

**Public Health and Pharmacy  
Collaboration in an Influenza  
Pandemic: Summary of Findings  
from an Exploratory Interview  
Project**



## Acknowledgements

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The project's design relied on interviews with senior public health leaders at the state and local levels, public health immunization and emergency preparedness officials, representatives of chain and independent pharmacies, and representatives of health provider associations. Nearly 70 people representing these different fields generously made room in their busy schedules to share their insights with the project team. We are grateful for their candor and willingness to explore complex issues with the team members.

The authors of this report assured respondents that they would not be quoted by name, but we do want to acknowledge the individuals who participated. They are listed in Appendix A, along with their affiliations.

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We know the next influenza pandemic is coming—but not how or when. In an ideal scenario, an early alert will offer enough weeks or months to develop and manufacture an effective vaccine and activate an efficient, accessible infrastructure to deliver it to the millions of people who will need to be vaccinated, all over the country.

Public health agencies at the federal, state, and local levels, in coordination with their private sector partners, are charged with coordinating the response to pandemic influenza, including pandemic vaccine allocation, distribution, administration, and any necessary vaccine tracking.

The 2009-2010 H1N1 influenza pandemic taught us many things. Among these lessons learned are the importance of planning, partnerships, and leveraging of resources. While federal, state, and local public health agencies effectively weathered the H1N1 storm, in a more severe crisis, such as the 1918 influenza pandemic, much greater demands and impacts on public health and healthcare, and society in general, can be expected. Such a severe pandemic will overwhelm existing capacities and capabilities with a predictable

increase in morbidity and mortality. It is, therefore, essential that agencies examine new or innovative approaches to ensure the timely and effective distribution of countermeasures.

Pharmacists have become significant providers of seasonal flu vaccine in many communities and will be on the front line providing vaccines to the public during such an emergency. Many state and local public health officials have already strengthened their relationships with pharmacists and pharmacy associations across the country since the 2009-2010 H1N1 pandemic, though for some public health agencies, working closely with pharmacies is a relatively new and recent venture. A 2012 Harvard School of Public Health poll on antiviral distribution found that more than two-thirds of pharmacists working in community settings reported that they had had no contact with health department staff in the past year.<sup>1</sup>

To explore how public health and pharmacies could better coordinate their vaccine distribution and administration efforts during a severe pandemic, the Association of State and Territorial Health Officials (ASTHO) contracted with Cole Communications, Inc., to interview nearly 70 public health leaders, immunization

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<sup>1</sup> Harvard School of Public Health. *The Voice of Pharmacists: A Poll about Alternative Methods for Antiviral Distribution During a Pandemic Influenza*. 2012.

Available at <http://www.hsph.harvard.edu/horp/>. Accessed 5-13-2014.

and emergency preparedness managers, chain and independent pharmacy representatives, and health provider association representatives.

The interviewers posed a scenario of unlimited vaccine supply available for distribution within 30 days of the declaration of an influenza pandemic, with a distribution volume of approximately 30 million doses per week—roughly four times the volume of peak vaccine administration during the H1N1 pandemic in 2009.

What would public health and pharmacies need from each other to make the allocation, distribution, and administration of vaccine as efficient as possible under such a scenario? What systems and relationships are already in place to foster better coordination, and what are the main areas of concern and potential improvement? How do public health and pharmacy respondents view the trade-offs between speed and efficiency on the one hand, and keeping track of and determining distribution on the other?

This executive summary highlights findings and recommendations describing the interview respondents' perspectives on public health and pharmacy capacity, allocation and reallocation, distribution and redistribution, fiscal and compensation issues, data and tracking issues, and overall coordination and communication.

***This report is a synthesis of the general comments, opinions, and professional judgments shared by those interviewed as part of this project and does not necessarily reflect a consensus of all participants nor should it be construed as conveying the position or policy of ASTHO and/or CDC. The information gleaned from this process will help motivate and focus future discussion and actions to improve the nation's readiness for a severe influenza pandemic.***

#### ***Capacity: Concerns and Confidence***

Both pharmacy and public health respondents expressed some concerns and anticipated obstacles to smooth distribution and administration of this volume of vaccine. However, they generally expressed optimism that each sector could meet the challenge, with additional work and coordination among other vaccine providers within the healthcare system. The overall message from both sectors: It won't be easy, but it can be done.

The pharmacy sector's confidence stemmed from their growing experience and comfort with providing seasonal flu vaccinations, their distribution networks for medications and other goods, and their ability to draw on retired pharmacists and nurses in a surge situation (especially among chains).

Public health respondents expressed confidence, too, but for different reasons. The intensive investments in preparedness planning



since 2001 are one source of confidence, but so are more recent experiences such as the 2009-2010 H1N1 pandemic. However, the scope of coordination and logistics of distribution and vaccine administration will be entirely different in a severe pandemic, with the possibility of much larger vaccine supply early in the response and greater demand for vaccine.

Public health's overall confidence in its ability to meet the needs posed in the scenario is tempered by the fact that budget cuts have, in many health departments, reduced staffing and capacity for vaccination activities and oversight of vaccine distribution and reporting requirements. The ability to effectively respond to a future severe pandemic is predicated, in large part, on the infusion of sufficient additional federal funding to meet program demands across the country. For many respondents, the attrition and reduced capacity has spurred greater recognition of the pharmacies and pharmacists' potential to serve as a resource in a pandemic scenario.

For public health agencies (at all levels) that have not yet worked closely with pharmacies in emergency response and pandemic preparedness planning but would like to in the future, options include:

- **Identifying more opportunities for pharmacists and their associations to collaborate with public health**, such as inviting pharmacists to participate in

emergency planning groups or having cross-representation from public health and pharmacy groups on mutually relevant task forces. In some areas, public health also has been a supportive partner as pharmacists seek a larger role in immunization.

- **Developing formal but *flexible* memoranda of agreement (MOAs) or understanding (MOUs) with pharmacies**, working closely with state boards of pharmacy and state pharmacy associations. Because state laws governing pharmacists' roles vary, the specifics of these agreements need to be negotiated at the state and local levels.
- **Assessing state and local pharmacy capacity more systematically through surveys, joint exercises, and simulations.** Few public health respondents felt they had a current, comprehensive picture of state and local pharmacy capacity in their jurisdictions or even understood chain and independent pharmacy interest and capacity in participating at various levels in a pandemic scenario. A lack of basic data about pharmacies, their interests, and their capacity hinders informed collaborative decision making about allocation, reporting, and compensation options.

#### *Allocations of Vaccine*

The scenario utilized for key informant interviews suggested an unlimited, steady vaccine supply. Nevertheless, public health respondents expressed a keen sense of



responsibility and accountability for ensuring the best match between vaccine supply and demand in their jurisdictions. To do this, they would need near-real-time information to detect imbalances and take necessary corrective action. For public health respondents, accountability requires data, and ensuring the flow of data requires systematic oversight and a certain degree of control to ensure that data was reported to public health by vaccine providers/administrators. Indeed, this is public health's charge during a crisis; only the public health system maintains a broad picture of how an epidemic is unfolding and where and how it can be stemmed, including through tracking of available resources. While pharmacies and distributors conduct this type of allocation for their inventories daily, there remain barriers to presenting these data to public health agencies systematically.

Specifically, local and state public health respondents want to know:

- Which providers (pharmacy and others) are available to provide vaccinations?
- What do providers need from public health (training, guidance, prior agreements, and supplies)?
- What local/state population variations could affect *pro rata* allocations and subsequent secondary redistributions (e.g., populations crossing state borders to live or work, or large student or employer populations)?

To redistribute vaccine supplies from areas with a surplus to those with a shortage, accurate data on vaccine distribution and dispensing are needed. Public health's confidence in whether pharmacies can supply these data varied considerably, while pharmacies generally suggest they can and do on a daily basis.

State and local jurisdictions reported using a variety of information to allocate initial doses of vaccine during the 2009-2010 H1N1 pandemic, including demographic data, past seasonal flu vaccination activity among providers, and data regarding ongoing dispensing of vaccine. Collecting examples of basic allocation algorithms used or contemplated for the purpose of planning future allocations might be helpful, predicated on the types of data available.

Respondents recognized that a pandemic requires flexibility in responding to changing conditions. However, if allocation decisions are based on clear criteria, these should be adhered to as much as possible with as much transparency as possible regarding changes in allocation decisions as situations evolve during a response. One way to do so is to **convene an oversight or planning group, as several states have done, to reach consensus on allocation decisions and provide broader support for the rationale behind these decisions. This group can convene periodically during a response.** If groups are convened for this purpose (either as part of the state or local incident command



structure or separately), pharmacy representatives should be included as active members.

### *Distribution and Redistribution*

Public health respondents who worked with pharmacies during H1N1 reported that direct distribution to chain pharmacy distribution centers provided both speed and flexibility in moving vaccine. If non-shortage but high-volume conditions prevailed, many agreed that direct chain distribution would offer some significant advantages in speed and efficiency of both distribution and administration.

Speed and efficiency, however, are not enough to overcome public health's concerns about potential loss of visibility and oversight—and thus loss of opportunities for state and local public health input regarding where vaccine is within distribution systems, as compared to where it should be.

Public health officials are not yet confident that they will receive the data they need from pharmacies to confirm that vaccine is moving to the people and places where it should be within a state, county, or city. Both pharmacy and public health respondents acknowledged that this is not necessarily due to any flaws or reluctance on the part of pharmacies to share data, but instead is due to variations in state information systems and their ability to communicate bilaterally between various providers and public health. There was also

concern about the lack of collaborative planning between public health and pharmacists at state and local levels.

Public health respondents generally maintained that they would prefer to use a tested mechanism like McKesson (the contracted distributor for the Vaccines for Children [VFC] program and during the 2009-2010 H1N1 pandemic) in a future pandemic. They would be open to another model of directing stockpile or manufacturer shipments to chain distribution centers, but only if they could track, influence, and direct the amount of vaccine being shipped to each store.

In effect, *if* there were 1) a sufficient supply of vaccine, 2) strong reporting and tracking that let all parties know exactly where vaccine was being distributed and administered in something close to real time, and 3) the ability to draw on state and local expertise on allocation of vaccine, *then* public health would feel more comfortable with direct-to-chain distribution (for redistribution to their stores). This would yield the most rapid and efficient distribution of vaccine, shortening the time between vaccine manufacture and administration.

Given this reality, how can we take advantage of chain distribution and tracking systems' efficiencies, while reassuring public health that vaccine is reaching the right people and places?





Some respondents believe the answer is local: Allow direct shipment of vaccine from stockpiles or manufacturers to chain distribution centers for redistribution, but have store managers initiate the requests after consulting with the local or state health department, as appropriate. This, of course, depends on local health departments having the capacity and interest in playing this role. This approach also depends on pharmacy chains delivering the store-level data within their reach to public health. In addition, this approach significantly increases the number of providers health departments would need to frequently follow up with on ordering, in VTrckS, and manually. Finally, some large pharmacy chains may not be able to manage individual store requests but would be able to move vaccine store to store through regional or national communications networks in their systems.

The positive experiences with CDC's VFC distributor, McKesson, are reassuring, and many respondents would like to preserve this as an effective and familiar arrangement. However, in a pandemic situation, relationships would need to be developed with other major wholesalers to distribute to the independent pharmacy stores that often serve rural and frontier communities, based on store orders and coordinated again with local and/or state public health.

### *Fiscal and Compensation Issues*

Respondents recognized that vaccinating every eligible person who seeks vaccination at a specific location regardless of their insurance status or ability to make a co-payment is the most efficient and rapid option for reaching the entire population. Just as with 2009-2010 H1N1, the scenario envisioned vaccine supplied to pharmacies free of charge, but pharmacies still must bill insurers or seek modest vaccine administrative fees to cover the costs of staff time and other resources. During 2009-2010 H1N1, incomplete or inadequate reimbursement was an issue for some (but not all) pharmacies; this scenario, with a fourfold increase in the number of vaccine doses that might be available per week over 2009-2010 H1N1, changed the financial equation.

Many respondents are optimistic that expanded insurance coverage under the Affordable Care Act (ACA) beginning in early 2014 will reduce the number of uninsured. Yet all recognized that there always will be some proportion of the population without coverage, including low-income undocumented workers who remain ineligible for subsidized coverage.

