

January 24, 2020

Erin Campbell Bureau of Health Services Financing P.O. Box 91030 Baton Rouge, LA 70821-9030

Re: Proposed Rule Changes to LAC 50:XXIX.123, 919 and 993

Dear Ms. Campbell,

On behalf of our members operating chain pharmacies in the state of Louisiana, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit comments to the Bureau of Health Services Financing ("Bureau") in support of the proposed rule changes under LAC 50:XXIX.123, 919 and 993 relating to Vaccine Administration and Reimbursement. We commend the Bureau for pursuing rulemaking to expand the types of vaccines that pharmacy providers can offer and be reimbursed for providing to Medicaid beneficiaries. This rule change will broaden access to important immunization services for Medicaid beneficiaries, ultimately helping to improve the health of covered individuals, leading to healthier communities in general and reducing overall healthcare spending. We thank the Bureau for considering our feedback in support of this proposal.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Member companies have nearly 600 pharmacies within the state of Louisiana, employing more than 36,000 individuals. Nationally, they fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

Expanded access to pharmacist-provided vaccination services extends the reach of public health. Vaccines have prevented at least 10 million deaths between 2010 and 2015 alone, and many million more lives have been spared from suffering and disability associated with vaccine-preventable disease. Global eradication of deadly, yet formerly common diseases, such as polio, is finally within reach thanks to widespread vaccination efforts. Yet, many Americans still do not receive critically important vaccines, with rates lagging far behind national goals and objectives. According to a 2018 *Health Affairs* article, only 8% of Americans aged 35 and older reported having received all of the appropriate, high-priority clinical preventive services recommended for them, and nearly 5% reported having received none of

them.^{iv} More than 3 million individuals die from vaccine preventable diseases every year, including up to 90,000 adult deaths in the United States^v and thousands more suffer serious health problems and disability.^{vi} In an effort to improve health and increase protection against vaccine-preventable disease and death, the National Vaccine Advisory Committee's Standards for Adult Immunization Practice advises that all healthcare providers assess patients for their immunization status at every patient encounter and administer needed vaccines.^{vii}

Patients visit community pharmacies 10 times more often than they visit other healthcare settings, making community pharmacies convenient healthcare destinations and community pharmacists particularly well positioned to expand access to cost-effective vaccination assessment and delivery. Viii, ix As the face of neighborhood healthcare, pharmacists can help states increase their vaccination rates and further reduce the incidence of vaccine preventable diseases. Given community pharmacists exceptional potential to increase immunization rates, X NACDS supports policies – including the Bureau's proposed rule change enabling Medicaid beneficiaries to obtain all recommended vaccines at their local pharmacies – that expand access to the convenient, accessible and cost-effective vaccination services available from pharmacy providers.

As immunizers, pharmacists have been shown to increase overall vaccination rates.xi A 2017 study found that each additional year of exposure to pharmacybased immunization services was associated with greater odds of patients reporting an influenza or a pneumonia vaccination. This study estimated that 6.2 million additional influenza immunizations and 3.5 million additional pneumococcal immunizations are attributable to pharmacy-delivered immunization services each year.xii In fact, the Centers for Disease Control and Prevention (CDC) reported in 2018 that 32.2% of all influenza vaccinations were administered at a pharmacy. xiii Further, a 2019 study found that a community pharmacy vaccination program demonstrated a 74% increased vaccination rate for pertussisxiv and community pharmacists have demonstrated success at identifying at-risk patients and providing pneumonia vaccination at a significantly higher rate than the benchmark for traditional care.xv Considering the evidence illustrating how pharmacists broadly improve vaccination coverage for other vaccines over time, coverage for all pharmacist-provided vaccines (in addition to the influenza vaccine) in the Medicaid program will improve broader vaccination rates in the Medicaid population.

Many adults have not received all the indicated vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), the body of medical and public health experts that provides recommendations on the use of vaccines in the civilian population of the United States. Unfortunately, the adult population lags behind the Healthy People 2020 goals for the most commonly recommended vaccines which include influenza, pneumococcal, Tdap (tetanus, diphtheria, and pertussis), herpes zoster, and HPV.xvi Specifically, vaccine coverage rates for adults

in 2017 were 45.4% for influenza (HP2020 goal 70% xvii), 24.5% (aged 19-64) and 69% (aged 65 and up) for pneumococcal, 49% for human papillomavirus (HP2020 goal of 80% for female adolescents aged 13-18 xviii), 34.9% among all adults for Zoster, and 31.7% for Tdap.xix The Healthy People 2020 objectives also include goals for reducing the number of cases of additional vaccine-preventable diseases, including hepatitis A, hepatitis B, measles, mumps, and varicella.xx Disparities in vaccination coverage rates are even greater for at-risk populations, including seniors, communities of color, limited English proficient persons, and people with chronic illnesses. Enabling pharmacists to provide vaccine services to Medicaid beneficiaries. inclusive of all recommended vaccines indicated for individuals, can further support broadly and comprehensively improving the proportion of vaccinated Medicaid beneficiaries.

