

Tammy R. Beckham, DVM, PhD
Director, Office of Infectious Disease and HIV/AIDS Policy
U.S. Department of Health and Human Services
330 C Street, S.W.
Suite L100
Washington, D.C. 20024
Sent via email to: NVP.RFI@hhs.gov

October 24, 2019

Re: Request for Information (RFI) from Non-Federal Stakeholders: Developing the 2020 National Vaccine Plan

Dear Dr. Beckham:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to respond to the Office of Infections Disease and HIV/AIDS Policy's Request for Information (RFI) from Non-Federal Stakeholders: Developing the 2020 National Vaccine Plan. Our recommendations are intended to support increasing lifespan immunization rates by focusing on improving vaccine accessibility and strengthening our vaccine infrastructure.

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. Chains employ nearly 3 million individuals, including 157,000 pharmacists. 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.

NACDS offers recommendations aimed at increasing overall immunization rates across the country by broadly and comprehensively increasing the accessibility of vaccines to Americans and strengthening the vaccine infrastructure. The literature demonstrates that community-based pharmacies are integral to achieving these objectives — and we recommend that the 2020 National Vaccine Plan support and measure the following to enhance comprehensive **patient access** to all vaccine delivery options:

- Standardized, national authority for all qualified vaccine providers, including pharmacists in the community setting, to administer all recommended vaccines across ages and states without unnecessary restrictions;
- Payment parity across settings, providers, and insurance plans for adequate and consistent coverage and payment for the administration of immunizations for all beneficiaries, including the

consistent coverage and reimbursement of community pharmacy-based vaccine services and delivery;

And, to improve and advance the vaccine infrastructure:

- 3) Increase direct payment opportunities for vaccine providers, including pharmacists, for contribution to improving vaccination rates and improving quality scores across all vaccine types and quality programs to sustain and incentivize vaccine delivery; and
- 4) Standardize immunization information system (IIS) data and visibility requirements across all providers and settings of vaccine delivery in all states to improve the ability of vaccine providers to identify vaccination gaps and act on them.

A. Background: Community Pharmacy's Proven Ability to Expand and Improve Vaccination Delivery As the most accessible and most frequently visited<sup>1,2,3</sup> member of the healthcare team, pharmacists are particularly well positioned to continue expanding access to vaccination assessment, education, and delivery in neighborhoods across the country. In fact, pharmacists have successfully provided vaccines to patients in the U.S. for more than two decades. A 2017 study found that each additional year of exposure to pharmacy-based immunization services was associated with greater odds of patients reporting receipt of 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 pharmacydelivered immunization services each year. 4 Specific to influenza vaccination, similar findings have been reported including that policy changes permitting pharmacist immunization resulted in immunization coverage rates rising from 32.2% in 2003 to 40.3% in 2013.5 In 2018, the CDC reported that 32.2% of all influenza vaccinations were administered at a pharmacy.<sup>6</sup> Further, a 2019 study found that a community pharmacy vaccination program demonstrated a 74% increased vaccination rate for pertussis<sup>7</sup> 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.8 A 2018 study that modeled the clinical and economic impacts of using pharmacies to administer influenza vaccinations estimated that including pharmacies in addition to other locations for vaccination (e.g. clinics, physician

<sup>&</sup>lt;sup>1</sup> Manolakis PG, Skelton JB. Pharmacists' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Provider. Am J Pharm Educ. Dec 2010. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/

<sup>&</sup>lt;sup>2</sup> Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. <a href="http://www.ncmedicaljournal.com/content/78/3/198.full">http://www.ncmedicaljournal.com/content/78/3/198.full</a>

<sup>&</sup>lt;sup>3</sup> Wright, D, Twigg, M. (2016). Community pharmacy: an untapped patient data resource. Integrated Pharmacy Research and Practice. 5:19-25

<sup>4</sup> https://www.japha.org/article/S1544-3191(18)30231-0/pdf

<sup>&</sup>lt;sup>5</sup> https://www.sciencedirect.com/science/article/pii/S0149291817307713?via%3Dihub

<sup>&</sup>lt;sup>6</sup> CDC. Influenza: General Population Early Season Vaccination Coverage. 2018. <a href="https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm">https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm</a>

