Unlocking the Unrealized Potential of Adult Immunization

A NEHI White Paper

NEHI Network for Excellence in Health Innovation

The COVID-19 Pandemic Puts Adult Immunization in the U.S. in a New Light

The United States is currently in the grip of an unprecedented global pandemic. While an intensive effort is underway to develop a coronavirus vaccine, as of now there is no guarantee when or if an effective vaccine may be available.

Nevertheless, the COVID-19 outbreak creates urgent new impetus for health care policymakers to assess and improve the state of adult immunization in the United States. New action is needed to raise rates of adult immunization that continue to fall well short of the levels necessary to blunt the yearly impact of influenza and other vaccine-preventable diseases, and to better prepare the country for the impact of diseases like COVID-19.

This paper is the result of an assessment of adult immunization policy that NEHI undertook in 2019, including insights from a meeting of public and private sector experts convened in Washington in July 2019, well before the first outbreak of the coronavirus.

There have been several significant developments in adult immunization policy and practice over the last decade. For example, the Affordable Care Act mandated that most private sector health insurance plans offer coverage with no co-pay obligations for vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). The ACA also mandated coverage of a free (no co-pay) annual wellness visit with a physician for every Medicare beneficiary, creating a new opportunity for physicians to assess patients' immunization status every year and offer needed immunizations. Over the same period of time community pharmacies continued to play an increasing role in administering yearly influenza immunizations. Flu shots are now more conveniently accessible. Building on this, states across the country have continued to expand the authority of community pharmacists to administer other, non-flu immunizations, increasing access and availability.

Immunization rates for several ACIP-recommended vaccines have improved, most notably immunizations of older adults (60 years and over) for Herpes zoster (Shingles).[1] But immunization rates for other adult vaccines not only fall far short of 100 percent, but for younger (non-Medicare) adults they fall far short of the more modest goals set by the federal government's Healthy People 2020 national public health plan. By the end of the 2018-2019 flu season the overall adult immunization rate had not yet reached 50 percent, while among adults with high health risks aged 18-49 immunization rates for influenza had not exceeded 40 percent by 2018.[2]

Before the coronavirus pandemic struck the U.S., estimates of the impact of adult immunization underscored how high the stakes are for patients at risk, and for the health care system as a whole. Through early March (2020) estimated that hospitalizations attributed to influenza totaled between 370,000 and 670,000 cases.[3] A recent (2016) analysis of the cost burden of vaccine-preventable disease on health care in the U.S. estimated the impact at $9 billion per year, two-thirds of which can be attributed to preventable influenza. Even then, this estimate does not encompass the longer-term burden of care for illness and disability caused by vaccine-preventable disease.[4]

COVID-19 is now putting the care of patients with health risks to a severe test As work continues to find effective vaccines and treatments for COVID-19 there can be little debate that we must continue to improve the rate of adult immunization in the U.S. As this paper will outline, adult immunization policy remains a patchwork. While insurance coverage of adult immunization is more favorable than it was in the past, coverage still varies considerably between public health insurance programs and health plans in the private sector, creating confusion and complexity, and depressing uptake of immunizations among patients who still face out-of-pocket cost obligations. Performance incentives available to traditional immunizers, such as hospital systems and physician practices, are not generally or directly available to the community pharmacies that are increasingly well positioned to expand outreach to adults who are not up to date on immunizations. Immunization information systems that enable all immunizers to access reliable information on patient immunization histories have grown throughout the country, but their capabilities still vary, as do requirements for submitting immunization data to them.

If a coronavirus vaccine does reach approval in the future, it will increase the urgency for improvement in adult immunization, but there is no reason to await this event. Policymakers should take a few critical steps now.

Executive Summary:

In the last decade health insurance coverage of adult immunizations has improved significantly and yearly immunizations for influenza have become increasingly more convenient, but these improvements have not succeeded in raising adult immunization rates to the levels set by national health policy goals or the levels needed for national emergency preparedness.

Meanwhile, U.S. health care payers continue to shift payments for health care providers towards value-based payment arrangements, including incentives for improved population health. Lagging rates of adult immunization represent a drag on this movement towards value-based care. Vaccine-preventable disease imposes an annual cost estimated at $9 billion on the health care system and falls most heavily on highly vulnerable patients often targeted for value-based care, such as older patients and patients with multiple chronic conditions.

The odds that any one adult is up to date on recommended immunizations depends in large part on the type of insurance coverage he or she has, and the state in which he or she lives. Coverage of immunizations is not consistent across all types of health insurance, and laws and regulations that govern who can administer immunizations are not consistent across states and localities.

Subject to a mandate of the Affordable Care Act, adults with ACA-regulated health insurance no longer pay an out-of-pocket cost for recommended immunizations. But many Medicare, Medicaid, and some individuals with ACA-regulated insurance still face out-of-pocket costs that deter immunizations, including costs incurred when immunizations are delivered outside a prescribed provider or pharmacy network.

Community pharmacists now administer over a third of all flu shots in the country, and evidence shows that community-based immunization is effective in raising immunization rates. But state regulations are inconsistent and without regard to evidence based impact. A community-based immunizer's authority differs from state to state, vaccine by vaccine, by the age of the patient, and by other factors. This patchwork deters consistent public health messaging to promote adult immunization and creates cost and complexity for pharmacists and other immunizers attempting to screen, administer and bill their services.