Pharmacists complement other healthcare professional efforts to increase vaccination rates by reaching populations less likely to be seen by other **clinicians.** The CDC reports that individuals whose last routine medical checkup was over one year ago were more likely to receive vaccinations in a nonmedical setting than those whose last routine medical checkup was more recent.xxi According to the PrescribeWellness 2017 Vaccination and Preventive Care Survey, most Americans prefer visiting their local pharmacy to get recommended vaccines. versus visiting a physician's office. Over 1,000 adults over age 35 were included in this survey, and of the 62% of survey respondents who chose pharmacy over practitioner, most of the reasons hinged on convenience. However, research suggests that pharmacists are not shifting patient populations from medical clinics into pharmacies, but instead are identifying new, previously unvaccinated populations for immunization. xxii, xxiii Further, as more patients seek specialty care for chronic illness, opportunities for vaccination may decrease, with growing need for additional convenient vaccine providers such as pharmacists. Specifically, while the use and demand of cardiologist-provided care increases, evidence suggests that about half of cardiology practices do not stock influenza vaccine^{xxiv} despite that flu vaccine is correlated with reduced risk of heart attack.xxv Obstetriciansgynecologists have expressed interest to collaborate with pharmacies and pharmacists to refer patients for vaccination, and a tip sheet exists that offers guidance on how to do so.xxvi The availability of immunizations in non-physician practice settings such as pharmacies helps fill immunization gaps and complements synergistic efforts across the healthcare continuum to comprehensively and costeffectively provide vaccinations to individuals who may have fewer opportunities to access vaccines in other settings.

Community pharmacies offer an accessible option for the public to receive vaccinations. The access factor appeals to the public and has led to increased vaccination rates in certain populations, including adults under the age of 65. A recent study on community pharmacy-provided vaccines revealed that patients accessing vaccinations during hours when traditional vaccine providers are

unavailable are more likely to be younger than 65 years of age.xxvii Further, market research demonstrates the evolution of healthcare due to expectations of younger generations, like millennials, who opt for alternative, efficient, and convenient healthcare options, challenging the status quo of traditional office-based care.xxviii According to the Kaiser Family Foundation, 45% of those aged18 to 29 report no primary care provider, compared with only 12% of people age 65 and older.xxix Given such trends, the broad availability of vaccines at community pharmacies creates opportunities to improve vaccination rates and herd immunity, especially with the potential to improve health and vaccine coverage among "harder-to-reach" populations, a patient category that many Medicaid beneficiaries fall within.xxx

Pharmacies are a crucial resource for increasing vaccine distribution reach and capacity to avert morbidity and mortality during outbreaks, epidemics, and pandemics. As such, they should be leveraged alongside other Medicaid vaccine providers to fill this role. During the 2009 H1N1 influenza pandemic, the CDC distributed 5,483,900 doses of 2009 H1N1 vaccine to 10 chain pharmacies that in turn distributed the vaccine to more than 10,700 retail stores nationwide. Approximately 10% of adults who received 2009 H1N1 influenza vaccine reported receiving it at a pharmacy.**

A 2018 study simulating the spread of an influenza epidemic found that administering vaccines through pharmacies (in addition to traditional locations) during an epidemic can increase vaccination coverage, mitigating up to 23.7 million symptomatic influenza cases, providing cost-savings up to \$2.8 billion to third-party payers and \$99.8 billion to society. Noting that pharmacies have potential advantages as immunization sites including numerous locations in closer proximity to residential neighborhoods, extended operating hours seven days a week, and the ability to serve individuals (including those without an established healthcare provider) on a walk-in basis, the study concluded that pharmacies have a crucial role to play in averting a substantial number of symptomatic influenza cases, deaths, and cost during an epidemic.xxxiii It is reasonable to expect that pharmacy vaccine providers could have a similar impact on increasing vaccine distribution reach and capacity, and ultimately, improving outcomes during outbreaks of other types of vaccine-preventable disease.

To best deploy pharmacists in situations of emergencies, epidemics, and vaccine shortages, it is critical that pharmacists are recognized and reimbursed as vaccine providers for all FDA-approved vaccines within the state of Louisiana, without limiting pharmacy vaccine reimbursement to only a subset of vaccines. As the proposed rule accomplishes this, we commend the Bureau for its forwarding thinking approach.

Expanding pharmacists' ability to provide a broader array vaccination services to Louisiana Medicaid beneficiaries can lead to decreased healthcare

costs for the Medicaid program. Vaccination is often cited as the most cost effective preventive health intervention, with the CDC estimating that the vaccination of children born between 1994 and 2018 has saved the U.S. nearly \$406 billion in direct medical costs and \$1.88 trillion in total society costs. xxxiii An economic evaluation published in 2014 reported a net savings of \$13.5 billion in direct costs and \$68.8 billion in total societal costs due to immunization among members of the 2009 US birth cohort alone. xxxiiv Experts estimate that unvaccinated individuals and resulting health effects lead to approximately \$7.1 billion in healthcare costs annually. xxxv

A study published by Harvard Medical School reported the mean cost of vaccination at a variety of healthcare settings, noting vaccinations at community pharmacies were significantly lower cost than scheduled physician visits and mass vaccination clinics.xxxvi As noted by the Department of Defense in a 2011 final rule expanding the portfolio of vaccines that TRICARE beneficiaries may obtain from community pharmacies, significant savings were achieved under the TRICARE program when the program was first implemented to allow beneficiaries to obtain flu and pneumococcal vaccines from retail pharmacies. It was estimated that for the first six months that beneficiaries could obtain their vaccinations from pharmacists, 18,361 vaccines for H1N1, flu, and pneumococcal were administered at a cost of nearly \$300,000; had those vaccines been administered under the medical benefit, the cost to TRICARE would have been \$1.8 million.xxxvii Clearly this represents significant healthcare savings, which one would expect to be amplified and replicated where pharmacists are recognized as vaccine providers and therefore able to immunize a broader patient population. Indeed, this is why the Department of Defense opted to expand the types of vaccines that TRICARE beneficiaries may obtain from community pharmacies to include all CDC-recommended vaccines.

In conclusion. Considering the numerous benefits of improving access to the full range of vaccinations provided by pharmacists, we strongly support the Bureau moving forward with this rulemaking to expand the types vaccines that pharmacy providers can offer and be reimbursed for providing to Medicaid beneficiaries. Moreover, as additional changes may be made in the future to expand pharmacists immunization authority under the Pharmacy Practice Act to include administration of non-flu vaccines to individuals younger than 18 years of age, we encourage consideration by the Louisiana Department of Health's Vaccines For Children Program to be mindful of those changes and to make corresponding updates to program coverage to support pharmacy deliver of vaccination services to children and adolescents.