<sup>&</sup>lt;sup>7</sup> 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

<sup>8</sup> https://www.ncbi.nlm.nih.gov/pubmed/21864625

offices, urgent care centers) could prevent up to 16.5 million symptomatic influenza cases and 145,278 deaths at an estimated cost savings of \$4.1 to \$11.5 billion.<sup>9</sup>

As the literature demonstrates, extending pharmacist authority to provide immunizations has improved vaccination coverage. <sup>10</sup> Pharmacies have also been shown to be a cost-effective healthcare setting for providing immunization services. <sup>11</sup> For these reasons, CDC has supported pharmacists as fully recognized vaccine-providers. <sup>12</sup> Not only does care improve while avoidable total costs decrease, but patients experience greater choice in healthcare options that are accessible and more affordable for them when pharmacists can better offer and sustain vaccine delivery. We appreciate the opportunity to provide feedback on the development of the 2020 National Vaccine Plan and look forward to partnering with the Department of Health and Human Services (HHS) to achieve the final priorities and objectives.

## B. NACDS Recommendations for 2020 NVP Priorities Improve vaccine accessibility Improve infrastructure to support vaccine delivery

NACDS recommends that increasing lifespan immunization rates should be a priority for the 2020 National Vaccine Plan, with a focus across all patient age groups as recommended by the Advisory Committee on Immunization Practices (ACIP). Research has shown that immunization rates can be improved when vaccines are more accessible to patients – and there is a strong infrastructure to support their delivery. The imperative to include both accessibility and vaccine infrastructure as priorities in the NVP is described below:

#### Improving the Accessibility of Vaccines

NACDS recommends that the NVP make improving the accessibility of vaccines a priority given that convenience is often cited as an influential contributing factor of vaccination uptake and is an important aspect of reducing vaccine hesitancy.<sup>13</sup> Vaccine convenience includes not only the physical location and hours of vaccine delivery, but also the ability to afford vaccination.

**Physical location.** Over 90% of Americans live within 5 miles of a pharmacy and research indicates that pharmacies are the most visited healthcare setting. Pharmacies also offer expanded hours, many even

<sup>&</sup>lt;sup>9</sup> Bartsch SM et al. <u>Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic.</u> Vaccine (2018)

<sup>&</sup>lt;sup>10</sup> Drozd EM, Miller L, et al. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States. Aug 2017. Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004. <a href="https://www.ncbi.nlm.nih.gov/pubmed/28781217">https://www.ncbi.nlm.nih.gov/pubmed/28781217</a>

<sup>&</sup>lt;sup>11</sup> Burson, R., Buttenheim, A., Armstrong, A. et al. (2016). Community Pharmacies as Sites of Adult Vaccination: A systematic review. *Human Vaccines & Immunotherapeutics*, 12:12, 3146-3159.

<sup>12</sup> https://stacks.cdc.gov/view/cdc/50403/cdc 50403 DS1.pdf

<sup>13</sup> https://www.sciencedirect.com/science/article/pii/S0264410X15005009

<sup>&</sup>lt;sup>14</sup> 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

24 hours a day 7 days a week with a pharmacist on site. The reach of community pharmacies across rural and urban, including underserved areas, can help address the disparities in immunization rates across different locales, populations and cultural groups. Pharmacists are well positioned to improve vaccination rates, as indicated above, and studies show that community pharmacies are accessible care settings for receiving immunization and that pharmacists are not shifting patient populations from medical clinics into pharmacies, but are instead identifying new, previously unvaccinated populations for immunization. <sup>15</sup> Therefore, pharmacists complement the efforts of other healthcare professionals to fill immunization gaps and support synergistic vaccine access strategies. One study showed that between August 2011 and July 2012, pharmacists administered 6,250,402 vaccinations, of which 30.5% were provided during off-clinic hours, 17.4% were provided on weekends, 10.2% in the evenings, and 2.9% during holidays – underscoring that consumers seeking immunizations through community pharmacies were utilizing services during non-traditional hours. <sup>16</sup>