Closing gaps in adult immunization will require:

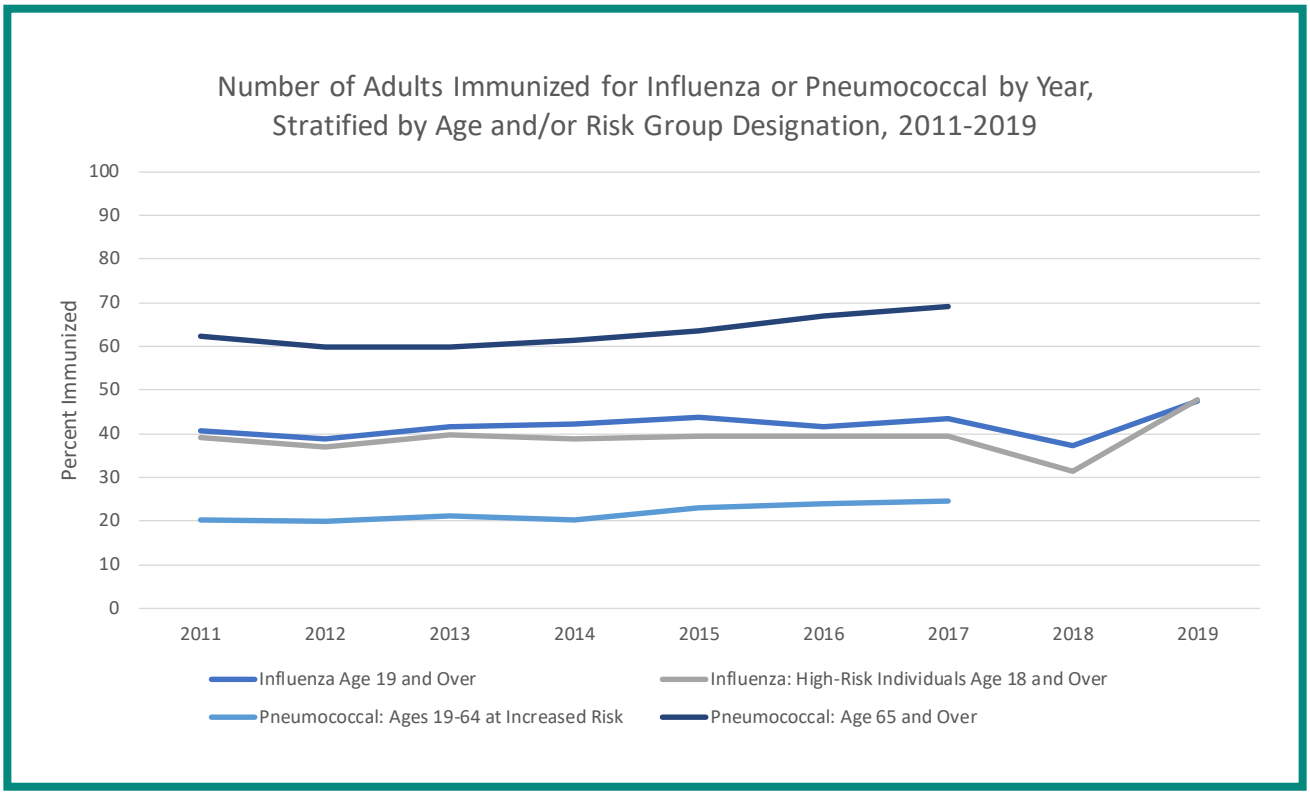
1. Parallel action to reduce out of pocket cost barriers across all types of insurance coverage;

2. Harmonization of state-level requirements for community-based immunizers such as community pharmacists;

3. Improved immunization information systems that serve both traditional immunizers (such as physician offices) and community-based immunizers; and

4. New incentives to encourage immunizers in all part of the emerging "immunization neighborhood" of traditional and community-based immunizers.

Continued innovation is needed to demonstrate how full alignment of capabilities and incentives throughout the "immunization neighborhood" will raise lagging rates of adult immunization. As a step towards coordinated action the CMS Innovation Center should welcome community-wide and multi-payer experiments in raising adult immunization rates.



i. "Flu Vaccination Coverage, United States, 2018–19 Influenza Season," Centers for Disease Control and Prevention, last reviewed September 26, 2019, https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm.

ii. "Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2017," Centers for Disease Control and Prevention, last reviewed February 8, 2018, https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html.

Background

Progress may be fitful, but U.S. health care payers still aim to shift the U.S. health care system away from piecemeal, fee-for-service payment. This shift is moving health care providers toward alternative payment models, such as payment under Accountable Care Organization models, which reward delivery of care that meets quality standards and produces positive patient outcomes at sustainable rates of health care spending. Secretary of Health and Human Services Alex Azar has described the shift as the country's "only option" for delivering better care at sustainable costs.[5] A fundamental principle of the shift to value is that health care payment should reward and even incentivize evidence-based, high-value medical services.

Adult immunization is, first and foremost, an intervention for saving lives and safeguarding public health. Immunizations for influenza and other vaccine-preventable diseases among adults are consistently rated at or near the top of all evidence-based health care practices. As such, adult immunization can play a key role in the health care system's shift to value in at least three ways: preventing illness among the healthy, reducing transmission of illness from the healthy to the sick (that is transmission of those vaccine-preventable diseases that are contagious), and preventing or reducing the impact of illness among vulnerable or chronically ill individuals. Chronically ill persons are at greatly elevated risk for complications if they contract influenza, pneumonia or other vaccine-preventable diseases.[6]

Careful management of high-risk, chronically ill patients has become an important goal of health care providers operating under value-based payment models. For example, through early March of 2020 the CDC estimates that 35.5 million illnesses, 490,600 hospitalizations and over 35,000 deaths occurred as a result of influenza during the 2018-2019 flu season.[7] Influenza immunizations prevented some 58,000 hospitalizations and an estimated 3400 deaths.[8] A recent (2016) analysis of the cost burden of vaccine-preventable disease on health care in the U.S. estimated the impact at $9 billion per year, two-thirds of which can be attributed to preventable influenza. Even then, this estimate does not encompass the longer-term burden of care for illness and disability caused by vaccine-preventable disease.[9]

However, the full value of adult immunization to the U.S. health care system has yet to be realized. Flu immunization rates in recent years have fluctuated from 60-76 percent among Medicare-eligible (65+) adults, and between 40-47 percent among the population aged 50-65 years old.[10] The CDC estimates that influenza immunization rates among high-risk individuals aged 18-49 never exceeded 40 percent in 8 years from 2010-2018, a period in which the Affordable Care Act extended first-dollar (no co-pay) immunization coverage to patients covered under ACA-regulated health plans.[11] Adult immunization rates fall far short of the goals outlined in the Department of Health and Human Services decennial Healthy People strategic plan, and far short of the 80 percent benchmark the federal government has set for emergency response to influenza pandemic. Before the onset of the COVID-19 pandemic, Secretary Azar had described the threat of flu pandemic as "the single greatest biodefense threat our country faces."[12] Yearly influenza immunization rates would need to increase by 50% or more to reliably meet the 70% goal set by the Healthy People 2020 strategic plan. Gaps in immunization with other CDC-recommended immunizations persist among adults of all ages.[13]

These shortfalls in adult immunization persist despite important progress achieved in recent years. Three developments are most notable.