Immunizations are one of many patient care services that pharmacists are well-trained and positioned to deliver to Medicaid beneficiaries. Should the Bureau have an interest to explore additional service areas for pharmacist delivery and reimbursement, we welcome continued conversation. Along these lines, we have

included appendices that provide details on the qualifications of pharmacists as compared to other clinicians (Appendix 1), the proven clinical and economic value of pharmacy care (Appendix 2), and state opportunities for pharmacy care (Appendix 3). NACDS thanks the Bureau for considering our comments on this proposed rule. We welcome the opportunity to discuss this matter further; for follow-up, please contact NACDS' Mary Staples, Director of State Government Affairs, at (817) 442-1155 or mstaples@nacds.org.

Sincerely,

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer

Stan P. Allem

i https://www.who.int/publications/10-year-review/vaccines/en/

ii https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html

iii https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1248

iv Borsky A, Zhan C, Miller T, Ngo-Metzger Q, Bierman AS, Meyers D. Few Americans Receive All High-Priority, Appropriate Clinical Preventive Services. Health Affairs. 2018;37(6):925-928. doi:10.1377/hlthaff.2017.1248

^{*} https://www.agingresearch.org/press-release/50000-to-90000-adult-deaths-a-year-caused-by-vaccine-preventable/

vi https://www.chop.edu/centers-programs/vaccine-education-center/global-immunization/diseases-and-vaccines-world-view

vii http://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html

viii Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full

ix Winegarden W. Promoting Access and Lowering Costs in Health Care: The Case of Empowering Pharmacists to Increase Adult Vaccination Rates. The Pacific Research Institute. April 2018. https://www.pacificresearch.org/wp-content/uploads/2018/04/AdultVaccination F web.pdf

^{*} https://www.ncbi.nlm.nih.gov/m/pubmed/16602227/

xi https://www.sciencedirect.com/science/article/pii/S0149291817307713?via%3Dihub

xii https://www.japha.org/article/S1544-3191(18)30231-0/pdf

xiii CDC. Influenza: General Population Early Season Vaccination Coverage. 2018. https://www.cdc.gov/flu/fluvaxview/nifsestimates-nov2018.htm

xiv NK Wehbi, JR Wani, DG Klepser, J Murry, AS Khan. Impact of a Technology Platform to Increase Rates of Adult Immunization in Pharmacies. Vaccine. Volume 37, Issue 1, 3 January 2019, Pages 56-60. https://www.sciencedirect.com/science/article/pii/S0264410X18315664?via%3Dihub

xv https://www.ncbi.nlm.nih.gov/pubmed/21864625

xvi https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives

xvii https://www.cdc.gov/nchs/ppt/hp2020/hp2020_IID_GH_progress_review.pdf

xix https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html

xx https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives

xxi Centers for Disease Control and Prevention; "Place of influenza vaccination among adults—United States, 2010-11 influenza season"; MMWR Morb Mortal Wkly Rep. 2011;60(23):781-785.

xxiii Steyer TE, Ragucci KR, Pearson WS, Mainous AG 3rd; "The role of pharmacists in the delivery of influenza vaccinations"; *Vaccine*; 2004;22(8): 1001-1006.

- xxiii Goad J, et al. "Vaccinations Administered During Off-Clinic Hours at a National Community Pharmacy: Implications for Increasing Patient Access and Convenience" Ann Fam Med. 2013 Sep; 11(5): 429–436.
- xxiv https://www.sciencedirect.com/science/article/abs/pii/S0749379703003921?via%3Dihub
- xxv https://www.cdc.gov/flu/highrisk/heartdisease.htm
- xxvi The American College of Obstetricians and Gynecologists; "Developing an Immunization Referral System." 2018. https://www.nacds.org/wp-content/uploads/2019/02/Referral-System-Tip-Sheet-2019.pdf
- xxvii Goad J, et al. "Vaccinations Administered During Off-Clinic Hours at a National Community Pharmacy: Implications for Increasing Patient Access and Convenience" Ann Fam Med. 2013 Sep; 11(5): 429–436.
- xxviii https://www.forbes.com/sites/allbusiness/2018/11/27/millennial-expectations-fundamentally-changing-healthcare-landscape/#3f96577a7fe5
- $\frac{\text{xxix}}{\text{https://www.beckershospitalreview.com/patient-flow/millennials-are-upending-the-primary-care-model-4-things-to-know.html}$
- xxx Goad J, et al. "Vaccinations Administered During Off-Clinic Hours at a National Community Pharmacy: Implications for Increasing Patient Access and Convenience" Ann Fam Med. 2013 Sep; 11(5): 429–436.
- xxxii Koonin LM, et al. "CDC's 2009 H1N1 Vaccine Pharmacy Initiative in the United States: Implications for Future Public Health and Pharmacy Collaborations for Emergency Response." Disaster Med and Public Health Prep. 2011 Dec:5(4); 253-255.
- xxxiii Bartsch, S., Taitel, M., DePasse, J., Cox, S., Smith-Ray, R., et. Al; "Epidemiologic and Economic Impact of Pharmacies as Vaccination Locations During an Influenza Epidemic"; *Vaccine*; 2018; 36(46): 7054-7063.
- xxxiii https://www.vaccinateyourfamily.org/why-vaccinate/vaccine-benefits/costs-of-disease-outbreaks/
- xxxiv https://pediatrics.aappublications.org/content/133/4/577
- vara S, Portnoy A, Getaneh H, Clark S, Knoll M, Bishai D, Yang HK, Patwardhan PD. Modeling The Economic Burden Of Adult Vaccine-Preventable Diseases In The United States. Health Aff. 2016 Nov 1;35(11):2124-2132.
- https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.0462
- xxxvi Prosser LA, Obrien MA, et al. Non-traditional settings for influenza vaccination of adults: costs and cost effectiveness.
- Pharmacoeconomics. Feb 2008. https://link.springer.com/article/10.2165%2F00019053-200826020-00006 vocvii 76 FR 41063-41065.