If pharmacies are encouraged or required to vaccinate all who present to be vaccinated (and who meet age and other criteria that would allow them to be vaccinated in that setting), then they should be reimbursed for vaccinations not covered by an existing payment mechanism.



Respondents agreed that a federal reimbursement mechanism is the most feasible approach, in a model similar to the Emergency Prescription Access Program. Such a program could either establish a standard reimbursement to all providers or come into play when certain thresholds of uncompensated care are reached.

Public health respondents opted for a federal fund not only because of budget challenges and limitations at the state and local levels, but also because they do not want to add complex fiscal reimbursement and tracking responsibilities to their pandemic portfolio.

Even for those patients who are insured, states vary on whether or not pharmacists can be reimbursed as medical service providers. This is not a new challenge; ASTHO and others have been working on this issue with America's Health Insurance Plans, the trade association representing the health insurance industry, since 2009-2010 H1N1. Pharmacy groups also are advocating for status as healthcare providers and members of a patient's team of healthcare providers on a state-by-state and individual health plan basis. If this change were made consistently across all states, some reimbursement issues identified here would be resolved.

Since reimbursement is tied to reporting, another suggestion (from pharmacies) was to set up systems in which influenza vaccine would

be treated like a prescription for reporting and reimbursement purposes, with a zero co-pay option to include those who were not insured. This would track store-level immunization doses and billing simultaneously, without requiring changes to existing pharmacy data systems.

#### *Data, Tracking, and Reporting*

Many individuals from each sector were able to describe an ideal reporting and tracking system: It is bidirectional, exchanging data between providers and public health, and generates data in real time. That system is possible in some locations with a highly functional immunization information system, but it is not in place in many others. State-by-state differences in IIS make data entry and sharing challenging for pharmacies. Yet, as noted above, most of the reassurance public health seeks from pharmacies (and other providers) to fulfill its role of protecting and monitoring the public's health rests on reporting system and data sharing.

The biggest reporting frustration for pharmacy chains will come as no surprise: the variation across states in requirements, protocols, and procedures for participation in immunization registries or other mechanisms that would fulfill the tracking/reporting functions required during a pandemic. Even among the relatively small sample of states represented in our interview pool, we heard about a wide range of registry capabilities among immunization grantees. The American Immunization Registry Association



(AIRA) Immunization Information Systems (IIS) Functional Standards<sup>2</sup> for registries should be promoted among state immunizations programs, with incentives provided to those immunization programs that do not meet them.

When asked what belonged in a minimum data set for a pandemic situation, interviewees had different preferences and not all had an opinion. The most commonly cited minimum list of items included the following:

- Name.
- Date of birth
- Patient ZIP code or address.
- Vaccine Universal Product Code (vaccine product and lot number).
- Adjuvant and antigen uses (if adjuvanted pandemic vaccine required).
- Date of vaccine administration.

To address the issues of incompatible data systems and inconsistent state requirements, one company saw an opportunity to develop an interface between pharmacy data systems and state immunization registries. As of June 2013, the system was being used by a major pharmacy chain in 28 states, with another 17 state registries expected to be participating by the end of 2013, for a total of 45. The pharmacy chain's central database is mined for data related to immunization activities; these are

then tailored to meet the specific, unique requirements of each state's registry without requiring further data entry or customization by the pharmacy's system or the registry. The costs for data collection and transmission to state IIS are borne by Walgreens, not the states.

This interface between pharmacy data systems and state registries may serve as a model for tracking and reporting issues for a significant portion of pharmacy-based immunizations, both routine and pandemic-related. However, this solution is still months or years away, depending on the chain and state IIS, and is unlikely to be adopted by smaller-volume independents or even smaller state or regional chains. It may also be difficult for some state IIS.

If CDC and the states agreed to apply the already established AIRA IIS Functional Standards and offer options for providing these data through the registries or other mechanisms, perhaps this, along with targeted outreach by state and local health departments, would help bring the remaining pharmacies into the fold. This solution would also support reporting by other providers, who performed in some cases more poorly than pharmacies in terms of reporting H1N1 vaccination doses to public health authorities. For inventory management, the ordering and delivery tracking systems of McKesson or other

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<sup>2</sup> CDC. "Immunization Information System (IIS) Functional Standards." Available at

<http://www.cdc.gov/vaccines/programs/iis/func-stds.html>. Accessed 5-9-2014.



wholesalers or the CDC Inventory Management and Tracking System (IMATS) could be utilized for this reporting.

These and other options require a determination of what public health really needs to know during and after a pandemic and consensus within public health about the rationale behind data tracking and reporting requirements so that more consistent requests can be communicated to those being asked to provide the data. Coordination among the states would greatly help, especially for large chain pharmacies that work across multiple states with data reporting requirements.

### *Coordination*

Despite concerted efforts in many states to increase contact and coordination between the pharmacy and public health sectors since H1N1, room for improvement remains.

An important existing mechanism for coordination is the incident command system (ICS) that would be activated by a crisis as severe as a global influenza pandemic. Many public health respondents pointed to their ICS relationships as a natural and useful platform for better coordination with pharmacies, but not all had used their ICS structures and planning groups in this way. Respondents suggested that if they have not already done so, state health departments should include state boards of pharmacy, pharmacy associations, schools of pharmacy, and individual chain and

independent store representatives in their planning efforts.

In particular, respondents saw ICS as well positioned to adjust to the expected waves of a pandemic and their uneven geographic impact. Through ICS, some observed, crucial reallocation functions could be coordinated, especially if the initial *pro rata* allocations of vaccine did not match the pandemic's progression.

Options for improving coordination for both routine and pandemic situations include:

- **Reviewing state pandemic flu plans** to determine whether pharmacy roles during different phases of a pandemic response are delineated or could be strengthened, and how pharmacies may be appropriately engaged earlier in pandemics.
- **Exploring local, state, and federal MOU options**, as noted above, and engaging boards of pharmacy in reviewing, supporting, and disseminating them.
- **Assessing existing ICS and other emergency planning groups** to determine how they include pharmacy representatives.
- **Identifying specific information gaps and training needs among pharmacists and other vaccine providers about immunization**, and working with partners to address those needs through webinars, workshops, conferences, or other means.



- **Building on public health-pharmacy partnership guidance and templates from ASTHO’s 2009 *Operational Framework*<sup>3</sup> and a partnership checklist and best practices described in a recent NACCHO report<sup>4</sup>** to identify ways that state and local public health agencies and pharmacies can plan together for anticipated pandemic situations.
- **Considering support of pharmacy efforts to change legislative restrictions on their scope of practice** regarding routine and emergency-related immunization administration to all ages and reporting of vaccine data.
- **Exploring opportunities for public health officials to support pharmacies in these roles**, including offering training on specific topics, conducting joint training/tabletop exercises, speaking at each other’s conferences, and other options relevant to individual states and counties.

### *Recommendations*

The suggestions raised by interviewees range from relatively feasible in the short term (such as fostering more pharmacy-public health contact and partnerships through activities such

as joint training exercise or basic MOUs) to more ambitious and complex (making immunization registries more consistent, creating a national vaccine administration cost reimbursement plan for immunizing the uninsured during a pandemic).

As a starting point to decide which options could be addressed, how, and by whom, the project team recommends **convening a roundtable/planning process that provides an ongoing forum for stronger coordination between pharmacies and public health**. This group could tackle specific barriers and solutions in three phases:

- Most urgently for a pandemic occurring soon, before some of the major concerns and barriers identified in this report and elsewhere could be addressed.
- On an ongoing basis, to adjust to changes in the underlying conditions (such as data and reporting systems, vaccine demand, and vaccine prioritization) that would affect a pandemic response.
- Beyond pandemic scenarios, to explore other opportunities for pharmacy/public health collaboration once the most urgent

<sup>3</sup>ASTHO. “Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine.” Available at <http://www.astho.org/Display/AssetDisplay.aspx?id=2613>. Accessed 5-9-14.

<sup>4</sup>NACCHO. “Building and Sustaining Strong Partnerships between Pharmacies and Health Departments at State and Local Levels.” Available at <http://preparednesssummit.org/wp-content/uploads/2014/03/NACCHO-Pharmacy-Report.pdf>. Accessed 5-9-14.



and complex pandemic planning items were addressed.

A recurring theme in these interviews was the lack of current information that local and state public health officials have about pharmacy capacity to assist in a pandemic. To remedy this situation, CDC, ASTHO, and NACCHO (among others) could support the development of **community-level pharmacy profiles about pharmacy capacity and other features**. Staffing and logistics associated with surge capacity, store locations, populations served (especially high-risk or unique in other ways), data collection and reporting capacity, levels of experience and interest in participating as vaccinators during a pandemic, and pharmacy connections to other community resources are all important data points that could be collected and mapped more systematically before a pandemic makes this information urgent.

Whether or not a planning group is convened, CDC and ASTHO could identify several high-priority recommendations from this report that would advance pharmacy/public health collaboration. Our nominees include:

1. **Develop a model for integrating pharmacy representation into ICS structures to enhance communication, coordination, and problem-solving.** Some states have successfully integrated pharmacy representation into their ICS structures, which assists in coordination and communication at the state and local level. These entities can help address issues around reporting, distribution, and redistribution as necessary.
2. **Explore options for pharmacy and state immunization registry electronic interface options, including** the current model in place in 17 states through Walgreens (and specifically how it could be made accessible beyond the major chains) or others.
3. **Standardize, and if possible reduce, the required minimum data set** for reporting immunization doses to IIS during a pandemic.
4. **Work with stakeholders to develop distribution/redistribution tracking strategies.** Instead of relying exclusively on McKesson or any single VFC contractor to distribute vaccine to independent pharmacies, consider **working with other wholesalers to develop a direct distribution route to them** comparable to that used for pharmacy chains, with reporting and tracking systems supporting this approach. State and local health departments should **work with pharmacists in advance about reporting expectations and their flexibility in being able to redistribute vaccine** to meet public health needs in areas needing greater vaccine access.



5. **Examine payment/reimbursement options for pharmacies to cover or defray vaccine administration costs**, including working with varying plans and insurers to reimburse pharmacy-based vaccinations as a medical service.

### *Conclusion*

Pandemic flu plans, tabletop exercises, emergency preparedness and immunization conferences, 2009-2010 H1N1 after-action reviews and improvement plans, ASTHO's 2009 *Operational Framework* guidance, and more recent work on pharmacy distribution of antivirals, collections of best practices, CDC cooperative agreements dedicated to public health/pharmacy collaboration—all of these investments and insights have moved public health and pharmacies further into each other's arenas, often in very constructive and productive ways that will pay off during a future crisis. Further, the role of pharmacies in seasonal influenza vaccination has expanded significantly since 2009, with 18-20 percent of influenza vaccines for adults administered in pharmacies nationally.

Across the country, progress has been made to integrate pharmacists in public health vaccine response, but it has not been uniform nor has its full potential been characterized or realized. Some of the variation is natural, as each state and local jurisdiction constructs the most appropriate mix of partners and capacity for a pandemic response to meet its respective

jurisdiction's needs, but in others it may be an untapped and largely unexplored surge resource. As these relationships mature, it will be critical to communicate effectively with the public about roles and responsibilities so they know where to go when for vaccine.

If a pandemic follows the scenario outlined in these interviews, it will be a crisis, but one that remains the best-case scenario because vaccine supplies would be plentiful and arriving as planned and announced (unlike H1N1). This best-case scenario still yielded plenty of concerns and barriers that need to be addressed, but the most basic one may be that even after H1N1, public health does not have a universal expectation that it should be working closely with pharmacies, nor do pharmacies necessarily expect to be in routine contact and partnership with public health. In addition, the views of corporate pharmacy leaders may not be shared at the store level, where the day-to-day logistical challenges are likely to be most intense.

Changing these expectations at all levels—local, state and federal, corporate chain headquarters, and individual store—will be an ongoing challenge, but one that is already being met by many of the people interviewed for this report.