1 First as noted above, in 2010 the Affordable Care Act mandated that private health insurance plans cover influenza immunization and other immunizations recommended by the CDC's Advisory Committee on Immunization Practices (ACIP), with no out-of-pocket cost to the patient. [14] The ACA's zero cost-sharing mandate extends to over 50 percent of individuals in the U.S. These are individuals covered by fully insured plans (individual and small group plans), and self-insured plans offered by employers and unions. (As of 2019 approximately 13 percent of private sector employees were covered in health plans "grandfathered" and still exempt from the ACA mandate on zero cost sharing.[15])

2 Second, nearly every state has extended authority to pharmacists to administer immunizations. Over one-third of all yearly influenza immunizations are now administered to adults by pharmacists in the community, and pharmacists play a key role in targeted immunization campaigns against serious public health problems such as local outbreaks of Hepatitis A and Hepatitis B.[16] Immunization at community pharmacies has vastly expanded the network of immunizers available to reach out to individuals indicated for immunizations or immunization updates.

3 Third, a growing list of innovative pilot projects in both the physician office setting and in community pharmacies have demonstrated that well-designed, pro-active strategies can raise adult immunization rates, as compared to the results of usual care. Some of the most innovative projects have shown that immunization rates can be raised among hard-to-reach adults, such as adults with inconsistent histories of immunization, and among adults with chronic illness who are at high-risk of severe medical complications from contracting influenza or other vaccine-preventable diseases.[17]

These innovations have not yet translated to the health care system at large, as is clear from the nation's low rates of adult immunization. It seems apparent that the existing adult immunization ecosystem, from insurance benefit design, to provider incentives, to supportive infrastructure such as immunization registries, is not adequate to boost adult immunization rates and close the gap with national goals such as those outlined by the Healthy People 2020 strategic plan, soon to be superseded by Healthy People 2030.

Rising Rates of Adult Immunization -- Recommendations for Action

The lagging rates of immunization among American adults are often contrasted to the higher rates of immunization among children. Despite recurring controversies over mandated immunizations of children, pediatric immunization rates remain over 90 percent in most states.[18]

Three aspects of pediatric immunization policy stand out that contrast with adult immunization policy.

1. Immunization mandates increase immunization rates among children. In most states, children must be immunized in order to attend school, unless their families formally opt-out of immunization. For adults, immunizations are elective.

2. Families face lower barriers from out-of-pocket costs for immunizing their children. The same Affordable Care Act mandate that eliminates out-of-pocket costs for adult immunizations applies as well to pediatric immunizations. Co-payments may apply in situations when an adult or a child receive an immunization at a site outside their insurance carrier's provider network (further details below), but children can be immunized for free under the federal Vaccines for Children (VFC) program if their families cannot afford out-of-pocket costs.

3. Immunization data and data exchange are well established and better supported for pediatric immunizations. Most states have maintained pediatric immunization data registries for decades. Pediatric immunization registries maintain immunization histories that are available to support timely administration of immunizations to kids by physicians or by other qualified immunizers. Adult immunization registries (immunization information systems – IIS) are a more recent innovation. As will be noted below, requirements to report adult immunizations to registries are inconsistent from state to state, as is exchange of data with the community pharmacies that now play an increasingly prominent role in delivering influenza immunizations and, depending on local law and regulation, other immunizations as well.

State and federal courts have generally upheld state-mandated or employer-mandated immunizations for health care workers, such as hospital employees and nursing home staff.[19] Immunizations are required for members of the military as well, subject to certain defined exemptions.[20] The COVID-19 pandemic may revive debate about the imposition of employer-mandated immunizations in other, non-health care industries in which employees come into regular contact with the public.[21] For now, raising rates of adult immunization will require raising the odds that adults in need of a recommended immunization are (1) identified by authorized immunizers when an immunization is appropriate and indicated for the immunization due to their age, prior immunization history, or their individual health risks[22]; (2) made aware of their immunization status; (3) face lower barriers to access, such as barriers imposed by out-of-pocket cost obligations, and (4) gain convenient access.

NEHI recommends action in four areas, based on current literature and NEHI's outreach to public health, provider, health care payer, and biopharma experts:

- **Affordability**: Reach adults who do not stay up to date with recommended immunizations due to the burden of out-of-pocket costs.
- **Access:** Expand the role of community pharmacists in delivering adult immunizations through expanded scope-of-practice, reimbursement and performance incentives.
- **Information:** Invest in further development of accurate, real-time sources of adult immunization status accessible to all immunizers
- **Innovation:** Invest in innovation that demonstrates the optimal role of adult immunization in the system-wide shift to value-based care – and in pandemic preparedness as well.

Affordability: Reach adults who do not stay up to date with recommended immunizations due to the burden of out-of-pocket costs.

In 2014 the independent Community Preventive Services Task Force, the nation's leading arbiter of effective, evidence-based practices in population health, reaffirmed its finding that lowering out-of-pocket costs for patients improves adult immunization rates.[23] Out-of-pocket cost has been shown to be the single most reliable predictor of immunization abandonment; that is immunizations ordered for administration at a pharmacy, but abandoned because the patient fails to follow through to receive and pay for the immunization. Multiple research studies since 2014 have correlated higher immunization rates with insurance benefits that minimize or eliminate out-of-pocket cost obligations.[24]

The Affordable Care Act's mandate on coverage of preventive health services has expanded no-co-pay coverage of adult immunizations, but it does not guarantee that patients with ACA-regulated insurance will face no co-pays. Insurers may assess a co-pay for immunizations delivered at a site that is out-of-network (a provider or pharmacy network) under a patient's insurance coverage. Moreover, ACIP-recommended vaccines subject to the no co-pay mandate fall into two categories. Yearly influenza immunization and a few other immunizations are recommended for all adult patients under a so-called "full recommendation." Several other vaccines are also recommended conditionally, subject to the judgment of an individual clinician treating an individual patient. Immunizations in both categories are subject to the ACA's no –cost share mandate, but the conditional recommendations have engendered confusion among clinicians as to which immunizations are cost-free to patients, and which are not.[25]

Meanwhile, coverage of adult immunizations under the Medicaid program varies from state to state. States choose which immunizations to cover, and whether to impose cost-sharing fees on patients. A Kaiser Family Foundation survey conducted after implementation of the Affordable Care Act's Medicaid expansions suggested that approximately half of state Medicaid programs cover adult immunizations; most of these states impose no cost-sharing.[26] Medicaid now covers about one in five Americans, so that gaps in Medicaid coverage of adult immunizations, and immunizations without cost sharing in particular, represent a major lost opportunity for disease prevention.

