigan Academy of Family  
77 Physicians, the American Medical Association, and the  
78 American Academy of Family Physicians to evaluate whether a Rapid  
79 Diagnostic Testing (RDT) program, which would allow a pharmacist to  
80 administer and interpret certain diagnostic tests, perform physical  
81 assessments, make a diagnosis and prescribe medication that are beyond a  
82 pharmacist's scope of practice, violates federal and state fraud and abuse laws;  
83 and be it further

84

85 **RESOLVED:** That MSMS work with the Michigan Academy of Family  
86 Physicians, the Michigan Pharmacists Association, and other stakeholders to  
87 develop a legislative and/or regulatory remedy to encourage the lawful  
88 integration of medication therapy management activities as part of an  
89 integrated, physician-led health care team, patient-centered medical home, or  
90 patient-centered medical neighborhood.

91

92

93 **WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**