



## The Role of Pharmacists in Public Health Response

### Introduction

Pharmacists' public health roles and responsibilities have expanded in recent years in response to public health emergencies (PHEs), providing greater access to services within communities. From the mid-1990s through the COVID-19 pandemic, the role of pharmacists has evolved to be more public-health focused.<sup>1 2</sup> Services commonly provided by pharmacists now include patient education, medication management, immunization, screening, and treatment and pharmacist training to deliver these services is consistent nationwide. In addition, pharmacists are highly accessible, with more than 90% of Americans living within 5 miles of one of the more than 59,000 community pharmacies in the US.<sup>3 4 5</sup> Given this consistency in training and accessibility to the community, pharmacists are well positioned to be key partners in the delivery of public health services.<sup>6</sup>

Federal initiatives – such as the US Department of Health and Human Services (HHS) Vaccine National Strategic Plan and the Biden Administration's "Test to Treat" – have recognized the impact pharmacists can have in expanding access to public health services such as immunizations, testing and treatment to improve health outcomes and reduce disparities. For instance, the Vaccines National Strategic Plan includes a goal to eliminate barriers and incentivize vaccination in pharmacies<sup>7</sup>, while the Biden Administration's "Test to Treat" initiative aims to provide equitable access to healthcare by including pharmacies as sites where patients can receive both testing and treatment with oral antivirals.<sup>8</sup>

Ultimately, pharmacists can practice at the top of their license when they have both scope of practice authorization and reimbursement for such services. However, historically, variation in state scope of practice laws and the lack of reimbursement pathways have been and continue to be barriers to delivery of key public health related activities by pharmacists nationally. Notably, during the COVID-19 pandemic, scope of practice limitations were temporarily mitigated by the emergency declaration under the PREP Act, which pre-empted state and local scope of practice limitations in the areas of immunization administration, testing and treatment.<sup>9 10</sup> Further, flexibilities in pharmacist reimbursement for critical pandemic-related services were added towards the start of the pandemic through regulation.

Absent concerted policy action, the gains seen by communities across the nation during the pandemic from expanded pharmacist services will be at risk when the PHE ends. Therefore, federal policymakers must take immediate steps to establish a codified regulatory framework under Medicare for pharmacist delivery of certain immunizations, testing, and treatment as proposed in H.R. 7213.<sup>11</sup> Passing H.R. 7213 would not only establish appropriate payment to pharmacists for the services delivered, but also ensure continuity in equitable access to pharmacist services and improved care seen during the pandemic.<sup>9 10</sup> These changes will create

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the proper infrastructure to support pharmacists becoming permanent partners in our nation's response to public health crises.

The following sections outline the evolution of the public health importance of pharmacists and their ability to provide immunization, testing, and treatment services for infectious diseases. They also describe in greater detail the current challenges facing pharmacist involvement, including the wide variation in state scope of practice and reimbursement policies as well as Medicare payment to pharmacists being limited to the administration of immunizations. In each section, considerations for policymakers are provided to mitigate the barriers pharmacists currently face in delivering these critical services.

## **Overview of Pharmacists' Role as Public Health Partners**

Pharmacists help address healthcare gaps that disproportionately affect marginalized communities, including the 13% of US residents living in a county with a primary care physician (PCP) shortage.<sup>12</sup> Notably, rural residents are 5 times as likely to live in a county with a PCP shortage.<sup>12</sup> Since these areas often need to rely on access to non-physician healthcare providers for care, pharmacists have filled this gap in several important ways. Integration of pharmacists into care teams for patients in underserved areas has been demonstrated to improve outcomes for a range of conditions, such as diabetes.<sup>5</sup> Pharmacists often provide medication management services, including through telepharmacy, allowing them to address health gaps in underserved areas.<sup>13</sup> As pharmacy scope of practice has expanded, pharmacists have become key public health educators, counseling patients on conditions including diabetes, smoking cessation, hypertension, and substance abuse.<sup>14</sup> A study in rural Montana showed that 15 out of 17 pharmacies that performed blood pressure drug management interventions saw improved patient medication adherence, from 73% to 89% in 3 years.<sup>15</sup> Supporting pharmacists' delivery of immunization, testing, and treatment services can expand the impact of these community-based clinicians as public health partners.