Convenience and access are important aspects of improving immunization rates across age groups – for busy parents who seek vaccines for themselves and their children, for older adults, and especially for reaching adolescents and millennials. In fact, this study also revealed that patients accessing vaccinations during hours when traditional vaccine providers are unavailable are more likely to be younger than 65 years of age. Further, patients younger than 18 years of age received vaccinations during these "off-clinic hours" more than any other age-group in the study. The CDC reports that influenza vaccination rates are lower for younger people, specifically in the preliminary analysis for flu season 2017-2018, coverage for adults 18-49 years was 26.9% and 59.6% among adults ≥65 years. <sup>17</sup> According to an article published in the official journal of the American Academy of Pediatrics, the current healthcare system has not adequately met the vaccination needs of the adolescent population in the United States over the years. However, overall vaccine rates could potentially be increased through complementing the efforts of primary care physicians with efforts to deliver vaccines in other healthcare settings that adolescents tend to frequent, such as pharmacies. 18 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. 19 According to the Kaiser Family Foundation, 45% of 18 to 29 year olds report no primary care provider, compared with only 12% of people age 65 and older. 20 Given such trends, the broad availability of vaccines at community pharmacies without unnecessary restriction creates alternative opportunities to improve vaccination rates and herd

<sup>&</sup>lt;sup>15</sup> Steyer TE, Ragucci KR, Pearson WS, Mainous AG 3<sup>rd</sup>; "The role of pharmacists in the delivery of influenza vaccinations"; *Vaccine*; 2004;22(8): 1001-1006.

<sup>&</sup>lt;sup>16</sup> Goad, J., Taitel, M., Fensterheim, L. et al. (2013). Vaccinations Administered During Off-Clinic Hours at a National Community Pharmacy: Implications for Increasing Patient Access and Convenience. *Annals of Family Medicine*, 11(5), 429-436.

<sup>&</sup>lt;sup>17</sup> https://www.cdc.gov/flu/fluvaxview/coverage-1718estimates.htm

<sup>&</sup>lt;sup>18</sup> Schaffer, S., Fontanesi, J., Rickert, D., Grabenstein, J., Rothholz, M., Wang, S., et al. (2008); "How Effectively Can Health Care Settings Beyond the Traditional Medical Home Provide Vaccines to Adolescents?; *Pediatrics (Vol. 121, pp. S35-S45)*.

<sup>&</sup>lt;sup>19</sup> https://www.forbes.com/sites/allbusiness/2018/11/27/millennial-expectations-fundamentally-changing-healthcare-landscape/#3f96577a7fe5

 $<sup>\</sup>frac{\textbf{20}}{\textbf{https://www.beckershospitalreview.com/patient-flow/millennials-are-upending-the-primary-care-model-4-things-to-know.html}$ 

immunity, especially with the potential to improve health and vaccine coverage among "harder-to-reach" populations.<sup>21</sup>

To date, pharmacists can vaccinate for influenza, pneumonia and herpes zoster in all 50 states. For example, a CDC-funded adult immunization initiative identified strategies to boost pharmacy-based immunizations through increased stakeholder collaboration. More than 300 pharmacies across four states explored and developed approaches to incentivize community pharmacies and other stakeholders to improve rates for influenza, pneumococcal, and herpes zoster vaccine, in addition to pertussis. This 2016-2017 collaborative effort resulted in 304,405 immunizations administered with the most consistent increases across all sites seen for influenza (20-45%) and pertussis (13-74%) vaccines.<sup>22</sup>

However, such authority is not expanded to all vaccines nor all age groups and requirements for prescriptions or protocols is variable across the country. Building on innovations over the last two decades, pharmacists can improve vaccination rates more broadly if they could comprehensively offer the full gamut of vaccines to the entirety of the population they serve. Unfortunately, their ability to do this is hampered due to restrictive and inconsistent state laws that restrict the type of vaccines they can provide and the age of patients they can serve. Unnecessary restrictions on pharmacists' ability to immunize patients based on age, type of vaccine, and/or requirements for prescriptions or protocols vary widely by state, despite similar and comprehensive requirements for pharmacist education and training on vaccine delivery and administration. Based on an analysis 24 from 2016,

- 17 states allow pharmacists to independently administer select vaccines, and in some of the 17 states, only a few vaccines can be independently administered
- 28 states, DC, and Puerto Rico, allow pharmacists to provide immunizations only following prescriber-issued protocols or prescriptions, depending on the patient's age and/or specific vaccine.
- 5 states use the most restrictive model which limits patient care access and choice, only allowing pharmacists to immunize through a prescriber-issued protocol

In sum, as a strategy to mitigate this issue and improve patient access and convenience to vaccine delivery, NACDS recommends the NVP support and measure the expansion and standardization of state laws for all qualified vaccine providers, including pharmacists in the community setting, to administer all recommended vaccines to the broadest extent to best serve the public, without restriction on vaccine type, patient age, or administrative requirements like prescriptions and protocols.