Medicare's prescription drug insurance programs (Medicare Part D and prescription drug coverage under Medicare Advantage) are required to cover all ACIP-recommended immunizations but have no requirement for first-dollar coverage. Medicare Part B – the Medicare program that reimburses physicians and other professionals with legal status as Medicare providers – covers three immunizations without a patient co-pay (the annual influenza vaccine, pneumococcal vaccine, and Hepatitis B vaccination for certain high-risk patients), but provides little or no coverage for other ACIP-recommended immunizations, including immunizations for shingles. Meanwhile, community pharmacists generally have limited status to bill Medicare Part B for immunizations[27], while physicians have limited status to bill Medicare Part D for immunizations. As the insurer of nearly all of America's rapidly growing population of older patients, Medicare has a unique stake in realizing the long-term payoff of higher adult immunization rates. The "Protecting Seniors Through Immunization Act," introduced as identical, bipartisan bills (S. 1875 and H.R. 5076) would create consistent coverage of all ACIP-recommended vaccines across both Medicare Part B and Part D, including first -dollar coverage.

Recommendations:

1. Insurance coverage for ACIP-recommended adult immunizations should be complete and consistent across settings, immunization providers, and programs including Medicare, Medicaid, and commercial lines of business.

2. Patients should not be subject to cost-sharing for ACIP-recommended adult immunizations, including those covered under Medicare Part D.

3. All immunization providers should be compensated for both the immunization product and the immunization administration so that they can sustainably offer immunizations to patients.

Access: Expand the role of community pharmacists in delivering adult immunizations through expanded scope-of-practice, reimbursement and performance incentives.

As noted, influenza immunization in the U.S. is now delivered through a distributed network of immunizers that extends beyond traditional sites of care such as physician offices. Community pharmacists in particular play a key role in this emerging "immunization neighborhood," where they now deliver over a third of all yearly influenza immunizations. Community pharmacies have been called on to address other pressing needs as well, including administration of Hepatitis A and Hepatitis B immunizations in communities that have seen local outbreaks associated with the opioid addiction epidemic.[28] The immunization neighborhood is now regarded as essential infrastructure for the nation's emergency preparedness against infectious disease pandemics, such as a return of pandemic influenza.[29] The immunization neighborhood is also essential infrastructure for meeting national adult immunization goals such as those set by Healthy People 2020, soon to be superseded by Healthy People 2030.

Pharmacies enjoy an advantage in both convenience and cost over traditional sites of service. Over 90 percent of Americans live within 5 miles of a pharmacy, and most adults visit local pharmacies far more frequently than they visit their regular health care provider. A 2016 study of Medicaid recipients at high health risk found them ten times more likely to visit a pharmacy than any other health care setting.[30] An estimated 23 percent of American adults report that they have no regular relationship with a physician or other health care provider, and estimates range as high as 33 percent of all adults in some states.[31] Immunizations at pharmacies are available either on demand or with little advance notice, as opposed to appointment-based immunizations at physician offices or traditional clinics. One study conducted from 2011-2012 indicated that over 30 percent of immunizations delivered at pharmacies were delivered at hours when traditional clinical sites are typically closed, including over 17 percent provided on weekends.[32]

Community pharmacies often enjoy an advantage in operational efficiencies as well. Many pharmacies can keep immunizations in inventory more conveniently and at less cost than smaller physician practices. Data on administration of adult immunizations in the physician office and community pharmacy setting suggest that community pharmacies can be a lower cost provider, offering savings of up to 20 percent.[33] However, there are several persistent barriers that stand in the way of greater use of pharmacists as adult immunizers.

State laws and regulations determine which immunizations community pharmacists may lawfully administer. Nearly every state now allows pharmacists to administer at least some immunizations, and the long-term trend in so-called pharmacy scope-of-practice laws is one in which pharmacists are gaining increased authority.[34]

However, relatively few states allow community pharmacists to freely assess adult patients and administer immunizations on their own authority. A 2016 study found that only 10 states allowed pharmacists to administer certain immunizations without a prescription order from a physician or some other third-party authorization. Thirty-five states allowed pharmacists to administer certain immunizations under a general authorization, such as a standing order from physician groups that allows a pharmacist to administer an immunization without a patient-specific prescription. Many states restrict pharmacists to administer immunizations only to patients of a certain age, such as restricting immunizations to patients over the age of 16.[35] Pharmacists are allowed to administer the yearly flu immunization in nearly every state, but restrictions on their ability to administer other ACIP-recommended immunizations diminishes the advantage that community pharmacies enjoy as a convenient location for patients to seek out immunizations. 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 influenza or a pneumonia immunization. The 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.[36] Similar findings, specific to influenza immunization, suggest that growth in pharmacist-administered immunizations resulted in immunization coverage rates rising from 32.2% in 2003 to 40.3% in 2013.[37]

Second, immunizers often face a complex set of requirements for reimbursement of immunizations from health care payers, due in part to the inconsistencies in insurance coverage of adult vaccines cited earlier. For example, while the Affordable Care Act mandates that ACA-regulated health plans must cover ACIP-recommend vaccines at no out-of-pocket cost to patients, health plans may impose a co-pay on patients if

they receive an immunization from outside their provider or pharmacy network, thus creating extra billing requirements for out-of-network immunizers. The differing coverage policies in Medicare Part B and Medicare Part D also creates complexity that deters physicians, their staffs, and community pharmacists from offering immunizations. Research findings suggest that coverage of adult immunizations under both medical and pharmacy insurance benefits can lead to significantly higher rates of immunization.[38]

Stakeholder groups have called for a radical simplification of coverage and payment policy for immunizations. Adult immunizations could be covered wholly under insurance medical benefits, under prescription drug benefits, or equally in both, with consistent rules for reimbursement across all plans. (As noted the bipartisan Protecting Seniors Through Immunization Act would create Medicare Part B –Part D parity in the coverage and reimbursement of adult immunizations.[39]) Adult immunization could be designated as an "always in network" service, subject to delivery by any willing provider.