## **Immunization**

### **Scope of Practice**

Pharmacists, aided through expanded scope of practice laws, have become essential vaccinators. After the role pharmacists played during the H1N1 pandemic, in large part due to pharmacists participation as mass immunizers under Medicare, all states quickly responded by expanding pharmacists' scope of practice to permit vaccine administration.<sup>16</sup> Pharmacists' administration of immunizations has been critical for preventing infectious diseases such as influenza, shingles, hepatitis A, hepatitis B, and pneumonia.<sup>17 18 2</sup>

Pharmacy immunization has increased vaccine uptake.<sup>19</sup> A meta-analysis of 21 pharmacy immunization program studies found that most programs (84%) where patients accessed

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vaccinations through a pharmacy increased utilization and affordability.<sup>20</sup> During the H1N1 influenza pandemic, pharmacists were essential in providing education and immunizations to patients.<sup>21</sup> In 1997, just 5 million doses of influenza vaccines were administered in 15,000 community pharmacies. By 2011-2012, 280,000 pharmacists had been certified to administer vaccines and delivered 26.6 million\* doses, 20% of influenza vaccines given that year.<sup>22 23</sup>

In August 2020, HHS amended the emergency declaration under the Public Readiness and Emergency Preparedness (PREP) Act to allow pharmacists to order and administer all ACIP recommended vaccines to individuals ages 3 and older, including COVID-19 vaccines.<sup>9</sup> Because it pre-empts state law, the PREP Act broadly allows administration of vaccinations by pharmacists to additional age groups and vaccines beyond those that may be allowed under state law. Pharmacists have been essential in enabling mass vaccination. Over 41,000 pharmacy retail locations in the US in the Federal Retail Pharmacy Program have administered more than 258.1 million doses of COVID-19 vaccines.<sup>24</sup> Additionally, there has been an increase in pharmacist-administered influenza vaccines. In the 2020-2021 flu season, pharmacies were the primary providers of flu vaccines for adults 18 years and older and were the second-leading providers of flu vaccines for children ages 6-18.<sup>22</sup> Pharmacists delivered approximately 50% of influenza vaccines, or approximately 98.8 million† doses.<sup>25</sup>

Pharmacy-based vaccination efforts also provide significant downstream economic benefits including: reduced infection rates, reduced subsequent healthcare costs, and lower cost of vaccinations.<sup>26 27</sup> For example, one meta-analysis found that influenza vaccination in pharmacies can prevent 23.7 million symptomatic influenza cases, resulting in cost savings of \$2.8 billion to payers and \$99.8 billion in societal costs such as lost productivity.<sup>26</sup>

One remaining barrier for immunization is that pharmacist's scope of practice varies by state. Differences include the age of patients pharmacists can immunize, requirements for consent from a child's parent or guardian, specific vaccines that may be administered, and whether a prescription is required or the pharmacist can provide the immunization based on a prescriber collaborative protocol or state standing order.<sup>28</sup> For example, 27 states allow pharmacists to administer all vaccines on the CDC immunization schedule for children from birth to 6 years old, while 18 states prohibit pharmacists from administering vaccines to children under 7 years of age.<sup>29 30</sup> Absent state action to expand scope of practice, pharmacists' ability to deliver certain immunization services may be limited following the end of the PHE, when the PREP Act flexibilities are no longer in effect.

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\* Number of doses administered in pharmacies were calculated based on the percentage of total doses and the percentage of pharmacy doses estimated by the CDC.

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## Reimbursement

Payers reimburse pharmacies for the vaccine product plus a separate administration fee. However, reimbursement varies by plan with some reimbursing under a medical benefit, and others via a pharmacy benefit. Additionally, some payers do not reimburse for the administration service and some only choose to reimburse certain vaccines.

Medicare Part B has traditionally reimbursed pharmacists only for influenza and pneumococcal vaccines, and only if they are enrolled as mass immunizers. Other commercially available vaccines are reimbursed under Part D.<sup>18</sup> Pharmacists' status as mass immunizers and eligibility for payment under Medicare Part B has been a key driver making pharmacy-based vaccination services widely available.