The next pandemic is inevitable, and so is the after-action report that will follow. Whether that pandemic occurs in the near future or after





the luxury of a longer planning interval, it is our hope that a future after-action report will document that public health and pharmacies made significant progress in strengthening their shared pandemic preparedness to ensure the most efficient and effective responses to a pandemic and reduce morbidity and mortality as much as possible.





*“Imagine that in the not-too-distant future, a severe influenza pandemic is declared ...”*

This was the opening of a pandemic influenza scenario posed to interviewees in a recent CDC and ASTHO study designed to explore opportunities for improving collaboration between public health and pharmacies during a pandemic.

Interview respondents—drawn from the arenas of public health immunization, emergency preparedness, state and local health department leadership, and chain and independent pharmacies and their associations—did not need much imagination to place themselves in this scenario. Indeed, as the interviews began in spring 2013, a new subtype of influenza, H7N9, had been found in China. Two months later, it had killed 36 people, with an alarming fatality rate of 25 percent among known cases (much higher than the 2 percent fatality rate of the 1918 influenza pandemic).<sup>5</sup> The H7N9 story is an unnecessary reminder to public health, pharmacy, healthcare, and emergency preparedness professionals that the threat of the next pandemic is always hovering.

Four years before H7N9, the 2009-2010 H1N1 pandemic had sounded similar alarms, although it affected different age groups. Although H1N1 ultimately killed an estimated 12,000 people in the United States, it fortunately was less lethal than prior pandemics, like 1918.

Still, the 2009-2010 H1N1 pandemic provided public health agencies the opportunity to test what nearly a decade of focused efforts had achieved in the realm of preparedness. It also demonstrated areas in which federal, state, and local public health agencies could improve, be it through further planning efforts or improved partnerships with one another as well as community and healthcare partners. Should a more severe influenza pandemic emerge, these enhanced partnerships may prove critical in ensuring the health and well-being of communities. One such partnership, with pharmacies, has received increased attention due to pharmacists’ potential reach and expertise, as well as their increasing role in seasonal influenza vaccine administration and the extensive distribution networks supporting them.

Over the last decade, pharmacists and retail pharmacies have rapidly expanded their roles as providers of seasonal influenza vaccinations for adults. During the 1998-1999 influenza season, just 5 percent of

adults were vaccinated in chain supermarket or drug store settings. By 2010-2011, this had jumped to 18.4 percent—nearly one in five of all adults vaccinated against seasonal influenza. Only physicians' offices were more common settings, at 39.8 percent.

The increase in vaccinations in nonmedical settings reflects changes in state laws designed to boost vaccination rates by making access more convenient and affordable. The number of states allowing pharmacists to administer influenza vaccinations to adults rose from 22 states in 1999 to all 50 states by mid-2009.

Just as pharmacists and pharmacies have become integral to providing routine seasonal influenza vaccine, they will play a crucial role in dispensing vaccinations during a severe influenza pandemic.

### *Interview Respondents and Methods*

To learn more about how collaboration between public health agencies and chain and independent pharmacies could be improved before the next pandemic, a team of interviewers under contract to ASTHO through a CDC-funded cooperative agreement used the scenario of a global influenza pandemic as a backdrop for interviews with nearly 70 respondents from the public health and pharmacy sectors, as well as several health provider associations. In most cases, these interviews were conducted as individual telephone interviews; some were conducted with two or three people if several respondents from the same state, agency, or pharmacy organization could be scheduled together. In addition to individual and small group telephone interviews, a group discussion was conducted with 18 NACCHO members in April 2013. Interviewees in each category were identified by ASTHO and CDC and are listed in Appendix A, along with their affiliations.

### *Interview Topics and Methods*

This report presents a summary of findings from these interviews, organized into the major categories covered during the conversations:

- Overall capacity to distribute and administer vaccine.
- Allocating vaccine to different sectors.
- Redistribution of vaccine.
- Fiscal and compensation issues.
- Reporting and tracking.
- Coordination across sectors and partners.



- Communication with the public.
- Legal issues.

Respondents also were asked to complete a table before the interviews that listed options in four main categories: allocation, distribution, vaccinating the uninsured or those otherwise unable to pay, and information sharing.

Interviewees were asked to rate each option using five-point Likert scales to gauge the feasibility and acceptability of the options presented and predict how they might affect the speed with which the public could be vaccinated. For example, if the respondent had a choice of whether or not to allocate vaccine to chain pharmacies as part of the U.S. government's *pro rata* (population-based) distribution of vaccine to states, would he or she rate these options as very acceptable/preferable (5); not sure, depending on various pros and cons (3); or unacceptable (1)? In terms of feasibility, regardless of whether the option would be preferred or not, could it be done relatively easily (5), possibly, with some difficulty (3), or not at all (1)? What about the effect on speed of distribution and administration of vaccine—would it contribute to faster and more efficient distribution and administration (5), slow things down considerably (1), or fall somewhere in between (3)?

The table was intended to stimulate more detailed, concrete discussion during the interviews and worked well for that purpose. As each feature (allocation, distribution, vaccinating uninsured adults, and information sharing) was discussed and rated, the interviewers probed to find out why the specific ratings were given, whether any low ratings constituted “deal-breakers” that would prevent such collaboration between pharmacies and public health, and how smooth implementation and speedy vaccination of a large proportion of the U.S. population could be helped or hindered.

Although not everyone completed the table before (or even during) the interviews, this report presents some of the differences in ratings from three main categories of respondents: public health agency directors and immunization managers (n=21); emergency preparedness managers (n=10); and pharmacy representatives (n=17, with two representing small, independent pharmacies).

One major caveat: While intriguing in the context of a qualitative interview project, these results should not be interpreted as quantitative data. As noted above, not everyone who was interviewed completed the table. Moreover, as with any Likert scale, there was considerable gravitational pull toward the middle-of-the-road answer (i.e., a score of 3), which essentially translates to “it depends.” Finally, in group interviews that included both immunization and emergency preparedness perspectives, the



respondents often combined their answers into a single score, after discussing why they may have differed initially. In the tables and preliminary analysis that introduce related discussion of the findings, these caveats should be kept in mind in interpreting the results.

The scenario, table, and questions posed to interviewees are included in a copy of the interview instrument in Appendix B.

### *Analysis*

The interviews were recorded, transcribed, coded, and analyzed using Dedoose qualitative analysis software. Each interviewer's list of interviewees included representatives from all the major categories included in the study: federal public health (CDC), public health immunization managers, emergency preparedness managers, public health leadership (state and local), chain pharmacies, independent pharmacies, pharmacy associations, and health provider associations.

Team members debriefed periodically to compare notes from their ongoing interviews. Once the interviews were completed, transcribed, and coded, the team reviewed all the transcripts in their coded categories and again compared their analyses, impressions, and recommendations to develop the findings presented here.



## FINDINGS

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### *Setting the Scene: A Pandemic Flu Scenario Quadrupling Peak 2009-2010 H1N1 Vaccine Dose Volume*

As noted above, the interviews began with a specific scenario:

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*Imagine that in the not-too-distant future, a severe influenza pandemic is declared.* Although we won't know the exact details until this actually happens, we can make some educated guesses about likely features that would affect vaccine distribution. We want to use variations in these features to stimulate your thinking about what barriers to rapid, efficient vaccine distribution and vaccine administration can be anticipated, and potential solutions.

Assume that stockpiled H5N1 vaccine will be available for distribution within 30 days of the declaration of an influenza pandemic. We anticipate 30 million vaccine doses could be distributed per week. This number of doses per week is more than four times the peak number of doses distributed during the 2009-2010 H1N1 outbreak.

So, state public health departments, private providers, and chain and independent pharmacies will have about 30 days to receive and start rapidly administering vaccine to patients as soon as vaccine arrives. Rapid vaccine administration is key in this scenario as rapid spread of the pandemic virus is anticipated. Ensuring large numbers of vaccine providers are preidentified is likely key to being prepared for rapid administration of vaccine.

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Not surprisingly, interviewees quibbled with some of the assumptions underlying this scenario. Because vaccine had not been available steadily and in the expected volume during the 2009-2010 H1N1 outbreak, the notion that there would be no shortages (and thus no disputes over who received vaccine first or how much) was questioned and would have altered responses to our questions considerably. The scenario also did not stipulate priority populations eligible to receive vaccine before others. It did not specify a vaccine format (e.g., multiple doses, nasal administration), which again would affect answers to some interview questions, particularly regarding reporting on doses administered. Overall, many respondents questioned whether H1N1 and seasonal flu experience provide much valid insight, since vaccine providers generally have not had to contend with the panic and fear generated by high fatality rates.

Despite these reservations, respondents did react to the main point of the scenario: a fourfold increase in volume compared to 2009-2010 H1N1, with just 30 days to prepare and an approximately 10-week stretch of sustained surge to vaccinate the bulk of the U.S. population.



The sections that follow present these reactions, with illustrative quotes from respondents throughout and insights from the table described above where relevant. Each section concludes with options for addressing concerns or gaps identified during the interviews. These are summarized and reviewed with overarching recommendations for next steps in a final section of the report.

### **Capacity: Confidence and Concerns**

Both pharmacy and public health respondents anticipated obstacles to smooth distribution and administration of this volume of vaccine, but generally expressed optimism that each sector could and would rise to the occasion, along with other providers of vaccine within the healthcare system.

#### ***Why Pharmacies Are Confident***

Confidence from pharmacy respondents—especially those working within large pharmacy chains—stemmed from experience with their distribution networks for both pharmacy/medical supplies and other goods. “This is what we do,” said one, “and we’re really good at it.” Along with finely honed distribution networks comes the use of predictive modeling to predict fluctuations in demand, the capacity to generate and adjust store-level data in real time for ordering purposes, and the ability to shift or augment resources by calling in retired pharmacists or nurses. Many schools of pharmacy are now providing immunization training during their programs’ first year, increasing the pool of student pharmacists prepared to help during a pandemic.

Independent pharmacies, while willing to do their part, were understandably less confident about their ability to staff up to meet elevated demand for vaccine for a 10-week period, although many do have plans in place to do so if required. Independent pharmacies also would find it more difficult to institute reporting and tracking mechanisms if they have not already done so (e.g., to report to a state immunization registry). However, because they rely on centralized distribution chains, their capacity to order and receive vaccine is less of a concern than the data/reporting and fiscal issues raised by vaccinating uninsured patients, described in greater detail below.

#### ***Why Public Health Is Confident***

Public health respondents at all levels—federal, state, and local—also expressed confidence in their ability to respond to the scenario’s predicted timing and volume, but for different reasons. First and foremost, despite glitches and difficulties, public health respondents are proud of their track record in H1N1 and other crises. Over the past 15 years, investments in emergency planning and preparation at all levels of public health have accelerated, including pandemic flu planning (with some plans more up to date than others, but at least in place), tabletop exercises, and related planning (such as the distribution



and dispensing of antivirals) that brings many of the same players to the table to coordinate. In addition, public health is confident in its role of identifying areas of need, targeting hard-to-reach populations, providing services regardless of ability to pay, and remaining accountable to the public.

Points of dispensing (PODs) for mass vaccination of the public (open PODs) or specific populations (e.g., closed PODs for large employers) were cited as viable, immediately available options for expanding capacity. Likewise, many public health respondents reported that their data systems keep improving, and so does their ability to train and entice other providers (pharmacists as well as private providers) to use them for consistent reporting. However, these gains are inconsistent across the country, as discussed in greater detail below. As one respondent noted, things are improving on all these fronts—overall capacity, reporting and data systems, preparedness planning—but a little more time would be extremely helpful. “If pan flu could just wait another 4-5 years,” she said, “we’ll be ready!”

*“If pan flu could just wait another 4-5 years, we’ll be ready!”*

*— State Health Official*

Public health’s overall confidence in its ability to meet the needs posed in the scenario is tempered by the fact that budget cuts have, in many health departments, reduced staffing and capacity for direct vaccination services, training and technical assistance to vaccine providers, and oversight of the distribution of vaccine and reporting required of others. For some, this attrition and reduced capacity has spurred greater recognition of pharmacies and pharmacists’ potential to serve as a resource in a pandemic scenario. Among the existing network of additional providers who could vaccinate large numbers of patients, many public health respondents reasoned, pharmacies are the ones with the greatest untapped (i.e., surge) potential.