The combined effect of restrictive scope-of-practice regulation of pharmacists and variable, complex billing requirements is to reduce the impact of community pharmacy on adult immunization rates. The impact is further muted by a misalignment of performance incentives between traditional providers (physicians, hospitals and delivery systems) and non-traditional immunizers such as community pharmacists. The misalignment reduces the impact that pharmacists and the "immunization neighborhood" could play in the health care system's movement towards value-based care.

As it happens, improvements of adult immunization rates have been goals of quality improvement in health care for many years, albeit one set of goals among many other goals. For example, varying measures of influenza and pneumococcal immunization among health plan subscribers have been reported as HEDIS (Healthcare Effectiveness and Data Information Set) measures since the 1990s.

Measures of adult immunization have been incorporated within the alternative payment models (APMs) for provider payment and quality improvement programs for physician practices that health care payers, and the Medicare program in particular, have launched over the last decade. Quality measures and payment incentives for adult immunization continue to evolve. CMS has indicated support for use of a new measure of adult immunization status in both the Medicare Merit-based Incentive Payment System (MIPS) incentive program and the Medicare Shared Savings Program (MSSP) Accountable Care program.[40] The Adult Immunization Status measure is a composite measure that combines assessment of immunization rates across four ACIP-recommended immunizations, (influenza, pneumococcal, zoster (shingles), and tetanus-diptheria). For now, however, physicians reporting to MIPS can elect to choose 3 immunization measures (influenza, pneumococcal, and zoster) among a total of 250 total measures. Provider organizations participating in the Medicare Shared Savings Accountable Care Organization Program (MSP) must report on a measure of influenza immunization, but as of 2019 are no longer required to report on a measure of pneumococcal immunization. [41]

The adult immunization measures in MIPS and the ACO program both leave room for substantial performance improvement. Two immunization measures (influenza and pneumococcal immunization measures) were among the ten most frequently chosen measures in the MIPS program in its inaugural year, (2017. Approximately 40 percent of participating physicians choose the immunization measures and reported immunization rates of 71 percent for influenza and 74 percent for pneumococcal immunization. In the 2019

Medicare Shared Savings Accountable Care Organization Program, the median benchmark rate for the ACO influenza quality measure (benchmark for providers performing in the 50th percentile of participants) is set at a 50 percent immunization rate.

In both the MIPS and the Medicare ACO programs the immunization rates reported by providers are not only based on immunizations delivered by the provider, but on immunizations that are up to date as reported by the patient or by reference to an immunization registry ---- in effect, providers can claim credit for immunizations delivered elsewhere in the "immunization neighborhood." Medicare Advantage health insurance plans are also eligible for incentives based on similarly reported rates of influenza and pneumococcal immunizations.

This credit is not generally shared with all immunizers in the form of payment incentives. Pharmacies, for example, do not have a direct opportunity to receive incentives for increasing vaccination coverage and uptake at all due to exclusion from participation in Federal healthcare quality programs to date, despite the fact that pharmacies are increasingly contributing to improved immunization rates.[42] Adult vaccination performance metrics may influence community pharmacies indirectly by helping to qualify pharmacies to participate in payers' pharmacy networks. Payers may negotiate bonuses or shared-risk payment with network pharmacies but there is little public documentation that adult immunizations are part of performance rewards payers may be offering as part of pharmacy pay-for-performance contracts for flu and pneumococcal immunizations, much less for administration of other immunizations such as Hepatitis A and Hepatitis B.

Recommendations:

1. Increase the opportunity for all immunization providers to receive incentives for improving immunization rates across providers, immunization types, and programs. Specifically, include more immunization quality metrics and incentives outside of influenza and pneumonia in existing programs through the use of composite measures or other means.

2. Create opportunities for direct, pharmacy-level quality measures and incentives for providing immunizations to adults instead of through the existing indirect, misaligned incentive programs that pharmacies are currently subjected to - where even high performing pharmacies incur penalties.

Information: Invest in further development of accurate, real-time sources of adult immunization status accessible to all immunizers

For immunizers, knowing when an adult is due for a recommended immunization, and whether he or she might have received it already, is crucial information to ensure that immunizations are administered safely and effectively. Reliable, real-time information on patient immunization records, available to all qualified immunizers, is a crucial factor in improving adult immunization rates. In 2014 the U.S. Community Preventive Services Task Force made a formal recommendation in support of immunization information systems (IIS) as a population health intervention, citing "strong" evidence gleaned from a systematic review of peer-

reviewed literature.[43] Information available in real time is crucial, because it enables immunizers to make an immunization available when the patient is available to receive it: during a visit to a doctor's office, or a stop at a pharmacy, or at visits to other immunization sites. Reliable real-time information also enables pro-active screening and outreach to individuals who miss or avoid immunizations, and outreach to high-risk patients.

As of now, the primary sources of patient immunization histories are state-operated immunization information systems (IIS) or registries. State IIS programs have grown considerably over the last two decades, but they still vary considerably as sources of comprehensive, up-to-date information on patient immunization status.

A survey published in 2015 found that by 2012 every state had established some form of immunization information system (IIS) or registry, and nearly every state system (96%) included information on adult immunization of some kind. However, only 31 state systems imposed a reporting mandate of any kind. Only 21 of the 31 states with reporting mandates required all immunizers to report to the IIS, and only 12 of the 31 states required reporting on immunizations administered to all age groups, including adults. Only 21 of the 31 states with reporting mandates actively enforced the mandate, mostly with a penalty that limits an immunizer's access to publicly funded immunizations.[44]

Access to IIS data is also limited, depending on each state's law and regulations, and depending on the technical specifications of each state's IIS that determine whether immunizers can easily view or download immunization histories. In many states, pharmacies may be required to submit immunization data, but not allowed or enabled to view IIS data in return. The lack of consistent reporting and visibility into immunization registries for patients of all ages across states, providers, and settings leads to not only lack of complete patient records but also hinders patient care and opportunity to improve immunization rates.