In March 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act added COVID-19 vaccines to Medicare Part B coverage.<sup>31</sup> Soon after, in interim final rule CMS-9912-IFC, CMS added COVID-19 vaccines to roster billing, thereby permitting mass immunizers, including pharmacists, to bill for COVID-19 vaccines.<sup>32</sup> While not explicitly codified in regulation, CMS is expected to continue allowing roster billing and reimbursement for COVID-19 vaccines under Part B. Alignment of state scope of practice laws allowing pharmacists to perform these services and reimbursement for such services is essential for broad pharmacist participation.

## Testing

### Scope of Practice

Prior to the COVID-19 pandemic, pharmacist testing services were underutilized due to state scope of practice laws restricting pharmacists from administering tests.<sup>33</sup> In 1992, Clinical Laboratory Improvement Amendments (CLIA) regulation allowed pharmacies to apply for waivers to administer low-risk point of care medical tests with a low error risk.<sup>34</sup> Since pharmacies have obtained CLIA waivers, pharmacists' provision of diagnostic services has contributed to the screening of both non-communicable (e.g., cardiovascular disease, diabetes)<sup>5</sup> and communicable diseases (e.g., human immunodeficiency virus (HIV), chlamydia, hepatitis C) in states that allowed pharmacists to administer tests.<sup>35 36 37</sup>

Many states do not include testing within pharmacists' scope of practice, and for those that do, policy for pharmacist CLIA-waived testing is often confusing or unclear.<sup>38</sup> For example, some states including CA and PA specifically outline which CLIA-waived tests pharmacists may administer.<sup>38</sup> Other states including WV and TX do not provide clear guidance on pharmacist administration of CLIA-waived tests.<sup>38</sup> Other scope of practice barriers include the absence of authority for collaborative practice agreements, where physicians delegate power to the pharmacist to make decisions on a patient's therapy. These agreements vary by state, but



usually can limit a pharmacist's ability to perform CLIA-waived testing apart from the collaborative agreement.<sup>38</sup>

The COVID-19 pandemic expanded pharmacist testing. Data from 2015-2020 show that 70% of the growth in number of pharmacies with CLIA waivers occurred from 2019-2020 due to the pandemic.<sup>39</sup> On May 19, 2020, HHS issued an advisory opinion stating that the agency's guidance under the PREP Act preempts state and local practice limitations on pharmacists' ability to order or administer FDA-approved COVID-19 countermeasures, including diagnostic tests.<sup>40 41</sup> Since then, testing has expanded, speeding time to treatment and facilitating improved clinical outcomes as community pharmacies created COVID-19 testing sites.<sup>42</sup> Testing for influenza and Group A Streptococcus has also grown.<sup>43</sup>

Absent action by states, the ability for pharmacists to provide testing services may once again be limited by state scope of practice restrictions. Additionally, without policy to ensure CLIA-waived testing is properly reimbursed, pharmacies may be discouraged from providing these services and rates of testing may decline to pre-pandemic rates.

## Reimbursement

Prior to the pandemic, payment for pharmacist-administered tests depended on whether payers chose to contract with pharmacies for this service, resulting in both limited and inconsistent payment. Under Medicare regulations, pharmacies could enroll as CLIA-waived labs but would not be paid unless the tests were ordered by a physician. Following HHS amendments to the emergency declaration under the PREP Act, pharmacists can order, render, and be paid for certain CLIA-waived tests. These amendments resulted in a rapid increase in the number of pharmacies with CLIA-waivers. Between 2015 and 2020, there was a 45% increase in CLIA-waived community pharmacies for a total of 4,865 new locations.<sup>39</sup> From 2019 to 2020 the number of pharmacies with CLIA waivers grew from 12,157 to 15,671, a 22% single-year increase.<sup>39</sup>