<sup>&</sup>lt;sup>21</sup> Goad JA, Taitel MS, Fensterheim LE, Cannon AE; "Vaccinations Administered During Off-Clinic Hours at a National Community Pharmacy: Implications for Increasing Patient Access and Convenience"; *Annals of Family Medicine*; 2013;11(5): 429-436.

<sup>&</sup>lt;sup>22</sup> NACDS. (2018). CDC Project – Immunization Rates and VBM.

<sup>&</sup>lt;sup>23</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741029/

<sup>&</sup>lt;sup>24</sup>https://www.pharmacytimes.com/publications/supplementals/2017/immunizationsupplementjune2017/authority-and-scope-of-vaccination-how-states-differ

Payment Parity. Out of pocket costs have been frequently cited as a barrier to vaccination, even as the most significant predictor of vaccine abandonment.<sup>25</sup> In fact, the Community Preventive Services Task Force, overseen by CDC, recommends interventions that reduce out of pocket costs based on strong evidence of effectiveness in improving vaccination rates, based on a systematic review completed in 2009 which included 20 studies.<sup>26</sup> Another study published in December 2018 found that mean out of pocket costs were higher for individuals who abandoned the herpes zoster vaccine compared to those who did not. Data analyses indicated individuals with out-of-pocket costs of \$80–\$90 were 21% more likely, and those with out-of-pocket costs >\$90 were 90% more likely to abandon than those with out-of-pocket costs <\$80.<sup>27</sup>

Further, patients have inconsistent insurance coverage across settings for vaccination.<sup>28</sup> This greatly hinders patient access to vaccines and limits the ability for pharmacies and other vaccine providers to more broadly improve vaccination rates. Medicare beneficiaries face challenges especially around costsharing for Part D vaccines at pharmacies, Medicaid coverage varies state by state, and there is variable coverage by commercial plans.<sup>29</sup> Despite the ACA mandate to cover vaccines without cost sharing, this does not always apply to all plans (grandfathered plans) nor does it always apply to all settings (e.g. out of network physician practices, pharmacies). 30 Some reimbursement issues arise due to coverage for the product but not the administration of the vaccine by a pharmacist. Further, many insurers do not cover pharmacy-administered vaccines or cover only a limited selection of vaccines at pharmacies.<sup>31</sup> In fact, based on research conducted by the UCLA Center for Health Policy, expanding coverage of all adult vaccines as a pharmacy benefit of all public and commercial insurance plans would improve vaccination rates especially in patient groups with socioeconomic challenges at highest risk for vaccine-preventable disease, based on experience of the Medi-Cal program in California.<sup>32</sup> After the Medi-Cal program adopted such a policy in 2016, it saw significant increases in the number of doses administered. During 2016 and 2017, the number of flu, pneumococcal disease, and shingles vaccine doses administered to Medi-Cal participants increased by 44.4%.33

Given the direct correlation between vaccine cost and uptake, NACDS recommends the NVP support and measure payment parity across settings, providers, and insurance plans for adequate and consistent coverage and payment for the administration of immunizations for all patients, including the consistent and complete coverage and reimbursement of community pharmacy-based vaccine services and

 $<sup>\</sup>frac{25}{https://www.ajpb.com/journals/ajpb/2016/AJPB\ JulyAugust2016/factors-associated-with-zostavax-abandonment\#sthash.85nSmz1P.dpuf$ 

<sup>&</sup>lt;sup>26</sup> https://www.thecommunityguide.org/sites/default/files/assets/Vaccination-Reducing-Out-of-Pocket-Costs.pdf

<sup>&</sup>lt;sup>27</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313857/

<sup>&</sup>lt;sup>28</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741029/