Recommendation:

Consistent, nationwide policy on immunization information systems should move away from the current reliance on one-off, piecemeal, state by state requirements. Immunization reporting by all immunizers should be mandatory, and all immunizers should have visibility into patient immunization histories. Two-way information flows between traditional immunization sites (such as physician offices) and community-based sites (such as community pharmacies) will facilitate pro-active screening and outreach to adults in need of immunizations. Accurate, real time immunization information is also needed for immunizers to assume real accountability for outreach to adults in need of immunizations, such as the accountability required by value-based payment models.

Innovation: Invest in innovation that demonstrates the optimal role of adult immunization in the system-wide shift to value-based care – and in pandemic preparedness as well.

While the COVID-19 response has highlighted the need for emergency measures to contain outbreaks of infectious disease, it should also underscore the importance of routine public health and health care measures that build resilience among patients and maintains capacity in the health care system itself.

Routine, year-to-year administration of the ACIP-recommended immunizations among adults builds such resilience among patients. Raising the rates of adult immunization nationwide is critical for savings lives and reducing the cost burden of vaccine-preventable disease. In addition, it will also strengthen the health of adults susceptible to future mass outbreaks of infectious disease, whether or not those outbreaks prove as lethal as the coronavirus outbreak. Full use of community pharmacies and other sites in the broader immunization neighborhood will ensure that patient health is maintained in normal times, and capabilities are in place to respond when pandemics or other major disease outbreaks occur.

To that end, the federal government should encourage and provide incentives for further innovations that fully utilize the capabilities of the in the "immunization neighborhood." Innovation should be encouraged across all health insurance programs and facilitate cooperation among public and private payers in concert with the continued, system-wide movement towards alternative provider payment models. Since the benefits of improved immunization are diffused across entire patient populations, individual payers have a limited incentive to invest aggressively in adult immunization measures. For any one payer, the number of patient immunizations needed to yield a measurable reduction in disease and health care costs in the short term will be relatively high compared to other interventions, such as interventions to treat chronic disease or acute illnesses.

Innovation throughout the immunization neighborhood should remain an important goal for provider payment reform as well. Innovative approaches that make targeted investments in immunization across all payers in a health care market or region would demonstrate the potential of immunization in improving health and lowering baseline health care spending for all payers. For example, CMS is actively sponsoring demonstration projects for "Accountable Health Communities."[45] An extension of this model to incorporate innovative collaborations with community pharmacies on adult immunization could be created and targeted to populations that are high priorities for providers offering care under alternative payment models: high-risk patients, high-need patients, patient populations burdened by adverse social determinants of health and longstanding racial and ethnic disparities.

Recommendation:

In light of the coronavirus pandemic, the CMS should invite proposals for innovative, community-wide and multi-payer initiatives to increase rates of adult immunization at the local level, and to rapidly disseminate highly effective models. Proponents should build on results from recent pilot projects among physician practices and community pharmacies that demonstrate efficient strategies to introduce immunization promotion into the workflows of both sites of care Local initiatives should be designed to complement ongoing efforts by public and private payers to move provider payment toward effective population health management and value-based care in general.

Conclusion:

The concept of the "immunization neighborhood" spanning physicians' offices, other traditional clinics, community pharmacies, public health agencies and others is perhaps the most compelling example of a development many U.S. health policymakers claim to desire: a distributed network of professionals in which lower-cost sites of service have demonstrated an ability to deliver high-value services, leaving higher-cost sites (such as hospitals and physician offices) to focus on "top of the license" medicine. The result is more cost effective for the health care system as a whole.

Yet despite these signs of progress, adult immunization rates in the U.S. have essentially remained static. Existing incentives, including patient incentives, are failing to deliver significant and sustained improvements in immunization rates.

Gaps in adult immunization persist at a point in time when public and private payers are betting more heavily than ever that a system-wide shift to value-based provider reimbursement will deliver better patient outcomes at lower long-term costs of care. Better performance from the entire "immunization neighborhood" could lighten the load on providers grappling with the transition to value-based payment. State and federal policymakers should respond with a more coordinated effort to lower patient cost barriers, extend full immunization authority and reimbursement to all qualified professionals such as pharmacists, improve and align performance incentives for all adult immunizers, and improve immunization data systems that bind all immunizers together for safe and effective immunization delivery.

The onset of the coronavirus pandemic makes the case for a more aggressive and coordinated, system-wide approach to adult immunization stronger. Routine administration of the ACIP-recommended immunizations to U.S. adults builds up the health and resilience of all adults, including adults with high health risks who may be most vulnerable to epidemic or pandemic disease. Aggressive utilization of all immunizers – including community-based immunizers such as pharmacists –will also strengthen and maintain the health care system's capacity to respond to massive outbreaks of disease such as those we are witnessing now, including the ability to respond with new immunizations that may be ultimately developed to treat coronavirus or other disease threats not yet known

Author

Tom Hubbard, *Vice President of Policy Research,* NEHI

Research and Project Support

Madeline Cree, *Health Policy and Program Associate*, NEHI
Sarah Brewer, *Policy Intern*, NEHI

Layout and Design

Keyton Sheely, *Manager of Communications and Member Relations,* NEHI

Support

NEHI wishes to acknowledge the support of the **National Association of Chain Drug Stores** and **Merck** for its adult immunization project.

Recommendations in this white paper are based on NEHI research and multi-sector expert roundtable conducted in July 2019. NEHI is solely responsible for findings and recommendations made in the white paper.

About NEHI

NEHI is a national nonprofit, nonpartisan organization composed of stakeholders from across all key sectors of health and health care. Its mission is to advance innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent.

NEHI brings together expert stakeholder perspectives with relevant research to devise policies that speed the adoption of innovations.