Appendix #1: All Professions Across the Continuum of Care Have Unique Expertise to Improve Care for Medicaid Beneficiaries

| Profession | Estimated Number Practicing | Role: Defined by Professional Association | Degree Level | Degree Program Pre- Requisites | Professiona l Program Length | Experiential/ Clinical Hours Requirements |
|-------------------------------------|-----------------------------------|--|----------------------------|--|---|---|
| Pharmacist ¹ | 319,000 | APhA: Pharmacists are healthcare professionals who help people achieve the best results from their medications. The pharmacist is the most knowledgeable healthcare professional when it comes to medicines and their use. | Doctoral | Bachelor's degree or required pre-professional courses if participating in a 5 or 6 year accelerated program | 4 years | 1740 hours (approximately 44 weeks) |
| Physician Assistant ² | 131,000 | AAPA: PAs are medical professionals who diagnose illness, develop and manage treatment plans, prescribe medications, and often serve as a patient's principal healthcare provider. | Master's | Bachelor's degree and completion of courses in basic and behavioral sciences Average of 3,000 hours+ of direct patient contact experience | 3 years (27 continuous months) | 2000 hours (approximately 1 year) |
| Nurse Practitioner | 270,000 | AANP: NPs assess patients, order and interpret diagnostic tests, make diagnoses and initiate and manage treatment plans—including prescribing medications. | Master's or Doctoral | Active Registered Nurse license 1 – 2 years of clinical experience | 2 – 3 years | 500 hours minimum |
| Physical Therapist ⁴ | 209,000 | APTA: PTs are movement experts who optimize quality of life through prescribed exercise, hands-on care, and patient education. | Doctoral | Bachelor's degree or, if participating in a 3+3 curricular format, 3 years of specific pre-professional courses must be taken before the student can | 3 years | 1200 hours (30 weeks) minimum |

 $^{^1\,}Guidance\,for\,the\,Accreditation\,Standards\,and\,Key\,Elements\,for\,the\,Professional\,Program\,in\,Pharmacy\,Leading\,to\,the\,Doctor\,of\,Pharmacy\,Degree.\,Accreditation\,Council\,for\,Pharmacy\,Education.\\ \underline{https://www.acpe-accredit.org/pdf/GuidanceforStandards2016FINAL.pdf}$

² American Academy of Physicians Assistants. https://www.aapa.org/

³ American Association of Nurse Practitioners. https://www.aanp.org/

⁴ American Physical Therapy Association. https://www.apta.org/

| | | | | advance into a 3-year professional program | | |
|---|------------------|--|----------------------------|---|-------------|--|
| Occupationa l Therapist ⁵ | 115,000 | AOTA: OTs help people across the lifespan participate in the things they want and need to do through the therapeutic use of everyday activities (occupations). | Master's or Doctoral | Doctoral Program: -Bachelor's degree or higher prior to admission | 2 – 3 years | Master's Program: -960 hours (24 weeks) minimum |
| | | | | | | Doctoral Program: -960 hours (24 weeks) + an additional 640 hours (16 weeks) |
| Clinical Psychologist s ⁶ | Not specified | APA: Clinical psychology is the psychological specialty that provides continuing and comprehensive mental and behavioral health care for individuals and families; consultation to agencies and communities; training, education and supervision; and research-based practice. | Doctoral | Bachelor's or Master's | 4 – 7 years | 1-year internship (hours not specified) |
| Clinical Social Worker ^{7,8} | Not specified | NASW: Clinical social work is the professional application of social work theory and methods to the diagnosis, treatment, and prevention of psychosocial dysfunction, disability, or impairment, including emotional, mental, and behavioral disorders. | Master's | Bachelor's | 2 years | 900 hours minimum |

⁵ American Occupational Therapy Association. https://www.aota.org/
⁶ Clinical Psychology. American Psychological Association. https://www.apa.org/ed/graduate/specialize/clinical
⁷ NASW Standards for Clinical Social Work in Social Work Practice. National Association of Social Workers.https://www.socialworkers.org/LinkClick.aspx?fileticket=Y0g4qdefLBE%3d&portalid=0
⁸ Educational Policy and Accreditation Standards. Council on Social Work Education (CSWE). https://www.cswe.org/getattachment/Accreditation/Standards-and-Policies/2015- EPAS/2015EPASandGlossarv.pdf.aspx

| Speech- Language Pathologist ⁹ | 175,000 | ASHA: Speech-language pathologists (SLPs) work to prevent, assess, diagnose, and treat speech, language, social communication, cognitive-communication, and swallowing disorders in children and adults. | Master's or Doctoral | Bachelor's degree | 2 – 4 years | 400 hours minimum |
|---|---------|---|----------------------------|--|------------------|--|
| Audiologist | 13,300 | ASHA: Audiologists provide patient-centered care in the prevention, identification, diagnosis, and evidence-based intervention and treatment of hearing, balance, and other related disorders for people of all ages. | Doctoral | Bachelor's degree | 4 years | 1820 hours minimum (approximately 46 weeks) |
| Chiropracto rs ¹¹ | 50,300 | WFC: A health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health. There is an emphasis on manual treatments including spinal adjustment and other joint and soft-tissue manipulation. | Doctoral | Bachelor's degree or at least 3 years of undergraduate study | 4 – 5 years | Clinical hours not specified 4,200 hours of combined classroom, laboratory, and clinical experience |
| Registered Dietician and Nutrition Professional s ^{12,13} | 80,000 | AND: Registered dietitian nutritionists are the food and nutrition experts who can translate the science of nutrition into practical solutions for healthy living. RDNs use their nutrition expertise to help individuals make | N/A | Bachelor's – RDN Master's or Doctoral – CNS | 6 – 12 months | 1200 hours – RDN 1000 hours – CNS |