<sup>&</sup>lt;sup>29</sup> "These services are free only when delivered by a doctor or other provider in your plan's network" <a href="https://www.healthcare.gov/coverage/preventive-care-benefits/">https://www.healthcare.gov/coverage/preventive-care-benefits/</a>

<sup>30 &</sup>quot;Copays vary by plan" https://www.medscape.org/viewarticle/830835 3

<sup>&</sup>lt;sup>31</sup> http://newsroom.ucla.edu/releases/requiring-insurers-to-cover-retail-pharmacy-vaccinations-for-adult-californians-could-save-lives-study-finds

<sup>32</sup> http://healthpolicy.ucla.edu/publications/Documents/PDF/2018/immunizationbarriers-brief-aug2018.pdf

<sup>33</sup> Ibid.

**delivery**. Such action would not only improve patient access, but would also incentivize pharmacies and other vaccine providers to more broadly and proactively target patients for vaccination without payment barriers.

## Strengthening the Vaccine Infrastructure

Sustainability of Vaccine Delivery - Direct Payment Opportunities. Quality measurement is emerging as a promising strategy and potential mechanism to overcome some of the barriers associated with improving immunization rates.<sup>34</sup> Vaccine-related measures appear in Federal quality initiatives, including the 2019 MIPS and MSSP programs. However, while most vaccine providers have the opportunity to earn incentives for improving rates of influenza and pneumonia vaccine coverage through such programs, there is opportunity to expand incentives to improve uptake of other important vaccines.<sup>35</sup> Strides are being made to better measure healthcare quality for additional vaccines. In fact, CMS proposed an adult composite immunization (Adult Immunization Status – AIS) measure for potential use in 2020 MIPS and MSSP programs.<sup>36</sup> Unfortunately, pharmacies, for example, do not have any direct opportunity to receive incentives for increasing vaccination coverage and uptake due to exclusion from participation in Federal healthcare quality programs to date. NACDS recommends the NVP support and measure direct payment opportunities for vaccine providers, including pharmacists, for contribution to improved vaccination rates and improved quality scores across all providers, vaccine types, and quality programs to sustain and incentivize vaccine delivery.

Immunization Information Systems (IIS). Based on findings from 240 articles and abstracts, the Community Guide found that IIS demonstrate ability to facilitate increasing vaccination rates.<sup>37</sup> Specifically, the studies described or evaluated IIS capabilities to: (1) create or support effective interventions to increase vaccination rates, such as client reminder and recall, provider assessment and feedback, and provider reminders; (2) determine client vaccination status to inform decisions by clinicians, health care systems, and schools; (3) guide public health responses to outbreaks of vaccine-preventable disease; (4) inform assessments of vaccination coverage, missed vaccination opportunities, invalid dose administration, and disparities; and (5) facilitate vaccine management and accountability.<sup>38</sup>

For IIS to be best utilized and leveraged as a valuable public health tool, all providers need to be actively engaged and committed to its use. Evidence shows that pharmacists can contribute in improving the vaccine delivery infrastructure by collecting and tracking important health-related information including connecting to and communicating with public health agencies, such as through state-based IIS. <sup>39</sup> For

<sup>34</sup> https://avalere.com/insights/emerging-opportunities-to-drive-adult-immunization-through-quality

<sup>35</sup> https://www.healthaffairs.org/do/10.1377/hblog20190522.213919/full/

<sup>&</sup>lt;sup>36</sup> https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-P.html

<sup>&</sup>lt;sup>37</sup> https://journals.lww.com/jphmp/Fulltext/2015/05000/Immunization Information Systems to Increase.2.aspx

<sup>&</sup>lt;sup>38</sup> Ibid

<sup>&</sup>lt;sup>39</sup> Isenor, J., Edwards, N., Alia, T. (2016). Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis. Vaccine, 34(47) 5708–5723.

example, the 2016-2017 CDC-funded adult immunization initiative found that pharmacy-based demonstration projects had success with connecting to and reporting immunization data to state-based registries. However, the lack of consistent reporting and visibility into vaccination registries for patients across states, providers, and settings hinders the value of IIS to improve vaccination rates and other benefits as listed above.<sup>40</sup> Pharmacists in particular often lack bidirectional access – the ability to both see and contribute information.<sup>41</sup> Based on an analysis<sup>42</sup> published in 2015,