Pharmacies offer other benefits, as well. Their locations are familiar to customers, including potentially high-risk populations, such as those receiving multiple prescription medications for chronic diseases or those such as adolescents who might not routinely access healthcare.

Pharmacies are increasingly thought of as routine locations for seasonal flu vaccination, and they often have parking lots that could serve as optional open POD sites. Pharmacies are open late and on weekends (and, in grocery store locations, could be open 24/7 during a pandemic), and more than 90 percent of the U.S. population lives within 5 miles of a pharmacy.



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*“The equivalent of the U.S. population passes through a pharmacy every 30 days. That’s 300 million people. I used to tell my public health colleagues, ‘If you aren’t working with pharmacy, you’re blind.’ We’re missing opportunities, because that’s where the population is.”*

— State Health Official

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The quote below represents this point of view on the importance of partnering with pharmacies:

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*“It extends the reach of public health. It takes the burden off of public health. If you’ve got all these other entities that are reaching out in your community offering a life-saving measure like this, then*

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*“At the time [H1N1], I remember thinking that we really didn’t want vaccine to go directly to pharmacies because we’d lose control of it then. But I’m more willing to do that now and more willing to say that using their distribution system, which is proven and is a fast and efficient system as far as I can tell ...”*

— State Health Official

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Another public health respondent expressed how her view of the role of pharmacies had shifted over time:

#### ***Public Health and Pharmacy Perspectives and Concerns***

While many public health respondents had gained confidence since 2009 in pharmacies’ capacity to assist with vaccine distribution and administration during a pandemic, this view was far from universal. For some, the view that pharmacies/pharmacists are unable, unwilling, or unprepared to take on a sustained surge in vaccination activities remains. For example, in a group discussion among local health officials on this topic, one said:

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*“I’ve watched big pharmacies, comparatively big, in my community take 30 minutes to fill a prescription. And so what’s in it for them? ... Do they really want to take on this public health task? And are they willing to do it at the same rate that we’re willing to do it? Our nurses get tired, but they come back the next day and they continue to do it.”*

— Local Health Official

Some public health respondents worried that pharmacists/pharmacies may not be fully prepared to turn people away if priority guidelines are set, nor would they be adept or experienced in crowd control if long (and potentially unruly) lines form inside and outside their stores. Some concerns also were expressed about logistics—particularly storage space for supplies and vaccine (including cold storage capacity), especially among smaller independent pharmacy stores.



Public health respondents were also concerned that pharmacies have a workflow and business model that may not be compatible with what would be asked of them during a pandemic, because they would have to suspend or delay some of their primary medication-dispensing activities—a stance shared by representatives of health provider associations. Some in public health voiced the opinion that excess pharmacy capacity might best be reserved for distributing antivirals, not vaccinations. In this view, public health could set aside teen pregnancy or STD control for a few months and concentrate fully on pandemic activities, while pharmacies would have more difficulty setting aside their normal operations, especially for a 10-week (or longer) period.

Pharmacists, on the other hand, assert that many in public health who hold these views may have an incomplete or outdated understanding of the modern pharmacy. At the individual pharmacist level, corporate chain representatives, and chain and independent pharmacy associations, respondents reiterated that today's pharmacy is a different animal from the pharmacy of the past:

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*"Most of my classmates, we got into pharmacy ... We didn't go into medicine because we didn't want to actually have to touch people, but that's not who's graduating from pharmacy school now. The pharmacists that we're educating with the doctor of pharmacy degree are expecting to go and take people's blood pressures and really interact with them and make a difference on their clinical course, as opposed to just being a service provider. So anything we can do to keep them happy in their profession and practicing to the extent of their education and their scope of practice is a very good thing."*

— Pharmacy Representative

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With a rapidly expanding role in providing vaccinations for seasonal influenza, pharmacy respondents noted that they have incorporated vaccine administration into their training and certification processes. Although they have faced resistance from private providers, pharmacists and their associations also have worked to change state laws to expand the age ranges and options for pharmacists to act as vaccinators.

As several respondents noted, pharmacies were the last to receive vaccine during 2009 H1N1. One reason for this was their inability to provide vaccine to children in most states. Still, many believed public health had included them late in the game almost as an afterthought, which may be related to



lack of pre-pandemic planning to incorporate pharmacies. Pharmacies are eager to avoid the “afterthought” scenario in the future. As one pharmacy respondent put it,

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*“I’m not saying that I want to be the first player in the game, but I do want to be considered at least an equal in my ability to service the people in the areas that our stores are in.”*

— Pharmacy Representative

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Representatives of chain pharmacies interviewed for this project were primarily corporate officers and staff who reflected flexibility and sincere willingness to work with public health and fully engage in responding to a pandemic. But, as one public health representative noted, “The chains at the corporate level are enthused and committed. The store managers—not so much.”

Pharmacy respondents also did not express concerns about managing long lines and crowds in and around their store locations, although public health respondents did express concerns that pharmacy managers may not be prepared for such scenarios.

#### *Options for Increasing Capacity and Addressing Concerns*

Options to address these issues include:

- **Identifying more opportunities for pharmacists and their associations to collaborate with public health**, thus debunking some misconceptions or mistrust. For example, some states and local jurisdictions have invited pharmacists to participate in emergency planning groups or have cross-representation from public health and pharmacy groups on various task forces. In some areas, public health has been a supportive partner as pharmacists seek a larger role in immunization, countering some opposition from private providers.
- **Developing formal but flexible MOAs or MOUs with pharmacies.** In some areas, public health agencies have developed local or state agreements governing vaccine distribution, administration, compensation, and reporting, working closely with state boards of pharmacy and state pharmacy associations. Because of variations in state laws governing pharmacists’ roles, the specifics of these agreements need to be negotiated at the state and local levels. (An example from Washington state is provided in Appendix C.)



- **Assessing state and local pharmacy capacity systematically, through surveys, joint exercises, and simulations.** Few public health respondents in these interviews felt that they had a current, comprehensive picture of state and local pharmacy capacity in their jurisdictions or even understood chain and independent pharmacy interest and capacity in participating at various levels in a pandemic scenario. A lack of basic data about pharmacies, their interests, and their capacity hinders informed decision-making about allocation, reporting, and compensation options.
- **Conducting state-level simulations at pharmacies on the impact of vaccine administration in combination with antiviral dispensing, dispensing of normal medications, security needs, and other features to test pharmacy capacity under these assumptions.** It remains to be seen how a pharmacy might handle many competing demands and priorities in an emergency situation, and questions from public health remain about how pharmacies would balance competing priorities should the vaccine campaign interfere with normal business activities.



## Allocations of Vaccine

Respondents were asked to rate two main allocation options: whether the vaccine allocation to pharmacies would be part of a state's *pro rata* allocation, or not. Table 1, below, shows little difference among the three perspectives regarding whether the allocation of vaccine to pharmacies in each state should be part of the *pro rata* distribution allocated by CDC to each state. This primarily reflects what occurred in 2009 during the H1N1 program. The pharmacy representatives see this as an extra step in getting vaccine to their stores and thus gave a lower rating on the effect on speed, but found this option to be equally feasible and acceptable.

Table 1: Allocation of Vaccine				
Option		Public Health Immunization and Sr. Mgrs.	Public Health Preparedness	Pharmacy Representatives
Chains part of state <i>pro rata</i>	Acceptability	3.7	4.1	3.7
	Feasibility	4.0	4.1	4.0
	Effect - speed	3.9	3.7	3.3
Chains not part of state <i>pro rata</i>	Acceptability	2.8	2.9	4.0
	Feasibility	3.5	3.8	4.4
	Effect - speed	3.6	3.1	4.3
Independents part of state <i>pro rata</i>	Acceptability	3.7	4.1	3.5
	Feasibility	3.8	3.8	3.7
	Effect - speed	3.6	3.8	3.2
Independents not part of state <i>pro rata</i>	Acceptability	2.8	2.8	3.8
	Feasibility	3.5	3.6	4.0
	Effect - speed	3.7	3.1	3.9

The major difference between the public health and pharmacy perspectives is allocating vaccine directly to pharmacies above/outside the state *pro rata* share of the national supply. The predominant public health position in these interviews was that allocating vaccine outside of the *pro rata* state allocation would impinge on their ability to direct vaccine within the state. The more carefully public health representatives considered the underlying scenario (through discussions of the factors influencing their rating), the higher the rating they provided for the acceptability of this option. The



pharmacy representatives clearly see allocation of vaccine to them outside the *pro rata* shares as more acceptable, more feasible, and more rapid.

We saw minimal differences between ratings of chain and independent pharmacies, but it should be noted that most of the pharmacy representatives interviewed were from the chain store sector.

Given a plentiful supply of vaccine and no shortages, respondents from all sectors were asked to describe ballpark allocations of vaccine allocated to public health, pharmacies, and private providers. Most respondents felt they did not have adequate information to offer an opinion about these rough allocations; many added that if vaccine supplies were indeed plentiful, it would be less of an issue.

Respondents had used various methods to determine allocations in the past. One, described as “a fairly complex allocation methodology,” applied Census and Behavioral Risk Factor Surveillance System data to allocate vaccine amounts during H1N1 by county based on percentages of births, numbers of pregnant women, and other demographic data. Those data were then matched to hubs for providers and the healthcare delivery system, where people would be likely to access care. Counties with a higher provider/access point score were allocated a higher percentage of vaccine than others, but the local health departments still made the decisions about whether vaccine would be shipped directly to pharmacies or would it come through the health department (e.g., for schools or other sites).

More relevant than initial allocation, especially to public health respondents, was the issue of reallocation and secondary distribution or redistribution. As was true for the answers about basic capacity, many respondents noted that they lacked adequate local data to make informed allocation and reallocation decisions about the proportion of vaccine supply that should flow to pharmacies or other providers.

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*“Last time, we had hospitals that couldn’t move vaccine through their system. We can’t just take it and move it to a different provider in a different region because that would be unfair to that area. So what we need is a system that allows us to move to more effective or efficient providers in the same region so the redistribution will be in how quickly it has been moved to the right populations.”*

— State Health Official

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A major concern voiced by public health program respondents about allocating vaccine was their keen sense of responsibility and accountability to ensure the best match between vaccine supply and demand in their jurisdictions. They indicated the need for near-real-time information to monitor this and take any necessary corrective action should an imbalance be detected. For public health respondents, accountability requires data, and ensuring the flow of data requires systematic oversight and a certain degree of control over those who would be providing vaccine and reporting data to IIS. Specifically, local and state public health respondents want to know:

- Which providers (pharmacy and others) are available to provide vaccinations?
- What do they need from public health (training, guidance, prior agreements, and supplies)?
- What local/state variations in populations could affect *pro rata* allocations and subsequent reallocations (e.g., populations crossing state borders to live or work, large student populations with different home addresses/ZIP codes, movement of large populations of tourists or other temporary residents; the existence of large employers who might be able to obtain vaccinations through a closed POD system)?

In order to redistribute vaccine supplies from areas with a surplus to those with a shortage, accurate data on vaccine distribution and dispensing are needed. These issues are discussed in greater detail in the section on tracking and reporting, below.

#### *Options for Addressing Concerns About Allocation*

Collecting examples of basic allocation algorithms (for in-state or in-county allocations) might be helpful, predicated on the types of data available.

Respondents recognize that a pandemic requires flexibility in responding to changing conditions. However, if allocation decisions made by public health agencies are based on clear criteria, these decisions should be adhered to and as much transparency as possible maintained. One way to do so is to convene an oversight or planning group, as several states have done, to reach consensus on allocation decisions and provide broader support for the rationale behind these decisions. If groups are convened for this purpose, either as part of the state/local incident command structure or separately, pharmacy representatives should be included.



## Distribution and Redistribution

Interview respondents were asked to compare two distribution options for getting vaccine to chain pharmacy sites during an influenza pandemic: 1) directly through a U.S. government contract with a firm like McKesson, which distributes vaccine for the VFC program as directed by state immunization programs, or 2) through regional or national pharmacy distribution channels.