Scope of Practice in Speech-Language Pathology. American Speech-Language-Hearing Association. https://www.asha.org/uploadedFiles/SP2016-00343.pdf
 About Audiology. American Speech-Language-Hearing Association. https://www.asha.org/Students/Audiology/
 World Federation of Chiropractic. https://www.asha.org/students/Audiology/
 Academy of Nutrition and Dietetics. https://www.eatrightpro.org/
 American Nutrition Association. https://theana.org/certify/CNScandidate

| | unique, positive lifestyle changes. | | |
|--|-------------------------------------|--|--|
| | ANA: Certified Nutrition | | |
| | Specialists practice science-based | | |
| | personalized nutrition therapy to | | |
| | power people to health. They are | | |
| | spearheading the transformation | | |
| | from population-based to | | |
| | personalized nutrition, and from | | |
| | disease care to authentic health | | |
| | care. | | |

| Appendix #2: The Proven Clinical & Economic Value of Community Pharmacy Care | | | |
|--|--|--|--|
| Clinical Value/Result of Pharmacist Intervention | Source | | |
| Chronic Disease Outo | comes | | |
| Pharmacist-provided medication therapy management for medically underserved patients in FQHCs resulted in A1c goal achievement in 52.84% of patients and hypertension control was reported in 65.21%. Pharmacists identified and resolved more than 1400 medication-related problems and addressed multiple adverse drug event issues. | Rodis JL, et al. Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. Journal of Primary Care & Community Health. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28381095 | | |
| Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger blood-pressure reduction when coupled with medication management in barbershops by pharmacists. The mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mmHg greater, respectively, in participants assigned to the pharmacist-led intervention than in those assigned to the active control. In the intervention group, the rate of cohort retention was 95%, there were few adverse events, and self-rated health and patient engagement increased. | Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. The New England Journal of Medicine. April 2018. https://www.nejm.org/doi/full/10.1056/NEJMoa1717250 | | |
| Patients' A1c measurements as part of the pharmacist program were significantly reduced. Researchers observed a 16% decrease in all-diagnosis costs. Another study, by the same author, found that more than 50% of patients showed a decrease in A1c at each follow-up visit, and more than 50% saw improvement in lipid levels at each measurement. Additionally, total direct mean costs decreased by \$1,200 to \$1,872 per patient per year compared with baseline. | Cranor CW, Christensen DB. The Asheville Project: Short-term outcomes of a community pharmacy diabetes care program. Apr 2003. https://www.sciencedirect.com/science/article/pii/S108658021530005X?via%3 Dihub Cranor CW, Bunting BA, et al; "The Asheville Project: Long- Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program;" Journal of the American Pharmacists Association; 2003. https://www.sciencedirect.com/science/article/pii/S1086580215300073? via%3Dihub | | |
| Patients in the pharmacy program had a lower risk for discontinuing therapy and in a cohort of 1,000 patients, the intervention resulted in a reduction of 7 nonfatal strokes, 2 fatal strokes, 16 nonfatal heart attacks, 7 fatal heart attacks, and 16 revascularizations over patients' lifetimes. The intervention also produced considerable net cost savings. | Vegter S, et al.; "Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis;" Journal of Managed Care & Specialty Pharmacy; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722 ; Last Accessed June 13, 2018. | | |
| The results for 6-month systolic BP reading showed significantly decreased rates for the pharmacist group versus the control group (-11.8mmHg vs - 6.2mmHg) and slightly smaller, but observable changes of diastolic BP in the intervention group versus the control group (-8.4 vs -6.2mmHg). Percentage of patients achieving good refill adherence was larger for the intervention group compared to the control group (59.7% vs 36.1%). | Shireman TI, et al.; "Cost-effectiveness of Wisconsin TEAM model for improving adherence and hypertension control in black patients;" <i>Journal of the American Pharmacists Association</i> ; March 2016. https://www.ncbi.nlm.nih.gov/pubmed/27184784 | | |
| A review by the Department of Veterans Affairs of over 60 research studies found that patients receiving chronic care management from a pharmacist had a higher likelihood of meeting blood pressure, cholesterol and blood glucose goals, compared to those receiving usual care | Greer N, Bolduc J, Geurkink E et al. (April 26 2016). Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care. Ann Intern Med. Epub ahead of print. | | |
| The pharmacy intervention group had statistically significantly higher improvements in the individual areas of A1c, blood pressure, and statin goal attainment. In this study, 40% of patients in the pharmacist intervention | Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home. JMCP. 2018;24(5):423-429. | | |