- 31 (58.5%) jurisdictions mandated at least 1 type of provider or entity to report immunizations and 22 (41.5%) had no mandate to report immunizations
- 21 of the 31 (67.7%) mandated all immunization providers to report, 27 (87.1%) mandated public health providers to report, 23 (74.2%) mandated Vaccines for Children providers to report, 21 (67.7%) mandated private providers to report, and 22 (71%) mandated pharmacies/pharmacists to report
- 12 of the 31 (38.7%) mandated that immunizations for all age groups be reported and 17 (54.8%) mandated that immunizations for children/adolescents/young adults (with upper age limits ranging from 18 to 26 years of age) be reported but not immunizations for adults
- 2 (6.3%) programs mandated reporting of immunizations for only young children (with upper age limits of 6 or 7 years of age)
- 26 of the 31 (83.9%) mandated that the report be to the IIS, 3 (9.7%) mandated that the report be to local public health, and 2 (6.3%) mandated that the report be to both local public health and the IIS

NACDS recommends the NVP support and measure standardized registry data and visibility requirements across all providers and settings of vaccine delivery in all states to improve the ability of vaccine providers to identify vaccination gaps and act on them, among other benefits, to improve vaccination rates. As detailed above, research has demonstrated that community pharmacies can improve immunization rates across populations by making vaccines more accessible. The 2020 National Vaccine Plan should encourage states and Federal policymakers to address barriers to improve access and the vaccine infrastructure by eliminating unnecessarily restrictive state laws, inconsistent payment/reimbursement coverage, variable IIS, and increase well-rounded incentive opportunity for pharmacists and other providers to advance immunization coverage across the country.

# C. NACDS Recommendations for 2020 NVP Goals, Objectives and Strategies

NACDS provides the following recommendations for 2020 NVP goals, objectives, and strategies to improve lifespan immunization rates by expanding access to vaccines and strengthening the vaccine infrastructure.

https://www.healio.com/infectious-disease/news/print/infectious-disease-news/%7B5aa0df49-3774-45f1-bda2-dc2f89bb1633%7D/progress-on-the-horizon-to-implement-lifelong-immunization-registries

<sup>41</sup> https://www.pharmacytoday.org/article/S1042-0991(16)30702-2/fulltext

<sup>42</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4671281/

## I. Priority: Improving the Accessibility of Vaccines

#### Goals:

- Expand the ability of patients to receive vaccines comprehensively at all sites of vaccine delivery, including pharmacies
- Ensure patients are able and encouraged to choose convenient, accessible opportunities for vaccination delivery that best meets their needs, without excess burden or restriction
- Improve the complete and consistent insurance coverage for vaccination to minimize costsharing/out of pocket costs for the public

#### Objectives:

- Ensure all qualified vaccine providers, including pharmacists, have standardized, national authority to administer all ACIP-recommended vaccines across ages and states without a prescription/protocol, providing the opportunity to more broadly improve vaccination rates and increase access to vaccines for patients
- Encourage all health plans and payers to offer complete and consistent insurance coverage for vaccination across all states, settings, and providers to improve patient access and vaccine affordability

#### Strategies:

- Facilitate dialogue and collaborate with state-level entities and policymakers, such as state medical boards, state boards of pharmacy and state boards of nursing, who typically regulate the ability of providers to administer vaccines
- Vocalize support for the value of pharmacists and other community-based providers to improve immunization rates through improved patient access and the need to reduce undue restrictions that prevent providers from more broadly expanding vaccine access
- Develop and support policies which provide standardized, national authority for all qualified vaccine providers, including pharmacists in the community setting, to administer all recommended vaccines across ages and states without unnecessary restrictions
- Create an evidence-based directive and imperative for all health plans, including commercial plans, state Medicaid plans, and Medicare plans for consistent and comprehensive coverage for all vaccinations (including mitigation of out of pocket costs for patients) in all community-based settings, including pharmacies
- Support policies for consistent and comprehensive vaccine coverage and payment at pharmacies
- Conduct a pilot project that tests or studies pharmacist expanded scope of practice to administer the full gamut of vaccinations
- Conduct a pilot project that tests or studies consistent and comprehensive insurance coverage for vaccine delivery across all settings and providers