References

1 "Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2017," Centers for Disease Control and Prevention, last reviewed February 8, 2018, https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html#flu.; See Figure One

2 "Estimates of Influenza Vaccination Coverage among Adults—United States, 2017–18 Flu Season," Centers for Disease Control and Prevention, last reviewed November 5, 2018, https://www.cdc.gov/flu/fluvaxview/coverage-1718estimates.htm.; See Figure Two

3 "2019-2020 U.S. Flu Season: Preliminary Burden Estimates," Center for Disease Control and Prevention, last reviewed March 13, 2020, https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm.

4 Mark Doherty et al. "Vaccine impact: Benefits for human health," *Vaccine* 34, no. 52 (2016): 6707-6714, doi: 10.1016/j.vaccine.2016.10.025.; Sachiko Ozawa et al. "Modeling The Economic Burden Of Adult Vaccine-Preventable Diseases In The United States," *Health Affairs* 35, no. 11 (2016): 2124-2132, doi: 10.1377/hlthaff.2016.0462.

5 Alex Azar III, "Remarks on Value-Based Transformation to the Federation of American Hospitals," (speech, Federation of American Hospitals, Washington, DC, March 5, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-value-based-transformation-to-the-federation-of-american-hospitals.html.

6 Mei Shang et al. "Influenza vaccine effectiveness among patients with high-risk medical conditions in the United States, 2012–2016," *Vaccine* 36, no. 52 (2018): 8047-8053, doi: 10.1016/j.vaccine.2018.10.093.; for full schedule of adult vaccine recommendations relative to high-risk individuals see "Table 2. Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2020," Centers for Disease Control and Prevention, last reviewed February 3, 2020, https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html.

7 "Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States — 2018–2019 influenza season," Centers for Disease Control and Prevention, last reviewed January 8, 2020, https://www.cdc.gov/flu/about/burden/2018-2019.html.

8 "2018–19 Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths Averted by Vaccination," Centers for Disease Control and Prevention, last reviewed January 16, 2020, https://www.cdc.gov/flu/about/burden-averted/2018-2019.htm.

9 Mark Doherty et al. "Vaccine impact: Benefits for human health," Vaccine 34, no. 52 (2016): 6707-6714, doi: 10.1016/j.vaccine.2016.10.025.; Sachiko Ozawa et al. "Modeling The Economic Burden Of Adult Vaccine-Preventable Diseases In The United States," *Health Affairs* 35, no. 11 (2016): 2124-2132, doi: 10.1377/hlthaff.2016.0462.

10 "Estimates of Influenza Vaccination Coverage among Adults—United States, 2017–18 Flu Season," Centers for Disease Control and Prevention, last reviewed November 5, 2018, https://www.cdc.gov/flu/fluvaxview/coverage-1718estimates.htm.

11 "Estimates of Influenza Vaccination Coverage among Adults—United States, 2017–18 Flu Season," Centers for Disease Control and Prevention, last reviewed November 5, 2018, https://www.cdc.gov/flu/fluvaxview/coverage-1718estimates.htm.

12 U.S. Department of Health and Human Services. 2019. "HHS Secretary Azar Statement on Flu Vaccine Executive Order."

13 For updated information on U.S. adult immunization rates see: "AdultVaxView," Centers for Disease Control and Prevention, last reviewed January 29, 2016, https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/index.html.

14 Immunization recommendations made by the Centers for Disease Control and Prevention (CDC) are based on recommendations made to the CDC from the Advisory Committee on Immunization Practices (ACIP). For the complete and updated list of CDC-recommended vaccines see: "ACIP Recommendations," Centers for Disease Control and Prevention, last reviewed December 4, 2019, https://www.cdc.gov/vaccines/acip/recommendations.html.

15 "2019 Employer Health Benefits Survey," Kaiser Family Foundation, September 25, 2019, https://www.kff.org/report-section/ehbs-2019-section-13-grandfathered-health-plans/#figure132.

16 "Early-Season Flu Vaccination Coverage–United States, November 2018," Centers for Disease Control and Prevention, last reviewed December 14, 2018, https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm.; CVS Health. 2018. "CVS Pharmacy Offering Hepatitis A Vaccine to Kentuckians Following an Increase in Confirmed Cases of the Virus."

17 "Adult Immunization (AI) Collaborative Groups 2 & 3," AMGA, accessed March 19, 2020, https://www.amga.org/performance-improvement/best-practices/collaboratives/adult-immunization/groups-2-and-3/.; For an evaluation of a community pharmacy-based program of targeted outreach to improve adult immunization rates, see: Nizar Wehbi et al. "Impact of implementing a technology platform in community pharmacies to increase adult immunizations rates," *Vaccine* 37, no. 1 (2019): 56-60, doi: 10.1016/j.vaccine.2018.11.043.; For an evaluation of the impact of community pharmacy-administered immunizations on immunization rates, see: Anik Patel et al. "The impact of pharmacy-based immunization services on the likelihood of immunization in the United States," *Journal of the American Pharmacists Association* 58, no. 5 (2018): 505 – 514.e2, doi: 10.1016/j.japh.2018.05.011.; For community pharmacy outreach to high-risk patients see: Michael Taitel et al. "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy," *Patient Preference and Adherence* 2012, no. 6 (2012): 323-329, doi: 10.2147/PPA.S29353.

18 "Immunization," Centers for Disease Control and Prevention, last reviewed March 17, 2017, https://www.cdc.gov/nchs/fastats/immunize.htm.

19 Terri Dobbins Baxter "Employer-Mandated Vaccination Policies: Different Employers, New Vaccines, and Hidden Risks," *Utah Law Review* 2017, no. 5 (2017): 885-938.

20 "Vaccines for Military Members," U.S. Department of Health and Human Services, last reviewed December 2017, https://www.vaccines.gov/who_and_when/military_members.

21 Terri Dobbins Baxter "Employer-Mandated Vaccination Policies: Different Employers, New Vaccines, and Hidden Risks," Utah Law Review 2017, no. 5 (2017): 885-938.

22 See the updated list of adult immunizations recommended by the CDC's Advisory Committee on Immunization Practices (ACP): "Recommended Adult Immunization Schedule

for ages 19 years or older," Centers for Disease Control and Prevention, January 1, 2020, https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf.