| group achieved all 3 clinical goals after intervention , compared with only 12% | |
|---|--|
| of patients in the usual care group. | |
| Pharmacy care program for elderly patients led to increases in medication | Lee JK, et al.; "Effect of a Pharmacy Care Program on Medication Adherence And |
| adherence, medication persistence, and clinically meaningful reductions in blood | Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial;" Journal of the American Medical Association; |
| pressure. After 6 months of intervention, medication adherence increased from | Available at https://jamanetwork.com/journals/jama/fullarticle/204402. |
| baseline of 61.2% to 96.9% and associated with significant improvements in | - Transacto at setting of fine the first fine the f |
| systolic BP (133.2 to 129.9) and LDL-C levels (91.7 to 86.8). | |
| Improved Medication A | dherence |
| Patients receiving the pharmacist adherence intervention increased between | Fikri-Benbrahim N, et al.; :Impact of a community pharmacists' hypertension-care |
| baseline and the end of the study (86.0% vs 96.5%) whereas the control group did | service on medication adherence."; The AFenPA study. Research in Social and |
| not have a significant change (86.5% vs 85.4%). The odds of adherence to | Administrative Pharmacy. Available at |
| antihypertensive drug therapy in the pharmacist group was three times | https://www.ncbi.nlm.nih.gov/pubmed/23391845. Last Accessed June 13, 2018. |
| higher than the control group. | |
| A review of 22 studies showed that community pharmacist-led interventions | Milosavljevic A, Aspden T, Harrison J. <u>Community pharmacist-led interventions</u> |
| improve patients' adherence and contribute to improved blood pressure | and their impact on patients' medication adherence and other health outcomes: a |
| control, cholesterol management, and chronic obstructive pulmonary disease | systematic review. International Journal of Pharmacy Practice. 2018; 26(5). |
| and asthma control. | |
| The intervention, which included pharmacist-led screening across 283 pharmacies | Pringle JL, et al.; "The Pennsylvania Project: Pharmacist Intervention Improved |
| for medication non-adherence and counseling for those at an increased risk, led to | Medication Adherence and Reduced Health Care Costs;" Health Affairs; August |
| statistically significant improvement in medication adherence, and an annual per | 2014; https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398. |
| patient cost savings of \$241 dollars for improved adherence to oral diabetes | |
| medications and \$341 related to improved adherence to statin medications. | |
| Pharmacists provided counseling for adherence to diabetes medications and | Brennan TA, et al.; "An Integrated Pharmacy-Based Program Improved Medication |
| recommendations for other medications often used in tandem with diabetes | Prescription and Adherence Rates in Diabetes Patients.;" Health Affairs; Available |
| medications aimed at reducing the risk of cardiovascular disease (ACE-inhibitors or | at |
| ARBS and/or statins). The return on investment of the initiative was estimated | https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url ver=Z39. |
| at 3:1. | 88-2003𝔯 id=ori%3Arid%3Acrossref.org𝔯 dat=cr pub%3Dpubmed; |
| Patients who received the outpatient pharmacy clinical service program were more | Spence MM, et al.: "Evaluation of an Outpatient Pharmacy Clinical Services |
| | Program on Adherence and Clinical Outcomes Among Patients with Diabetes |
| likely to be adherent with their diabetes medications (53.5% compared to 37.4%). | and/or Coronary Artery Disease;" Journal of Managed Care & Specialty Pharmacy; |
| This group was also more likely to continue taking their medication, less likely to | Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036 ; Last |
| have an emergency department visit, and the return on investment for this | Accessed June 13, 2018. |
| program was estimated at 5.79:1. | V. D. IP to I (M. J. at a mark) |
| Pharmacist-led Medication Monitoring and Optimization results: For osteoporosis, | Van Boven JF, et al; "Medication monitoring and optimization: a targeted pharmacist program for effective and cost-effective improvement of chronic |
| therapy discontinuation after 1 year was 16.1% in the pharmacist group, compared | therapy adherence"; Journal of Managed Care & Specialty Pharmacy; Available at |
| with 31.7% in the control group and was found to be cost-effective in 52,000 | https://www.jmcp.org/doi/10.18553/jmcp.2014.20.8.786. Last Accessed June 13, |
| patients yearly, initiating osteoporotic therapy with an incremental cost- | 2018. |
| effectiveness. For dyslipidemia, the therapy discontinuation rate was 13.6% in the | |
| pharmacist cohort and 25.9% in the control group. The cost-effective aspect was | |
| favorable for the primary prevention population and significant for the | |
| secondary prevention population (lower costs and more health gains). | |
| A comprehensive medication management program, led by pharmacists, targeted at | https://www.chcs.org/media/Slides-CMMC-National-webinar-3.1.19.pdf |
| high-risk individuals, resulted in 33% reduction in readmission rate, 31.5% | |
| reduction in costs, and an average of 12:1 ROI overall. | |
| In 2012, a Medicaid managed care plan established a collaborative MTM program | Ben Urick, Patrick Brown, and Jon C. Easter. Achieving Better Quality and Lower |
| for nearly 1,000,000 Ohio Medicaid beneficiaries. By the end of 2013, pharmacists | Costs in Medicaid Through Enhanced Pharmacy Services |