## II. Priority: Strengthening the Vaccine Infrastructure

#### Goals:

- Create and expand direct payment opportunities for all vaccine providers to incentivize and sustain vaccine delivery
- Improve accountability and ability for vaccine providers to leverage IIS to improve and advance vaccination delivery

## Objectives:

- Increase the opportunity for vaccine providers to receive incentives for improving vaccination rates across all providers, vaccine types, and programs, including direct payment opportunities for pharmacists providing vaccinations in community pharmacies
- Include additional vaccine quality metrics and incentives outside of only influenza and pneumonia in existing Federal healthcare quality programs through the broad adoption of composite measures (e.g. Adult Immunization Status measure AIS) or other means
- Create opportunities for direct pharmacy incentives for vaccine uptake and coverage of their populations; currently there are no direct incentives for pharmacy-level quality measurement
- Conduct a pilot project that tests or studies direct payment opportunity for pharmacy performance on vaccine-related quality metrics
- Encourage standardization of IIS data and visibility into the registry across all providers of vaccines, all patient ages, and all states

#### Strategies:

- Support direct payment/incentive opportunity based on vaccine-related quality measures
- Create and encourage an evidence-based directive and imperative for CMS to include pharmacists as eligible providers in Federal quality programs for incentivizing vaccine uptake
- Facilitate discussion and collaborate with health plans, including commercial, Medicaid, and Medicare plans, for direct payment opportunity for community-based vaccination delivery, including pharmacy-based vaccination delivery and pharmacy-level vaccine-related quality measures
- Develop and support policies for the use of more comprehensive vaccine quality measurement, such as the use of an adult composite measure (e.g. Adult Immunization Status – e.g.), in all applicable quality programs
- Foster collaborations between states, community pharmacies, medical settings and state Immunization Information Services to share data on immunization status and rates

### D. NACDS Recommendations for 2020 NVP Indicators

As outlined above, 2020 National Vaccine Plan goals should be updated to include a focus on lifespan immunization rates across all age groups, which remain low with room for improvement and often below national goals. For example, the CDC recently report that 65% of pregnant mothers in the US have not received recommended vaccinations (flu and Tdap).<sup>43</sup> The 2020 plan should set goals and measure

<sup>43</sup> https://www.cdc.gov/media/releases/2019/p1008-vaccination-moms-babies-unprotected.html

progress for the adult immunization schedule, as recommended by the ACIP, which includes influenza, pneumococcal, herpes zoster, Tdap, among others depending on indication. Objectives and indicators should be updated to reflect new research and recommendations from the ACIP.

However, the goals for adult immunization can only be achieved if there is access to vaccines and providers that can administer them in a cost-effective manner. The 2010 National Vaccine Plan's Midcourse Review included important indicators of access and coverage, such as the percentage of states that allowed pharmacists to administer vaccines and whether Medicaid programs covered ACIP-recommended vaccinations. The 2020 National Vaccine Plan should build on these indicators to encourage and measure access to community pharmacies and payment and coverage for immunizations delivered by pharmacists in these settings given the evidence on the impact of these providers and cost-effective care settings on adult immunization rates.

Meaningful Measures. In January 2019, NACDS sent HHS a letter with recommendations to inform the development of Healthy People 2030 (HP 2030). We believe it is beneficial to align the final HP 2030 objectives with the 2020 National Vaccine Plan to ensure that Federal, state, and external stakeholders are working towards the same public health priorities. In addition, dissemination and updates to goals and objectives should be coordinated with the Centers for Disease Control and Prevention (CDC) and the ACIP. NACDS recommends the NVP indicators are synergistic with the final HP 2030 objectives, and ACIP recommendations.