23 "Increasing Appropriate Vaccination: Reducing Client Out-of-Pocket

Costs for Vaccinations," Community Preventive Services Task Force, last updated January 20, 2016, https://www.thecommunityguide.org/sites/default/files/assets/Vaccination-Reducing-Out-of-Pocket-Costs.pdf.

24 Zhuliang Tao et al. "Impact of Out-of-Pocket Cost on Herpes Zoster Vaccine Uptake: An Observational Study in a Medicare Managed Care Population," *Vaccine* 6, no. 4 (2018): 78, doi: 10.3390/vaccines6040078.

25 Richard Hughes IV, Reed Maxim, and Alessandra Fix, "Vague Vaccine Recommendations May Be Leading To Lack Of Provider Clarity, Confusion Over Coverage," Health Affairs Blog, May 7, 2019, https://www.healthaffairs.org/do/10.1377/hblog20190506.172246/full/.

26 Alexandra Gates, Usha Ranji, and Laura Snyder, "Coverage of Preventive Services for Adults in Medicaid," Kaiser Family Foundation, November 13, 2014, https://www.kff.org/medicaid/issue-brief/coverage-of-preventive-services-for-adults-in-medicaid/.

27 Community pharmacists are eligible to bill Medicare Part B for influenza and pneumococcal immunizations delivered as "mass immunizers" under a "circumstantial privilege"; that is, for delivering immunizations to a specific group of people, such as at a pharmacy-based flu immunization clinic.

28 Monte Miller, "More Vaccines Administered," emissourian.com, August 17, 2019, https://www.emissourian.com/local_news/county/more-vaccines-administered/article_3c684c0e-c055-11e9-bef8-2b08e2661dad.html.; David Salazar, "CVS Health offers hepatitis A vaccine amid Florida county uptick," Drug Store News, November 3, 2017, https://drugstorenews.com/pharmacy/cvs-health-offers-hepatitis-vaccine-amid-florida-county-uptick.

29 Thomas Fitzgerald et al. "Integrating pharmacies into public health program planning for pandemic influenza vaccine response," *Vaccine* 34, no. 46 (2016): 5643-5648, doi: 10.1016/j.vaccine.2016.09.020.

30 David Wright and Michael Twigg, "Community pharmacy: an untapped patient data resource," *Integrated Pharmacy Research and Practice* 5, (2016): 19-25, doi: 10.2147/IPRP.S83261.

31 Data from the Behavioral Risk Factor Surveillance System (BRFSS) as reported by Kaiser State Health Facts, see: "Adults Who Report Not Having a Personal Doctor/Health Care Provider by Gender," Kaiser Family Foundation, accessed

March 19, 2020, https://www.kff.org/other/state-indicator/percent-of-adults-reporting-not-having-a-personal-doctor/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

32 Jeffery Goad et al. "Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience," *Annals of Family Medicine* 11, no. 5 (2013): 429-436, doi: 10.1370/afm.1542.

33 Puneet Singhal and Dongmu Zhang, "Costs of adult vaccination in medical settings and pharmacies: an observational study," *Journal of Managed Care and Specialty Pharmacy* 20, no.9 (2014): 930-936, doi: 10.18553/jmcp.2014.20.9.930.

34 Cason Schmit and Matthew Penn, "Expanding state laws and a growing role for pharmacists in vaccination services," *Journal of the American Pharmacists Association* 57, no. 6 (2017): 661–669, doi: 10.1016/j.japh.2017.07.001.

35 Cason Schmit and Matthew Penn, "Expanding state laws and a growing role for pharmacists in vaccination services," *Journal of the American Pharmacists Association* 57, no. 6 (2017): 661–669, doi: 10.1016/j.japh.2017.07.001.

36 Anik Patel et al. "The impact of pharmacy-based immunization services on the likelihood of immunization in the United States," Journal of the American Pharmacists Association 58, no. 5 (2018): 505 – 514.e2, doi: 10.1016/j.japh.2018.05.011.

37 Edward Drozd, Laura Miller, and Michael Johnsrud, "Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States," *Clinical Therapeutics* 39, no. 8 (2017): 1563-1580, doi: 10.1016/j.clinthera.2017.07.004.

38 Gaurav Deshpande et al. "Impact of medical and/or pharmacy reimbursement on adult vaccination rates," *American Journal of Managed Care* 24, no. 8 (2018): sp286-sp293.

39 U.S. Congress, Senate, *The Protecting Seniors Through Immunization Act of 2019*, S 1872, 116th Cong., 1st sess., introduced in House June 13, 2019, https://www.congress.gov/bill/116th-congress/senate-bill/1872?q=%7B%22search%22%3A%22S.+1872%22%7D&s=2&r=1.

40 Richard Hughes IV et al. "Immunization Implications in CY 2020 MPFS Final Rule," Avalere Health, November 20, 2019, https://avalere.com/insights/immunization-implications-in-cy-2020-mpfs-final-rule.

41 "MEDICARE SHARED SAVINGS PROGRAM QUALITY MEASURE BENCHMARKS FOR THE 2019 PERFORMANCE YEAR," Centers for Medicare and Medicaid Services, December 2018, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2019-quality-benchmarks-guidance.pdf.

42 Jennifer Bacci et al. "The effects of vaccination forecasts and value-based payment on adult immunizations by community pharmacists," *Vaccine* 37, no. 1 (2019): 152–159, doi:10.1016/j.vaccine.2018.11.018.

43 U.S. Community Preventive Services Task Force, "Practice Brief Report: Recommendation for Use of Immunization Information Systems to Increase Vaccination Rates," *Journal of Public Health Management Practice* 21, no. 3 (2014): 249-252, doi: 10.1097/PHH.0000000000000092.

44 Daniel Martin et al. "Immunization Information Systems: A Decade of Progress in Law and Policy," *Journal of Public Health Management and Practice* 21, no. 3 (2015): 296-303, doi: 10.1097/PHH.0000000000000040.

45 For background information on Accountable Health Communities see: "Accountable Health Communities Model," Centers for Medicare and Medicaid Services, last updated March 6, 2020, https://innovation.cms.gov/initiatives/AHCM.

NEHI Network for Excellence in Health Innovation

NEHI (Network for Excellence in Health Innovation)

133 Federal Street, Boston, MA 02110 | 617.225.0857

www.nehi.net