Distribution of vaccine to individual stores by McKesson was the standard operating procedure during the 2009-2010 H1N1 pandemic and thus is known to be feasible. As Table 2 shows, this was the approach immunization program staff preferred and works primarily by enrolling individual pharmacies as VFC providers (in some cases, with streamlined enrollment procedures and fewer restrictions).

Pharmacy representatives clearly, and not surprisingly, prefer that they distribute vaccine to their stores through their normal daily distribution system, which they believe to be absolutely feasible and much more efficient/rapid than the alternative. Chain representatives generally gave this option ratings of 5

Option		Public Health Immunization and Sr. Mgrs.	Public Health Preparedness	Pharmacy Representatives
Distribution to stores by McKesson as directed by state public health	Acceptability	4.2	3.7	3.8
	Feasibility	4.0	3.6	4.3
	Effect - speed	3.7	3.0	3.5
Distribution direct to chains for redistribution	Acceptability	3.6	4.6	4.8
	Feasibility	3.8	4.4	4.6
	Effect - speed	3.8	4.6	4.4

across the board. They found the alternatives feasible and acceptable, but saw them as inserting an extra step at the expense of speed and efficiency.

Interestingly, the emergency preparedness staff's ratings are more in line with the pharmacy perspective than that of their public health counterparts. Emergency preparedness staff seemed to be more in tune with the underlying scenario of rapidly moving vaccine to the community and into people, while immunization staff seemed more concerned with dealing with shortages and population priorities.





In addition to the ratings provided in the table exercise, respondents were asked to comment on various aspects of distributing and redistributing vaccine, including how state *pro rata* allocations could be maintained if pharmacies were able to use their own distribution channels, optimal approaches for distributing a high volume of vaccine, and possible barriers to be addressed before such distribution becomes necessary.

During the early stages of H1N1, state health departments directed the amount of vaccine that would be provided to each individual pharmacy as part of the overall allocation and distribution within the state. In states with relatively autonomous local health departments, such as home rule states, local health officials played a role in proposing provider allocations to the state for approval, including pharmacists within these allocations. In these scenarios, states were still directing the flow and reallocation of vaccine as needed, but with more input from local health departments. According to respondents, this system generally worked well, especially because it had to take into account vaccine shortages and placing some populations at higher priority to receive vaccine than others. Notably, these elements—vaccine shortages and priority populations—were not part of the scenario presented in the interviews.

### *Concerns and Trade-Offs*

Two concerns raised by respondents about distribution were not related to distribution mechanisms or allocations *per se*, but are worth noting. The first is that CDC required a 100-dose minimum for orders, which posed a problem for lower-volume providers, including pharmacies. In these situations, the 100-dose packages had to be divided into smaller batches—an extra step that felt unnecessarily cumbersome and time-consuming to many. The other concerned supplies that accompanied the vaccine doses. Some pharmacy respondents noted that while providing ancillary supplies (syringes, swabs,

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*“Don’t dictate to us what we should be using. Everybody has their own sharps guides. We’ve done our own training. We comply with OSHA regulations. We have approved sharps. During the last pandemic they tried to say, ‘Here’s the kind of syringe that you need to use because that’s what we’re supplying to you.’ Well, don’t supply us with those kinds of things. We don’t need them. I mean, we always worry about running out of sharps and Band-Aids and that sort of thing, but that, once again, is on the supply side of things, just to make sure that we have enough of those. But I would say stay out of the businesses acquiring the supply side of things and just worry about the vaccine itself.”*

— Pharmacy Representative

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sharps containers) was intended to be helpful, in practice it sometimes led to problems (e.g., receiving syringes without instructions, no process for disposal or return of unused items).

During the later stages of 2009-2010 H1N1 vaccine response, CDC and states allowed shipments of vaccine to central chain distribution centers, which in turn allowed chains to redistribute vaccine to individual stores through their established networks. At this point, shortages had eased, demand had dropped, and the main concern was improving access to vaccine and increasing coverage. Not surprisingly, pharmacy representatives preferred this option for distribution, although they also expressed flexibility in working with (or around) other arrangements. If they were to receive vaccine directly and cut out the middleman (McKesson), pharmacies believe they could distribute the vaccine more efficiently without sacrificing tracking, inventory, and redistribution. Many believe they are in a good position to determine how much vaccine each of their stores would need based on their current customer data and projections and patterns of demand from seasonal influenza vaccine. Pharmacists also provided weekly reporting to VTrckS regarding vaccine doses available per jurisdiction, and the data was made available on a weekly basis to health departments.

Public health respondents who worked with pharmacies during H1N1 reported positive experiences with pharmacy distribution in terms of speed and flexibility. Their ratings in the table reflected the view that in a non-shortage but high-volume scenario, direct chain distribution would offer some significant advantages if speed and efficiency were paramount.

The advantages of speed and efficiency, however, are not enough to overcome public health's concerns about losing necessary oversight over where vaccine is within distribution systems, as compared to where it should be. As noted above, health officials at all levels feel sense of responsibility for ensuring that vaccine is directed to the places and populations where it is needed.

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*"You've got to somehow build in systems that do, that allow for reallocation. Public health has to have the ability to maintain visualization across the community to understand where vaccine is, who's getting it and who's not, and the ability to readjust that."*

— State Health Official

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Pharmacy representatives, too, recognize this crucial role and responsibility of public health.

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*“If you’re getting who is administering where and you’re seeing a provider who hasn’t had any activity in a week, you need to get on the phone and say, ‘What’s going on?’ You’ve got vaccine, you’re not administering it. If you don’t need it anymore, let’s give it to somebody else. I think it would be the health department or whoever it is that distributed the vaccine. There should be some flag criteria that would get somebody to say, oh, we’d better make an outreach to this provider ... that’s any provider who is getting the vaccine. If it’s sitting on their shelf during a time of emergency, and we’re not seeing any movement, somebody’s got to raise the question.”*

— Pharmacy Representative

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Public health officials are not yet confident that they will receive the data they need from pharmacies to confirm that vaccine is moving to the people and places where it should be within a state, county, or city. Both pharmacy and public health respondents acknowledged that this is not necessarily due to any flaws or reluctance on the part of pharmacies to share data, but has more to do with the inefficiencies of variations in state immunization registries and their ability to communicate bilaterally between providers and public health. This is discussed in more detail in the section on tracking and reporting (page 24), but the point is that inconsistent data systems currently hinder the degree of collaboration and options that these two sectors could agree to ahead of time.

In responses to interview questions, public health respondents generally maintained that they would prefer to use a mechanism like McKesson in a future pandemic. They would be open to another model of direct stockpile or manufacturer shipments to chain distribution centers, but only if they could track, influence, and direct the amount of vaccine being shipped to each store. (This sentiment was strongest among state public health respondents, but was certainly voiced by local public health officials as well.)

In effect, *if* there were 1) an unlimited supply of vaccine, 2) strong reporting and tracking that let all parties know exactly where vaccine was being distributed and administered in something close to real time, and 3) the ability to draw on state and local vaccine allocation expertise, *then* public health would feel more comfortable with direct-to-chain distribution for redistribution to stores. CDC, ASTHO, NACCHO, and the Association of Immunization Managers as representatives of federal, state, and local



public health would of course play a major role in determining the initial amounts, but the actual distribution and redistribution would occur within the chain-to-store hierarchy. This would yield the most rapid and efficient distribution of vaccine, shortening the time between vaccine manufacture and administration.

No matter how alluring the efficiency gains, however, this is extremely unlikely. Initially, respondents found it difficult to conceptualize and accept unlimited vaccine supply. And as noted above, data systems are still far from this ideal, although there is some progress in this direction for some chains and some states. Still, we have noted these conditions because they suggest that if data systems were improved, the improved efficiency would become much more palatable to public health.

### *Options for Balancing Efficiency and Accountability*

Given what is known or believed to be known about pandemic vaccine distribution, what are possible options for taking advantages of the efficiencies of chain distribution and tracking systems, while reassuring public health that vaccine is reaching the right people and places?

Some respondents believe the answer is local: allow direct shipment of vaccine from stockpiles or manufacturers to chain distribution centers for redistribution, but have store managers initiate the requests after consulting with the local (or state, in other cases) health department. This, of course, depends on local health departments having the capacity and interest in playing this role, potentially many times over, since it would require conversations and negotiations with many entities. This approach also depends on pharmacy chains delivering to public health the store-level data they believe are within their reach, which can be used to make timely decisions about redistribution of vaccine. If this approach worked well in some jurisdictions, building on pharmacy/public health collaboration that has been strengthened since H1N1 and in some cases was in place long before, then it could reassure state and local public health officials who are skeptical about the flow of data from pharmacies.

The interview scenario specifically mentioned McKesson, and respondents drew on their experience with McKesson under the VFC program and during H1N1. Certainly, this arrangement should be preserved where it is already in place and working well. However, in a pandemic situation, CDC and ASTHO also could develop relationships with other major wholesalers to distribute to independent pharmacy stores based on store orders, coordinated again with local or state public health. In this option, the wholesalers would provide distribution data to state immunization registries so that state and local public health officials would be able to “maintain visualization across the community.”



### Fiscal and Compensation Issues

During H1N1, doses of vaccine supplied to pharmacies (and other providers) were provided by the U.S. government at no cost, but providers still incurred administrative costs associated with staff time and reporting responsibilities. When uninsured individuals and others who could not afford a co-pay to cover administrative fees sought vaccinations at pharmacies, in many cases there were no mechanisms in place to defray these costs.

During the table exercise posed at the beginning of the interviews, respondents from the public health and pharmacy sectors were asked to rate the acceptability, feasibility, and effect on speed of three options:

- 1) Requiring pharmacists to vaccinate anyone who showed up, regardless of their insurance status or ability to pay.
- 2) Not requiring pharmacists to vaccinate everyone, meaning that they would be encouraged to refer those who could not pay to go to public health clinics to receive their vaccinations.
- 3) Not requiring pharmacists to vaccinate everyone, but compensating them if they did vaccinate those who were uninsured or unable to pay.

Options		Public Health Immunization and Sr. Mgrs.	Public Health Preparedness	Pharmacy Representatives
Pharmacies required to vaccinate all regardless of ability to pay	Acceptability	4.7	4.2	3.5
	Feasibility	4.6	3.7	3.6
	Effect - speed	4.7	4.8	4.6
Pharmacies not required to vaccinate all—refer to PH clinics	Acceptability	1.7	2.3	2.8
	Feasibility	2.7	2.9	3.5
	Effect - speed	1.9	2.0	2.2
Pharmacies to vaccinate all and be	Acceptability	1.6	2.4	4.7



reimbursed for administration	Feasibility	1.6	2.7	4.3
	Effect - speed	1.9	3.0	4.2

Table 3, below, shows that while all respondents generally agreed that the second option (referring uninsured or unable-to-pay patients to public health clinics) was not desirable, 11 of the 21 immunization staff and senior managers gave this option the lowest rating: 1. Respondents from every sector recognized that many patients in this category, if referred and required to make an additional attempt to find a vaccination option, would end up not being vaccinated at all. All agreed to various degrees that this would be unacceptable and would severely undermine the shared public health goal of containing the pandemic’s spread.

Across categories, respondents recognized that vaccinating everyone is the most efficient and rapid option. However, immunization staff tended not to identify some of the feasibility issues raised by pharmacists, such as dealing with patients standing together in line and singling out those unable to pay in a public space—an awkward as well as time-consuming conversation. Many are optimistic that expanded insurance coverage under ACA beginning in early 2014 will reduce the number of uninsured, yet all recognized that there always will be some proportion of the population that remains without coverage, including low-income undocumented workers who remain ineligible for subsidized coverage and those living in states whose governors and legislators have declined to expand Medicaid coverage.

Thirteen of the 21 immunization staff and senior managers gave a rating of 1 to the third option—reimbursing pharmacies for administering vaccine—while 10 of 17 pharmacy representatives gave a rating of 5 to this option. Pharmacy representatives were also not in favor of incurring the costs of administration without reimbursement. In subsequent responses to interview questions, public health staff tended to agree that pharmacies should be reimbursed—just not from their state or local budgets. They see this as a federal responsibility; pharmacies largely agree.