However, there is still wide variability between states on the number of pharmacies with CLIA waivers. As of 2021-2022,<sup>†</sup> over 60% of pharmacies in some states (e.g., CO, ID) have CLIA waivers, while in other states (e.g., NY, MA) that percentage is under 15%.<sup>44 3</sup> Overall, the rapid rise in the number of pharmacies enrolling as CLIA-waived labs during the pandemic indicates that pharmacists will fill public health gaps for services within their license when the opportunity arises, but payment and scope of practice laws must be aligned. Absent a consistent mechanism allowing payment to pharmacies for testing, it is likely that pharmacies will no longer enroll as CLIA-waived labs, and the availability of community-based testing at

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<sup>†</sup> The percentage of pharmacies with CLIA waivers per state was estimated using total pharmacy per state data from IQVIA and state CLIA-waived pharmacy data from CMS.





pharmacies will likely decline. Allowing payment to pharmacists for CLIA-waived testing under Medicare will support continued investment in delivery of these services.

## Treatment

### Scope of Practice

Prior to the PHE, prescribing authority was typically limited by states to specific circumstances or products. In some states pharmacists can prescribe oral and/or injectable contraceptives.<sup>36</sup> States including CO and OR allow pharmacists to distribute emergency refills without a prescription for chronic care management.<sup>38</sup> OH permits pharmacists to authorize emergency refills up to 3 times in any 12 month period.<sup>45</sup> Additionally, some states (i.e. CA, CO, and OR) allow pharmacists to prescribe pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).<sup>46</sup> Many states allow pharmacists to dispense naloxone for opioid overdose management without a prescription through standing orders, naloxone provision protocols, or pharmacists as provider mechanisms.<sup>47</sup> Pharmacists in 4 states are allowed to dispense naloxone without a prescription, and 16 states and DC have specific conditions under which pharmacists are allowed to prescribe naloxone.<sup>47</sup>

Pharmacist prescribing and treatment authority, including the ability to refill maintenance medications without a prescriber order, has expanded during the COVID-19 pandemic as a result of the emergency declaration under the PREP Act.<sup>48 49</sup> Treatment has also expanded through test-to-treat programs for COVID-19.<sup>50</sup> Recently, the FDA authorized pharmacists to prescribe Paxlovid under its emergency use authorization.<sup>51</sup> However, in order to prescribe Paxlovid, pharmacists must have updated health records regarding certain conditions, and if information is deemed insufficient, the pharmacist must consult with the patient's health care provider to obtain patient medication and health condition history.<sup>51</sup>

### Reimbursement

Reimbursement for pharmacist treatment services (e.g., patient evaluation and prescribing) is uncommon and largely dependent on state Medicaid program policy or individual payers. For example, many Medicaid programs allow for the reimbursement of pharmacist prescribed pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), although this varies by state.<sup>52</sup> However, as states allow pharmacists to engage in treatment, and prescribing protocols are established, having a payment mechanism in place is critical to enable pharmacists to deliver these services.

## Conclusion

Policymakers have increasingly authorized pharmacists to provide services beyond dispensing. As pharmacy scope of practice has expanded, many healthcare services have become more accessible to patients, including several services specifically aimed at addressing public health

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needs such as immunizations, testing, and treatment. The COVID-19 pandemic has given pharmacists a chance to contribute to national public health measures in a way that meaningfully changed patient outcomes. However, current policies limit the ability of pharmacists to provide certain public health services due to scope of practice policies and/or insufficient reimbursement. Outside of the PHE, pharmacists rely on state scope of practice to determine which services they may provide.

### Call to Action

- As the PHE and its related policies end, state governments should take action to ensure the meaningful expansion of pharmacy scope of practice remains.
- Action should be taken at the federal level to ensure that, as states expand scope of practice, appropriate payment is in place to ensure that services within pharmacists' scope of practice can be delivered.
  - H.R. 7213, introduced March 24, 2022, would achieve this by recognizing pharmacists as providers under Medicare for certain immunization, testing, and treatment services beyond this PHE.
  - Not only would federal action ensure consistent payment for Medicare beneficiaries, but it may also impact a broader group of consumers since states and commercial payers often align their policies with Medicare.
  - Ultimately, federal action will help ensure that pharmacists can continue serving the role they have assumed as public health partners.

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