NACDS recommends that the 2020 National Vaccine Plan maintain the domestic indicators listed below from the 2016 National Vaccine Plan Mid-course Review: 44

- Percentage of adults aged >19 years who have one or more immunizations recorded in an IIS;
- Increase the percentage of children aged <6 years whose immunization records are in a fully operational, population-based IIS;
- Decrease the percentage of children in the United States who receive 0 doses of recommended vaccines by 19 to 35 months of age;
- Increase the percentage of adults who are vaccinated against zoster (shingles);
- Increase coverage with the recommended number of doses of HPV for females by 13 through 15 years of age;
- Percentage of pregnant women who report receiving influenza immunization during pregnancy;
- Percentage of states and territories that allow pharmacists to administer all routinely recommended vaccines for adults aged >19 without a patient-specific prescription; and
- Percentage of state Medicaid programs that provide coverage of all ACIP/CDC-recommended vaccinations for adults and prohibit cost sharing.

<sup>44</sup> https://www.hhs.gov/sites/default/files/nvpo-midcourse-review-final.pdf

NACDS recommends that the 2020 National Vaccine Plan include the indicators outlined below on lifespan immunization, as well vaccine accessibility and infrastructure:

## 1. Lifespan Immunization

- Percentage of noninstitutionalized persons aged 6 months and older who are vaccinated annually against seasonal influenza;
- Percentage of pregnant women who receive one dose of Tdap during pregnancy;
- Individual immunization objectives included in HP2020 for all ages for human papillomavirus, pneumococcal, shingles, and hepatitis B for health professionals updated to reflect current recommendations by the Advisory Committee on Immunization Practices (ACIP) and HP2030;
- An adult Immunization Composite Measure to assess overall completion of recommended vaccines for adults; and
- A Hepatitis B vaccine objective for full population (not only health professionals).

## 2. Vaccine Accessibility

- Measuring rates of commercial and government payer reimbursement of pharmacists in community pharmacy care settings for administration of ACIP-recommended vaccines;
- Measuring rates of commercial and government payer coverage for vaccines in all settings without out of pocket costs for beneficiaries; and
- Rates of broad community-based vaccine providers' ability to vaccinate (e.g. measuring pharmacist ability to provide all vaccines across all ages and states without restrictions such as protocols or prescriptions).

#### 3. Vaccine Infrastructure

- Rate of standardized reporting of all vaccines/ages across all vaccine providers to IIS;
- Rate of bidirectional functionality for pharmacists for all vaccines and ages, across all states;
- Rate and breadth of vaccine-related quality measures currently in use in Federal healthcare quality programs;
- Pharmacy opportunity to participate and be directly paid for performance on vaccine-related quality measures; and
- Percentage of Physicians Sharing Data with Other Providers and Hospitals (National EHR Survey).<sup>45</sup>

## E. NACDS Recommendations for 2020 NVP Stakeholders

Improving lifespan immunizations is a public health priority across HHS; however, accomplishing the final goals and objectives will require leadership and coordination within the Department and with external stakeholders. NACDS welcomes the opportunity to work with OIDP and other key agencies and offices to achieve the goals in the 2020 National Vaccine Plan. Pharmacists can play a large role in providing

<sup>&</sup>lt;sup>45</sup> Furukawa, M. F., King, J., Patel, V., Hsiao, C., Adler-Milstein, J., & Jha, A. K. (2014). Despite Substantial Progress In EHR Adoption, Health Information Exchange And Patient Engagement Remain Low In Office Settings. *Health Affairs*, 33(9), 1672-1679. doi:10.1377/hlthaff.2014.0445.

education on recommended vaccinations and delivering them in accessible, cost-effective community pharmacy care settings – especially for underserved populations.

Aside from coordination with HP2030 goals and ACIP, OIDP should also coordinate with states to modernize the ability of all vaccine providers, including community pharmacists, to administer all vaccinations to all indicated populations. Coverage and payment for vaccines administrated pharmacists and in pharmacy care settings is also essential to improving access and overall lifespan immunization rates — which will require encouraging forward thinking policies among payers, especially CMS.

Last, we recommend that OIDP hold regular opportunities for 2020-2025 key Federal agencies and offices across HHS, States and external stakeholders to convene on progress on the indicators in the 2020 National Vaccine Plan – and to identify and share strategies that are working from community to community.

#### Conclusion

As a committed partner to public health agencies in advancing population health, NACDS applauds OIDP's work in updating the National Vaccine Plan and looks forward to being an active partner in achieving the final goals and objectives. We appreciate the opportunity to provide comments to the OIDP to improve the health of the communities we serve.

Steven C. Anderson, IOM, CAE

President and Chief Executive Officer