Respondents from all sectors recognize that the financial calculus is different for chains and independents. Smaller independent stores operate within tighter margins and would be more vulnerable if they had to suddenly absorb an influx of uncompensated staff time that diverted pharmacists from their ongoing operations.

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*“They’d have to look at it in terms of, they’re getting people through the store and how much is that worth to them, in terms of additional sales ...”*

— State Public Health Representative

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*“We weren’t looking to make money [in H1N1]. But we weren’t interested in giving our good services away.”*

— Pharmacy Representative

Here again, different perspectives from the public health and pharmacy arenas come into play. Many public health respondents suggested that pharmacies should absorb the administrative costs because these would be more than offset by additional sales as patients/customers enter their stores (the “loss leader” view). Pharmacists argued that they should break even by having their administrative costs reimbursed or at least defrayed.

Even though most agree that pharmacies and other providers should be reimbursed for vaccines administered without compensation, those in public health also believe that in the absence of a compensation mechanism, pharmacies still should be required or highly encouraged to vaccinate everyone. For most, that is the current (and somewhat uneasy) *status quo*.

Some in public health believe that pharmacies that are unwilling to vaccinate everyone will simply choose not to participate, since participation is voluntary. Others noted that during H1N1, some who were reluctant to participate under these conditions did so, yielding to pressure from patients/customers and competitors who did participate. Respondents agreed that a larger-scale pandemic and national/global emergency would change both the pros and cons of participating, regardless of whether compensation mechanisms are devised between now and then.

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*“They do it because at that time [during disasters] money is not the object and everybody works double to do what they have to do ...”*

— Pharmacy Representative



### *Options for Addressing Fiscal/Compensation Concerns*

If pharmacies are encouraged or required to vaccinate all who present to be vaccinated and who meet age and other criteria that would allow them to be vaccinated in that setting, many respondents agreed they should be reimbursed for those not covered by an existing payment mechanism.

Respondents agree this is most feasible from a federal reimbursement mechanism, in a model similar to the Emergency Prescription Access Program, which assists with individuals' access to prescriptions and durable medical equipment when a federal disaster has been declared. This could either cover a standard reimbursement to all providers or come into play when certain thresholds of uncompensated care were reached. (Some pharmacy respondents reportedly did attempt to track the number of unreimbursed vaccinations they administered during H1N1, but they had no one to bill for them.)

Public health respondents opted for a federal fund not only because of the lack of funding available for this purpose at the state and local levels, but also because they do not want to add complex fiscal reimbursement and tracking responsibilities to their pandemic portfolio.

Even for patients who are insured, pharmacists face variations across states in terms of whether or not they can be reimbursed as medical service providers. This is not a new idea; ASTHO has been working on this issue with America's Health Insurance Plans, the trade association for health insurance industry, since H1N1, and pharmacy groups also are advocating for recognition as healthcare providers and members of a patient's team of healthcare providers on a state-by-state basis. If this change were made consistently across more states, some of the reimbursement issues identified here could be resolved.

Since reimbursement is tied to reporting, another suggestion from pharmacies was to set up systems in which influenza vaccine would be treated like a prescription for reporting and reimbursement purposes, with a zero co-pay option to include those who were not insured. This would track store-level immunization doses and billing simultaneously, without requiring changes to existing pharmacy data systems.

In a pandemic with significant fatalities and public fear, lines in pharmacies (and elsewhere) will be long and the urgency of rapid processing greater. Pharmacy representatives suggested that a roster-type procedure (e.g., name and date of birth) should be sufficient documentation for insurance billing purposes in that situation.





Some respondents suggested the option of issuing vouchers to employees or population groups that could then be redeemed at pharmacies for free immunizations, with no co-pays. In one example, a private university provided vouchers to its employees and their family members. In another, a pharmacy chain provided vouchers to community-based organizations in its headquarters city.

No matter how these options are addressed at the federal and state levels and with insurers, the arrangements should be made before the next pandemic:

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*“Because that’s going to be the holdup ... if we’re having to deal with how to bill and the pharmacists have any doubt on if we’re going to get paid or anything along those lines, then that’s going to hold everything up.”*

— Pharmacy Representative

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### Data, Tracking, and Reporting

If vaccine were allocated directly to chain pharmacies and distributed to stores through their own distribution networks, respondents were asked to rate options for two aspects of information sharing by pharmacies: dose administration and vaccine location (tracking).

Table 4, below, shows that all agree that reporting should occur, although the pharmacy representatives did recognize that it is certainly feasible/easier not to report. Daily and weekly reports are equally acceptable to immunization staff and senior managers. Pharmacy representatives preferred weekly to daily and consider it more feasible, primarily because it decreases the demands on pharmacy staff.

Table 4: Information Sharing by Pharmacies About Dose Administration				
Option		Public Health Immunization and Sr. Mgrs.	Public Health Preparedness	Pharmacy Representatives
Require reporting to registries DAILY—direct by pharmacies	Acceptability	4.2	3.3	3.8
	Feasibility	3.4	2.6	3.5
	Effect - speed	3.4	3.9	4.0
Require reporting to registries WEEKLY—direct by Pharmacies	Acceptability	4.2	4.1	4.4
	Feasibility	4.2	3.6	4.4
	Effect - speed	3.6	3.6	4.0
No requirement for reporting vaccines administered	Acceptability	1.1	1.4	2.2
	Feasibility	2.8	3.7	4.3
	Effect - speed	2.0	2.2	3.7

Table 5, below, again shows that all agree that reporting should occur, although the pharmacy representatives did recognize that it is certainly feasible/easier (though not acceptable) not to report. Immunization staff and senior managers prefer to have the chains reporting to them *by store* as opposed to aggregate state data. While the format of the table linked these choices to daily versus weekly, most found *weekly reporting by store* very acceptable. The pharmacy representatives found



reporting *by store* very acceptable, but preferred *weekly* to *daily* reporting—again, as with dose reporting, because this would lessen the demand on already stretched pharmacy staff. In any case, this

Option		Public Health Immunization and Sr. Mgrs.	Public Health Preparedness	Pharmacy Representatives
Require reporting of distribution at STATE level only—WEEKLY	Acceptability	3.5	4.2	3.9
	Feasibility	4.2	4.2	4.6
	Effect - speed	3.4	3.9	3.8
Require reporting of distribution at STORE level—DAILY	Acceptability	4.5	3.9	4.4
	Feasibility	4.0	3.3	3.8
	Effect - speed	3.6	3.9	3.8
No requirement for reporting where chains distributed	Acceptability	1.1	1.4	2.1
	Feasibility	2.9	3.4	4.3
	Effect - speed	1.5	2.2	3.3

reflects nearly full agreement across respondent categories.

### *Closing the Gap Between Ideal and Real Data and Reporting Systems*

Many individuals from each sector were able to describe an ideal reporting and tracking system: it is bidirectional, exchanging data between providers and public health, and generates data in real time.

*“We could provide daily on hands at the pharmacy that shows how many doses are being carried by every single one of our pharmacies across the country. That’s just the press of a button.”*

— Pharmacy Representative



That system is possible and in some places tantalizingly close, but it is not yet in place at the scope and national scale that would make it useful to all parties in a pandemic. Yet, as noted above, most of the reassurance public health seeks from pharmacies (and other providers) to fulfill its role of protecting and monitoring the public's health rests on an improved and more consistent system.

### Immunization Registries

One of the questions posed to interviewees was whether they considered their state immunization registries an effective mechanism for tracking pharmacies' vaccine administration. Like everything about registries, the answer varies considerably by state. While many state public health and immunization managers are proud of their individual registries, they do recognize their limitations, especially in a pandemic situation. Registry limitations cited by respondents included requiring consent forms, cumbersome enrollment procedures for providers, and issues with user-friendliness. During H1N1, some worked with CDC to implement alternate simplified reporting and tracking tools (for all providers, not just pharmacies) or used IMATS to track inventory and supplies. If a pandemic unfolds in the near future, these tools will probably be necessary and may remain the only options for some states.

The biggest reporting frustration for pharmacy chains will come as no surprise: the variation across states in requirements, protocols, and procedures for participation in immunization registries or other mechanisms that would fulfill required tracking/reporting functions during a pandemic.

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*"I guess the other part of the reporting piece would be a consistent reporting format from one locality to another. What we saw in the H1N1, especially as we were involved with the different states, is that everybody wanted a different level of information. In some cases they were fine with 'give us an aggregate number for all of your stores across the state,' in some cases they wanted it by store by day, in some cases they wanted it even in differing formats from that perspective. If there was a way to come up with a consistent request, and I know that every state is different and that kind of thing, but for this kind of activity, if we're expected to do a lot of work in a little amount of time to service folks, then the needs have to be fairly simple and consistent across the board."*

— Pharmacy Representative



### **An Approach to Bilateral Data Systems**

To address the issues of incompatible data systems and inconsistencies across state requirements, one company saw an opportunity to develop an interface between pharmacy data systems and state immunization registries. The system is currently being used by a major chain pharmacy in 28 states, with another 17 state registries expected to be participating by the end of 2013, for a total of 45. The pharmacy chain's central database is mined for data related to immunization activities; these are then tailored to meet the specific, unique requirements of each state's registry without further data entry or customization required by the pharmacy's system or the registry. The costs are borne by Walgreens, not the states.

An immunization manager in one of the participating states described how it works: Walgreens stores upload vaccine information daily to their corporate office, at which point the data are simultaneously uploaded to the state immunization registry. Local health departments then have instant access to the registry data and thus real-time access to immunization information for local Walgreens stores in their communities. If this system were more widely implemented, it could resolve most of the vexing data and reporting issues on which so much public health/pharmacy coordination depends, not only during pandemic emergencies but also in the more routine provision of seasonal flu and other immunizations.

Other pharmacy and grocery-based pharmacy stores have developed similar systems that allow direct reporting to registries or use products such as McKesson's EnterpriseRx, but these were reported to be less efficient. If more chains follow Walgreens' lead and use the option described above (developed by Surescripts), this offers the potential for greater standardization and comprehensiveness in reporting, without requiring changes by chains or registries. However, the costs may be prohibitive for some chains, depending on their immunization volume and whether they consider their existing systems to be adequate for the states in which they operate. This approach also may be out of reach for independents, although that remains to be seen.

### **Reporting Through Wholesale Distributors**

McKesson holds the current CDC contract for distributing vaccine through the VFC program; during a pandemic, this system would expand to other providers, including pharmacies. However, at least two other wholesalers serve independent pharmacies and small chains. All three are apparently capable of providing store-specific distribution data to states, though not all may be able to do so electronically. A review of distributor capabilities and willingness to integrate their data with state registries would be worthwhile. Otherwise, small independent pharmacies could be integrated into a VFC-like system (or



streamlined VFC option) for reporting and tracking purposes. However, thought must be given to addressing the potential for duplicate dose reporting due to redistribution.

One pharmacy respondent described an inventory dashboard that CDC developed during 2009-2010 H1N1, with manufacturers, distributors, and pharmacies reporting the status of vaccine in their respective pipelines—green for a plentiful supply, yellow for supply on its way but perhaps not keeping pace with demand, and red for out of stock (and not forthcoming).

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*“It would be phenomenal if everyone was able to report instantaneously what they had at hand, but I’m not sure that’s as important, as useful as folks would think it would be, knowing that we have a national distribution system and spot shortages can be relieved in 24 hours.”*

— Pharmacy Representative

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### Minimum Data Sets

Despite the existence of the AIRA IIS Functional Standards, few interviewees referenced them when asked about a minimum data set for a pandemic scenario. Instead, when asked what belonged in such a data set, interviewees had different preferences. Some interviewees did not have an opinion. The most commonly cited minimum list of items included the following:

- Name
- Date of birth
- ZIP code (or address)
- Vaccine Universal Product Code (vaccine product and lot number)
- Date of vaccine administration

Other items added by individual respondents (i.e., without the underlying consensus reflected in the above list) included gender, target/high-priority group status, risk factors, administration route, and insurance status.



Some respondents suggested that during a pandemic, pharmacies could collect and retain patient locating and vaccine information, but could report just the number of people they had vaccinated, their dates of birth, and remaining doses of vaccine.