| at 1,500 pharmacies had provided over 100,000 MTM interventions, 40% of which | North Carolina Medical Journal May-June 2017 78:188-189; |
|--|---|
| were associated with medication adherence. In a program evaluation, the managed | doi:10.18043/ncm.78.3.188 |
| care plan reported a 4.4:1 return on investment for total health care | |
| expenditures. | |
| Patients receiving the pharmacist adherence intervention increased between | Fikri-Benbrahim N, et al.; :Impact of a community pharmacists' hypertension-care |
| baseline and the end of the study (86.0% vs 96.5%) whereas the control group did | service on medication adherence."; The AFenPA study. Research in Social and |
| not have a significant change (86.5% vs 85.4%). The odds of adherence to | Administrative Pharmacy. Available at |
| antihypertensive drug therapy in the pharmacist group was three times | https://www.ncbi.nlm.nih.gov/pubmed/23391845. Last Accessed June 13, 2018. |
| | |
| higher than the control group. | Vyymma A Clymp D. Cabracaysica C et al. (2010) Medication Cynghyanigation |
| A study assessing pharmacy-based medication synchronization programs for | Krumme A. Glynn, R., Schneeweiss, S. et al. (2018). Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use. |
| Medicaid FFS beneficiaries with certain conditions (e.g., hypertension, | Health Affairs 37(1)125-133. |
| hyperlipidemia and diabetes) found improved adherence to cardiovascular | |
| medications, cardiovascular clinical outcomes and significantly lower rates of | |
| hospitalization and emergency department visits, compared to a control group. | |
| Transitions of Ca | re |
| Patients who received medication therapy management services from the | Luder HR, et al.; "TransitionRx: Impact of Community Pharmacy Postdischarge |
| pharmacist experienced significantly fewer readmissions than patients who | Medication Therapy Management on Hospital Readmission Rate."; Journal of the |
| received usual care. Approximately 20% of patients who received usual care were | American Pharmacists Association; June 2015. |
| | https://www.sciencedirect.com/science/article/pii/S1544319115300558 |
| re-admitted within 30 days compared to 6.9% of the patients who received | |
| pharmacist care. | N'W Class D Habitata Latal Badastina at a desiral a description |
| A budget impact analysis of a pharmacist-provided transition of care program | Ni W, Colayco D, Hashimoto J, et al. <u>Budget impact analysis of a pharmacist-provided transition of care program</u> . J Manag Care Spec Pharm. 2018;24(2):90-96. |
| predicts a potential cost savings of \$25 million to a managed Medicaid plan | provided transition of care program. I manage care spec 1 harm. 2010,24(2):30-30. |
| over a period of 2 years, corresponding to over \$4 per member per month. | |
| A meta-analysis of 32 articles found that, compared to usual care, pharmacy- | Rodrigues, C.R., Harrington, A.R., Murdock, N. et al. <u>Effect of pharmacy-supported</u> |
| supported transitions of care programs resulted in a significant 32% | transition-of-care interventions on 30-day readmissions: a systematic review and meta-analysis. Ann Pharmacother. 2017; 51: 866–889 |
| reduction in the odds of readmission | |
| A community pharmacy-based transitions of care program demonstrated that | Ni W., Colayco D., Hasimoto J., Komoto K., Gowda C., Wearda B., McCombs J. <u>Impact</u> |
| patients' risk of readmission can be decreased by 28% and 31.9% at 30 and | of a pharmacy-based transitional care program on hospital readmissions. Am. J. |
| 180 days, respectively, when pharmacists are added to usual care. In this | Manag. Care. 2017;23:170–176. |
| program, pharmacist interventions focused on patient education, resolving | |
| medication-related problems, and facilitating access to post-discharge | |
| appointments and medications | |
| Preventive Care and So | creening |
| Five years after national implementation of pharmacist-administered | Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization |
| immunizations, it is estimated that 6.2 million additional influenza | services on the likelihood of immunization in the United States. Journal of the |
| , and the second se | American Pharmacists Association. August 2018. |
| immunizations and 3.5 million additional pneumococcal immunizations are | https://www.japha.org/article/S1544-3191(18)30231-0/pdf |
| attributable to pharmacy-delivered immunization each year. | Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization |
| The cost effectiveness of a pharmacist-directed smoking cessation program that | services on the likelihood of immunization in the United States. Journal of the |
| achieved abstinence of at least 1 year in 25% of patients was studied. Depending on | American Pharmacists Association. August 2018. |
| the smoker's age at the time of cessation, the incremental discounted cost- | https://www.japha.org/article/S1544-3191(18)30231-0/pdf |
| effectiveness was \$720-1,418/life-year saved. | |
| Community pharmacists used a rapid antigen detection test for strep throat and | Klepser D, Bisanz SE, Klepser ME. Cost-effectiveness of pharmacist-provided |
| provided medication for positive results through the research project. The cost | treatment of adult pharyngitis. The American Journal of Managed Care. April 2012. |
| | https://europepmc.org/abstract/med/22554040 |

| associated with providing the treatment was compared to 5 physician-provided | |
|---|---|
| treatment strategies for strep throat. Pharmacist treatment of strep throat was | |
| the most cost effective. | |
| The provision of preventive services at community pharmacies is shown to be | San-Juan-Rodriguez A, Newman TV, Hernandez I, et al. Impact of community |
| effective at increasing immunization rates, supporting smoking cessation, | pharmacist-provided preventive services on clinical, utilization, and economic outcomes: An umbrella review. Preventive Medicine, 2018. |
| managing hormonal contraceptive therapies, and identifying patients at high | https://www.ncbi.nlm.nih.gov/pubmed/30145351 |
| risk for certain diseases. | |
| 3,726 patients were screened for depression by pharmacists during the study period. A total of 67 (1.8%) patients screened positive on the PHQ-2. Of the | Rosser S, Frede S, et al. Development, Implementation, and Evaluation of Pharmacist-Conducted Screening Program for Depression. Journal of the American |
| patients who completed the PHQ-9, approximately 25% met the criteria for | Pharmacists Association. Feb 2013. https://www.sciencedirect.com/science/article/pii/S1544319115302831?via%3 |
| consideration of diagnosis and were referred to their physician. Five patients | Dihub |
| presented with suicidal thoughts and were referred for urgent treatment. | |
| Approximately 60% of patients with a positive PHQ-9 had initiated or modified | |
| treatment at the time of follow-up. Using the PHQ, pharmacists were able to quickly | |
| identify undiagnosed patients with symptoms of depression. | |
| Pharmacist-initiated HCV screening in community pharmacy assists with | Isho N, et al.; "Pharmacist-initiated hepatitis C virus screening in a community |
| identifying patients at risk for HCV infection and provide patients with linkage to | pharmacy to increase awareness and link to care at the medical center."; Journal of the American Pharmacists Association; March 2017. |
| care. | https://www.japha.org/article/S1544-3191(17)30136-X/pdf |
| In Michigan, a pharmacist-provided HIV testing model, which incorporated rapid | Darin KM, et al.; "Pharmacist-provided rapid HIV testing in two community |
| HIV testing, counseling, and linkage to confirmatory HIV testing services, was | pharmacies;" Journal of the American Pharmacists Association; Feb 2015. |
| developed and implemented. Approximately 42% of the participants stated it was | https://www.japha.org/article/S1544-3191(15)30015-7/pdf |
| their first HIV test, many of whom reported high-risk behaviors in prior 6 months. | |
| This project demonstrated the acceptability and feasibility of pharmacist- | |
| provided rapid HIV testing and increase access of care | |
| within the community. | |
| A literature review showed that community pharmacy conducted and analyzed | Buss V.H., Naunton M. Analytical quality and effectiveness of point of care testing |
| point-of-care tests had satisfactory analytical quality. This review further | in community pharmacies: A systematic literature review. Res. Soc. Adm. Pharm. 2019;15:483–495. doi: 10.1016/j.sapharm.2018.07.013. |
| supports that community pharmacies are well positioned to deliver a wide range of | 2017,13.403-473. doi: 10.1010/j.sapiiai iii.2010.0/.013. |
| point-of-care tests and will allow for patients to have increased access to various | |
| screenings. | |