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*“In a severe pandemic, do we want to require, do we want to slow down the vaccination enough to get really picky about how and what providers report to our state immunization registry? I’m not sure that the value will be worth however much it might slow down our vaccination effort.”*

*— Emergency Preparedness Manager*

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### ***Options for Addressing Data/Tracking Concerns***

The interface between pharmacy data systems and state registries described above, if adopted more widely by more chains, may resolve tracking and reporting issues for a significant portion of pharmacy-based immunizations (both routine and pandemic-related). However, this solution is still months or years away, depending on the chain, and is unlikely to be adopted by smaller-volume independents or even smaller state or regional chains.

If CDC and states could agree on a streamlined data set and options for providing these data (through the registries or other mechanisms), this might bring the remaining pharmacies into the fold. This solution would also support reporting by other providers, who apparently performed more poorly than pharmacies in some cases in terms of reporting H1N1 vaccination doses to public health authorities.

Another option, at least for inventory management, is to use the ordering and delivery tracking systems of McKesson or other wholesalers or CDC’s IMATS for this portion of the reporting.

These and other options require a determination of what public health really needs to know during and after a pandemic and consensus within public health about the rationale behind data tracking and reporting requirements so that more consistent requests can be communicated to those being asked to provide the data.

Even among the relatively small sample of states represented in our interview pool, we heard about a wide range of registry capabilities among immunization grantees. Minimum performance standards for registries should be established, and incentives provided to grantees that do not meet them.







## Coordination Between Pharmacy and Public Health

Despite concerted efforts in some states to increase contact and coordination between the pharmacy and public health sectors since H1N1, room for improvement remains. As noted in a recent NACCHO report on building and sustaining partnerships between pharmacies and state and local health departments,<sup>6</sup> a 2012 Harvard School of Public Health poll regarding antiviral distribution found that more than two-thirds of pharmacists working in community settings reported that they had had no contact with health department staff in the past year.<sup>7</sup>

This lack of contact was echoed in many of the interviews for this project, but we also learned about creative and productive partnerships across the country. The NACCHO report lists several examples of partnership best practices that involve dispensing drills, marketing and awareness campaigns designed to boost access and immunization rates, joint training and tabletop exercises with pharmacy students and faculty, and emergency orders waiving age restrictions that prevent pharmacists from serving as immunizers for a larger proportion of the population. Additional examples from the interviews with public health agencies for this project include:

- Collaborating with a local chapter of the American Academy of Pediatrics to survey pharmacists about their education and knowledge needs regarding immunization, and then connecting them to webinars and other training events to respond to those needs.
- Inviting pharmacists and association representatives to state immunization conferences, and offering them continuing education units for attending.

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<sup>6</sup> NACCHO. "Building and Sustaining Strong Partnerships between Pharmacies and Health Departments at State and Local Levels." Available at <http://preparednesssummit.org/wp-content/uploads/2014/03/NACCHO-Pharmacy-Report.pdf>. Accessed 5-9-14.

<sup>7</sup> Harvard School of Public Health. "The Voice of Pharmacists: A Poll about Alternative Methods for Antiviral Distribution During a Pandemic Influenza." Available at <http://www.hsph.harvard.edu/horp/>. Accessed 5-9-14.



- Involving public health medical officers in authorizing collaborative practice agreements with pharmacists where these are required, to speed access and provide opportunities for developing relationships. An added bonus, one respondent noted, was some added leverage:

### *ICS and Coordination*

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“You can say, ‘Look, if you’re not going to send in your reports, I’m going to rescind the collaborative practice agreement and you’re not going to be able to do this vaccination anymore.’”

— Pharmacy Representative

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An important existing mechanism for coordination is ICS, which would be activated by a crisis as severe as a global influenza pandemic. Many public health respondents pointed to their ICS relationships as a natural and useful forum for better coordination with pharmacies, but not all had used their ICS structures and planning groups in this way. Respondents suggested that, if they have not already done so, state health departments should include state boards of pharmacy, pharmacy associations, schools of pharmacy, and individual chain and independent store representatives in their planning efforts. Boards of pharmacy and associations also can serve as conduits for communication and updates, although some state pharmacy association interviewees noted that their membership encompasses relatively small proportions of their states’ pharmacies.

In particular, respondents saw ICS groups as well positioned to adjust to the expected waves of a pandemic, with uneven geographic impact across the country. Through ICS, some observed, crucial reallocation functions could be coordinated, especially if the initial *pro rata* allocations of vaccine did not match the pandemic’s progression. ICS also are conduits for communication from the ICS Joint Information Centers (among partners, across political and government entities, and directly to the media and general public) and potentially for funding from emergency funds to compensate pharmacies for administrative fees.

Many respondents described frequent convening of their ICS, not just for training, tabletop exercises, and crises, but for more routine responses as well. In one state, the ICS worked well during H1N1, but:



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*“Once [H1N1] was over, we kind of stopped. And then we had an outbreak where we didn’t stand up incident command. We kind of just let it all fall together. It didn’t work as smoothly, so the decision was made that we just do that all the time now when we have outbreaks.”*

— State Health Official

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For public health respondents, an important attribute of ICS is the recognition, in a pandemic situation, that public health would have the authority over vaccine allocation, distribution, and reallocation/redistribution (i.e., that public health is accountable and directing the response). Being clear, direct, and transparent about public health’s role and responsibilities was recommended at both the state and local levels, especially if partnerships with pharmacies are relatively new.

Within the ICS and general emergency response structure, most participants reported strong relationships between emergency preparedness and immunization personnel. However, some strained relationships and difficulties were noted as well.

#### *Tools to Guide Future Coordination and Collaboration*

ASTHO’s [Operational Framework for Partnering with Pharmacies for Administration of 2009-2010 H1N1 Vaccine](#) recommended that state health departments formulate agreements with pharmacies at the corporate level, so that state and local health departments would not need to negotiate store-by-store agreements.<sup>8</sup> The *Operational Framework* provided a template agreement as a starting point, along with discussion of other planning considerations relevant both to H1N1 and future pandemics.

Because of variations in state laws governing the role of pharmacists in providing immunizations (in general, and during emergencies), state-specific agreements are required, even if these follow a general national template. In general, state and local public health respondents recognized the value of

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<sup>8</sup> ASTHO. “Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine.” Available at <http://www.astho.org/Display/AssetDisplay.aspx?id=2613>. Accessed 5-9-14.



consistency and basic parameters that everyone could follow but are wary of anything that looks or sounds like an all-purpose “one-size-fits-all” solution.

Although templates and models exist (see, for example, Washington state’s MOU between local health departments and pharmacies in Appendix D), respondents from both pharmacy and public health reported that they were not readily available, although most agreed they would be useful starting points. Some of the difficulty lies in anticipating so many specific variations and unknowns in a general document:

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*“Without knowing the specifics of a particular emergency, it’s hard to say what those procedures would be or what procedures you would need. If there’s a shortage of vaccine and then prioritizations need to be made, that’s a completely different procedure than just giving out the vaccine and recording this data ... What needs to be worked into the MOU is just that agreement to follow the procedures that are given.”*

— State Health Official

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From the pharmacy side, several respondents noted that pharmacies would naturally need to conduct legal reviews of such documents, but that once they are in place, they would be followed:

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*“Pharmacists are very good at following rules, and they listen to their lines of authority very directly. On the whole, public health has not engaged with the regulatory part of pharmacy, the board of pharmacy, to be part of their communication piece. I can tell you that any pharmacist working at any community pharmacy, if they’re told by their board of pharmacy that they need to do something, they are 300 times more likely to listen to it than the governor saying it!”*

— Pharmacy Representative

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Beyond a more binding MOU, respondents also expressed interest in a protocol that essentially updates the 2009 ASTHO *Operational Framework* from H1N1. Such a document, developed in close consultation with public health and pharmacy representatives, would cover:

- Specific roles and responsibilities of pharmacy and public health in a pandemic, including known variations that could affect these roles (such as home rule states).
- Reimbursement procedures or options.
- Requirements for provider enrollment processes, including any streamlining that would encourage pharmacies or other providers to participate and enroll ahead of time.
- Sample standing orders.
- Reporting expectations and templates.
- Storage and handling guidance.
- Communications guidance.
- ICS coordination.
- Contingencies and what-if scenarios, based on various possibilities.

#### *Options for Strengthening ICS and Other Coordination*

- Review state pandemic flu plans to determine whether pharmacy roles are delineated or could be strengthened, if appropriate.
- Explore local and state MOU options and engage boards of pharmacy in reviewing, supporting, and disseminating them.
- Assess existing ICS or other emergency planning groups to determine whether they include pharmacy representatives.
- Identify specific information gaps and training needs among pharmacists about immunization, and work with partners to address those needs through webinars, workshops, conferences, or other means. Topics could include information and training on registries and enrollment, guidance on vaccine storage/handling, and vaccinations for specific populations or age groups, among others.
- Review the 2009 ASTHO *Operational Framework* and templates (geared to state-level partnerships) as well as the 2013 NACCHO report (aimed at local partnerships between public health and pharmacies) to identify opportunities for strengthening and formalizing partnerships.



- Consider supporting pharmacy efforts to change legislative restrictions on their scope of practice regarding immunizations, both routinely and during emergencies.
- Explore specific opportunities for public health officials to support pharmacies in these roles, including offering training on specific topics, conducting joint training/tabletop exercises, speaking at each other's conferences, and so forth.



## Communicating with the Public

Although communicating with the public was not a major topic of discussion during the interviews, respondents did offer some suggestions and insights based on their prior experience with H1N1 and other crises.

Again, they noted that the scenario posed in these interviews—plentiful vaccine, no designated priority groups—would alter the communications messages and urgency considerably. The messages, respondents suggested, would be straightforward in the proposed scenario:

- We have vaccine and it will work.
- Here's where you should go to get it (including pharmacies, as appropriate, and coordinated with their own marketing). Any state-specific restrictions, such as age restrictions that would prevent pharmacists from providing vaccine to an entire family, should be clarified as early as possible and reinforced consistently.
- Here's what to do if you get sick.
- Here's when you should go to the hospital, and when you shouldn't.

In terms of conduits for messages to the public, most opted for primary messages crafted and cleared by CDC and then disseminated through their ICS's joint communications structure. However, they noted that this sometimes creates unnecessary delays as information is cleared. With widespread access to Google, Twitter, and other rapid-fire social media, the challenge of conveying accurate information has grown. Especially in a pandemic, respondents recognize that the web, television, and radio are the most likely venues for communication, not print media.

Respondents noted that although the ICS is set up to provide consistent, accurate information from a central source, partners can amplify those messages once they are determined. Health plans, insurers, providers, and of course pharmacies can all assist with getting accurate information out about vaccine availability and options and countering misinformation.



## RECOMMENDATIONS

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Throughout this summary, the members of the interview team have identified opportunities for CDC, ASTHO, and their partners to address some of the concerns and barriers identified by interview respondents. In addition to those specific suggestions, we offer this condensed list of recommended next steps:

1. **Convene a roundtable/planning process that provides an ongoing forum for stronger coordination between pharmacies and public health.** This group could tackle barriers and solutions in three phases:
  - **Phase 1: Immediate pandemic planning.** Many interview respondents' suggestions anticipated that data and other systems will improve in the near future—within several years. However, a pandemic could strike much sooner than that. The group could consider an immediate threat first, including what could be accomplished with current resources and systems. Identification of resources, including current plans and MOUs that can be shared across jurisdictions, would be a useful process for this group. Then, the group could turn to options if an influenza pandemic were to occur several years hence. What could be different? What would be the first items to address? For example, the group could consider the specific pros and cons of three broad distribution options: the current system, shipping directly to pharmacies, or a hybrid in which shipments would go directly to the pharmacies through the state's ICS (which, with pharmacy representation and input, would determine allocations for the state).
  - **Phase 2: Updated pandemic planning.** In a second phase, the group could consider updated conditions and adapt its Phase 1 plans and recommendations accordingly. This envisions a group that meets periodically to consider the landscape, rather than a one-time workshop or roundtable.
  - **Phase 3: Other post-pandemic opportunities.** Although pandemic response is the main focus, strengthening collaboration before a pandemic is likely to yield many other opportunities for pharmacy/public health collaboration. In the future, the group or a subset could serve as a venue for exploring these opportunities, once the most urgent and complex pandemic planning items were addressed.