| Appendix #3: | | | | | |
|--|--|---|--|--|--|
| State Opportunities for Pharmacy Care | | | | | |
| Preventive Care | Chronic Care | Acute Care | | | |
| | | Test and Treat for Seasonal Influenza and Group A | | | |
| Immunizations | Statin Therapy for Diabetes | Streptococcal Pharyngitis | | | |
| Immunization rates continue to hit below national benchmark goals. With numerous, convenient locations and extended hours, pharmacists provide an ideal option for patients to receive their vaccines and quality care. | With access to patients' medication history records, and occasionally patients' diagnoses, pharmacists are able to identify patients who have not filled a statin or have not appropriately continued therapy. Pharmacist interventions have shown to improve statin uptake and adherence. ¹⁴ | Expanded authority to test and treat for influenza and strep throat increases access to care and supports community antibiotic stewardship efforts. Sixteen (16) states allow pharmacists to test and treat patients as a result of a CLIA-waived test. | | | |
| Tobacco Cessation Services | Medical Devices | Treat Uncomplicated Minor Ailments | | | |
| Pharmacist-led smoking cessation interventions have been shown to be an effective approach to reduce smoking. ¹⁵ Twelve (12) states allow expanded pharmacist authority to initiate tobacco cessation aids. | It is not often realized that prescriptions are needed to purchase medical devices via insurance. At point of dispensing and counseling, pharmacists are knowledgeable which devices are necessary for patients, thus expanded pharmacist authority prevents unnecessary delay in patient access and poor medication administration. | When dealing with acute, minor conditions, convenient and accessible care is desired by most. Pharmacists are not only accessible, but well-positioned to provide prompt and affordable care. | | | |
| Hormonal Contraceptives | Additional Services: | Additional Services: | | | |
| Expanded pharmacist authority to initiate hormonal contraceptives increases access to care. Currently, ten (10) states/jurisdictions allow pharmacists to initiate contraceptives without a collaborative practice agreement. | Diabetes Management Hypertension Management Anticoagulation Asthma/COPD | Travel Health Services Cough/Cold Management | | | |
| HIV Prevention | Mental Health | | | | |
| Many states, including New Mexico, Iowa, and Washington, have piloted studies that show pharmacist-run, or pharmacist-involved, PrEP clinics are an effective way to increase uptake of the medication, which can then lead to decreased HIV | Pain Management | | | | |

¹⁴ Bui A, Kwon J, Kim J, Lucas, A. Overcoming Barriers to Statin Adherence. June 2019. https://www.uspharmacist.com/article/overcoming-barriers-to-statin-adherence
15 Khan N, Anderson JR, et al. Smoking Cessation and Its Predictors: Results from a Community-Based Pharmacy Tobacco Cessation Program in New Mexico. The Annals of Pharmacotherapy.
September 2012. https://naspa.us/wp-content/uploads/2018/10/Khan.-Smoking-Cessation-New-Mexico.pdf

| transmission. ^{16,17,18} To improve access to emergency PEP, New York allows pharmacists, through a non-specific patient order, to provide 7 days of PEP to patients without a prescription. ¹⁹ | |
|---|--|
| Naloxone | |
| States across the nation recognize the impact pharmacists can provide in helping improve access to care related to substance abuse. Currently, all 50 states authorize pharmacists to dispense naloxone, of which 28 states have expanded pharmacist authority to initiate naloxone. ²⁰ | |
| Additional Services: | |
| Health Screenings Health and Wellness Services | |

¹⁶ Ryan K, Lewis J, Sanchez D, et al. The Next Step in PrEP: Evaluating Outcomes of a Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic. ID Week 2018 Poster Abstract Session. Oct 2018. https://idsa.confex.com/idsa/2018/webprogram/Paper72194.html

¹⁷ Hoth A, Shafer C, et al. Iowa TelePrEP: A Public-Health-Partnered Telehealth Model for HIV Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State. Sexually Transmitted Diseases. May 2019. https://www.ncbi.nlm.nih.gov/pubmed/31157732

¹⁸ Tung EL, Thomas A, Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. Sex Health. Nov 2018. https://www.ncbi.nlm.nih.gov/pubmed/30401342

¹⁹ New York State Education Department, Pharmacy Unit. §6801. Definition of practice of pharmacy. http://www.op.nysed.gov/prof/pharm/article137.htm

²⁰ NASPA 2019. https://naspa.us/resource/naloxone-access-community-pharmacies/