2. **Support community-level pharmacy profiles about pharmacy capacity and other features.** A recurring theme in these interviews was local and state health officials' lack of current information about pharmacy capacity to assist in a pandemic. Staffing and logistics associated with surge capacity, store locations, populations served (especially high-risk or unique in other ways), data collection and reporting capacity, levels of experience and interest in participating as vaccinators during a pandemic, and pharmacy connections to other community resources are all important data points for informed decision making that could be collected and mapped more systematically before a pandemic makes this information urgent.
  
3. **Select specific barriers/concerns to address.** Whether or not a planning group is convened, CDC and ASTHO could identify several high-priority recommendations from this report that, if addressed, would advance pharmacy/public health collaboration in the future. Our nominees include:
  - **Develop a model for integrating pharmacy representation into ICS structures to enhance coordination and visibility.** Some states have successfully integrated pharmacy representation into their ICS structures, which can assist in state and local coordination and communication. These entities can address issues around reporting, distribution, and redistribution as necessary.
  - **Explore options for pharmacy and state immunization registry electronic interfaces—** either the Surescripts interface model (and specifically how it could be made accessible beyond the major chains) or others.
  - **Standardize, and if possible reduce, the required minimum data set** for reporting immunization doses during a pandemic. While the AIRA IIS Functional Standards for reporting exist, they are not applied consistently across jurisdictions, nor would they necessarily be wholly applicable or essential in a pandemic scenario. These standards are a useful starting point for discussion among the states and other stakeholders.
  - **Instead of relying exclusively on McKesson (or any single VFC contractor) to distribute vaccine to independent pharmacies, consider working with other wholesalers to develop a direct distribution route to them** comparable to that used for chains, with reporting and tracking systems supporting this approach.



- **Examine payment/reimbursement options for pharmacies to cover or defray administration costs**, including working with plans and insurers to reimburse pharmacy-based vaccinations as a medical service.



## CONCLUSION

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Pandemic flu plans, tabletop exercises, emergency preparedness and immunization conferences, H1N1 after-action reviews, ASTHO's 2009 *Operational Framework* guidance and more recent work on pharmacy distribution of antivirals, collections of best practices, CDC cooperative agreements dedicated to public health/pharmacy collaboration—all of these investments and insights have moved public health and pharmacies further into each other's arenas, often in very constructive and productive ways that will pay off during a crisis no matter when it may occur.

Despite these ongoing efforts across the country, though, progress remains uneven. Some of this is natural and appropriate, as each state and local jurisdiction constructs the most appropriate mix of partners and capacity for a pandemic response. But some of the variation appears to leave a potential surge resource for a pandemic response—in some areas, perhaps the only untapped surge resource—largely unexplored.

If a pandemic follows the scenario outlined in these interviews, it will be a crisis situation, but one that remains the best-case scenario because vaccine supplies would be plentiful and arriving as planned and announced (unlike H1N1). This best-case scenario still yielded plenty of concerns and barriers that need to be addressed, but the most basic one may be that even after H1N1, public health does not have a universal expectation that it should be working closely with pharmacies, nor do pharmacies necessarily expect to be in routine contact and partnership with public health. In addition, the views of corporate pharmacy leaders may not be shared at the store level, where the logistical challenges are likely to be most intense.

Changing these expectations at all levels—local, state and federal, corporate chain headquarter and individual store—will be an ongoing challenge, but one that is already being met by many of the people interviewed for this report.

The next pandemic is inevitable, and so is the after-action report that will follow. Whether that pandemic occurs in the near future or after the luxury of a longer planning interval, it is our hope that a future after-action report will document that public health and pharmacies made significant progress in strengthening their shared pandemic preparedness.



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**Elena Rios**



## APPENDIX B: INTERVIEW INSTRUMENT

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*Prior to each interview, respondents will have received:*

- A one-page description of the project.
- A table summarizing the possible variations in vaccine allocation, distribution, vaccination of uninsured adults, and information sharing.
- A list of the major categories of questions (but not the questions themselves).

### *Overall Scenario*

*Imagine that in the not-too-distant future, a severe influenza pandemic is declared. Although we won't know the exact details until this actually happens, we can make some educated guesses about likely features that would affect vaccine distribution. We want to use variations in these features to stimulate your thinking about what barriers to rapid, efficient vaccine distribution and vaccine administration can be anticipated and potential solutions.*

Assume that stockpiled H5N1 vaccine will be available for distribution within **30 days** of the declaration of an influenza pandemic. We anticipate **30 million vaccine doses could be distributed per week**. This number of doses per week is more than ***four times*** the peak number of doses distributed during the 2009-2010 H1N1 outbreak.

So, state public health departments, private providers, and chain and independent pharmacies will have about **30 days** to receive and start rapidly administering vaccine to patients as soon as vaccine arrives. Rapid vaccine administration is key in this scenario, as rapid spread of the pandemic virus is anticipated. Ensuring large numbers of vaccine providers are pre-identified is likely key to being prepared for rapid administration of vaccine.

We want to explore the implications of possible variations as this scenario could unfold related to:

- Whether or not the vaccine allocation to pharmacies would be part of a state's *pro rata* (population-based) allocation from the U.S. government (USG).
- Whether chain pharmacies would receive vaccine directly to their central distribution sites for secondary distribution to their individual stores/locations, or whether distribution to individual stores would occur through the same system that state immunization programs will use to identify and approve other vaccine administration locations for direct shipment from the CDC contractor (McKesson).
- Whether or not pharmacies will be required to vaccinate all patients who request vaccine at their location regardless of the patients' insurance status or ability to pay.



- Whether pharmacies will be required to enter vaccine administration data into state-specific registries or use third-party software or contract.
- Whether pharmacies would be able to frequently report state- or store-level data about vaccine distribution and availability.
- Whether pharmacists would be able to adhere to vaccine prioritization recommendations from public health.

### *Features, Options, and Ratings Table*

Each interviewee will be walked through the rows of the table on the next page, using a rating scale of 1-5 to rate each option in terms of its acceptability (how desirable/acceptable the option would be), feasibility (whether it could be done), and effect on speed (how fast).

- **Acceptability:** How desirable/acceptable would this option be, if you had a choice? (5 = very acceptable, would prefer it; 3 = not sure, has pros and cons; 1 = unacceptable)
- **Feasibility:** Could it be done? (5 = yes, highly feasible; 3 = maybe—might be tough, but manageable; 1 = no way, not feasible)
- **Effect on Speed:** Does it contribute to faster (re)distribution/administration (5), potentially slow things down (1), or somewhere in between?

As each feature (allocation, distribution, vaccinating uninsured adults, information sharing) is discussed and rated, ask these overall questions related to the rating/scores:

Which aspects (of allocation, distribution, vaccinating uninsured adults, and information sharing):

Are feasible to implement or could be managed, even with difficulty (i.e., got high or medium feasibility ratings)? Why?

Would absolutely *not* work (i.e., deal-breakers), and why? (lowest feasibility ratings)

Would make it/them possible or easier to implement? (for those with lower ratings)

Would support or hinder speedy/efficient administration of vaccine?



Features of Pandemic Response		Options	Acceptability Rating	Feasibility Rating	Effect on Speed
1. Allocation of vaccine	To chain pharmacies	A. Part of <i>pro rata</i> state distribution			
		B. <b>Not</b> part of USG <i>pro rata</i> state distribution in state			
	To independent pharmacies	A. Part of <i>pro rata</i> state distribution			
		B. <b>Not</b> part of USG <i>pro rata</i> state distribution in state			
2. Distribution of vaccine to pharmacies		A. Directly through USG McKesson contract to individual provider locations as directed by individual immunization programs			
		B. Separate contract and distribution system for regional or national pharmacies for redistribution through their established channels			
3. Vaccinating uninsured adults and non-VFC-eligible children without ability to pay at pharmacies		A. Required to vaccinate all who show up regardless of insurance status or ability to pay out-of-pocket			
		B. Not required to vaccinate all; uninsured or unable to pay out-of-pocket have to go to public health to get vaccinated			
		C. Not required to vaccinate all; public health reimburses pharmacy for vaccinating uninsured, after they are vaccinated at pharmacy			
4. Information sharing by pharmacies	On dose administration (frequency)	A. Reporting required into state-specific registries, <b>daily</b> direct inputs by pharmacies			
		B. Required into state-specific registries, <b>weekly</b> direct inputs by pharmacies			
		C. No requirement for reporting vaccines administered through registry			
	On vaccine location, if redistributed	A. Required to report vaccine distributed at the state level on weekly basis (e.g., how many doses distributed to each state or immunization program jurisdiction)			



	<b>by chains (tracking)</b>	B. Required to report vaccine distributed at the store location level on daily basis			
		C. No requirement to report where pharmacy chains distributed vaccine			

What are your major **concerns** about ramping up to deliver 30 million vaccines weekly within 30 days?

What specific policies, procedures, and practices **from pharmacies** would be most helpful **to public health during a pandemic**? Is this different than during regular influenza season?

Are there any **other features/options** (relevant to pharmacy/public health coordination during a pandemic) we should explore regarding pandemic vaccine distribution and administration?

*Questions on Specific Topic Areas*

- Capacity
- Allocating vaccine to different sectors
- Redistributing vaccine (from chains to stores) and administering vaccines in pharmacy settings
- Coordination/administration of guidelines and agreements
- Communication across sectors
- Communication with the public
- Fiscal/compensation issues
- Reporting/tracking
- Legal issues



## Capacity

### For Public Health

Do you believe state public health has the **capacity to receive and rapidly redistribute** influenza vaccine under this scenario? Why or why not?

What is the existing capacity of states [or, for state-specific respondents, your state] to **distribute** your *pro rata* share of the 30 million vaccines per week? (Assume you get 4x more a week than what you got during H1N1.)

What is the existing capacity of states to **vaccinate** their share of 30 million people per week?

Are vaccine providers (outside VFC) pre-enrolled, or could they be identified within the 30 days after a pandemic is declared?

If pharmacies now provide seasonal flu vaccine to 20% of the adult population, would you expect this proportion to stay the same in a pandemic/30-million-dose scenario, or increase?

- If increase — to what percentage?

Do you believe chain pharmacies currently have the **capacity to receive and rapidly distribute** 10% of the approximately 30 million vaccines per week? 25%?

- Why or why not?

**How long** would it take for pharmacies to ramp up to reach this capacity?

What about their **capacity to vaccinate** millions or more per week, quadrupling current peak demand during seasonal influenza vaccination?

- Why or why not?

Do you believe independent pharmacies have the **capacity to receive and rapidly distribute** 10% of the approximately 30 million vaccines per week? 25%?

- Why or why not?

**How long** would it take for pharmacies to ramp up to reach this capacity?

What about their **capacity to vaccinate** millions more per week, quadrupling current peak demand during seasonal influenza vaccination?

- Why or why not?



### *Allocating Vaccine to Different Sectors*

Under the pandemic scenario with large amounts of vaccine available from the stockpile, what proportion of vaccine should go to pharmacies and to public health? (Do you have a ballpark ratio in mind, such as 50/50 or 80/20?)

Private providers?

How would you determine the proportion of vaccine to allocate to each sector?

What factors should influence the allocation? Why?

What factors would make you more comfortable with the allocation of vaccine to each sector? Why?

### *Redistributing Vaccine (from Chains to Stores) and Administering Vaccines in Pharmacy Settings*

If vaccine is allocated to states *pro rata*, how should the pharmacy allocation be handled, since national chains would distribute to individual stores in each state?

How should pharmacies assure USG that state-level *pro rata* allocation is preserved (even though pharmacies may be distributing using a separate mechanism than states)?

If state-level *pro rata* allocation is not feasible for pharmacies to maintain, how would state-level allocation by USG be adjusted?

If the decision is made for chains to distribute vaccine via their own distribution channels, and not as part of CDC's system, will pharmacies be able to assure USG and states that state-to-state allocations remain fair, equitable, and consistent with the *pro rata* format? If so, how?

With such a high volume of vaccine being shipped daily, what is the optimal approach for distributing it to stores in an efficient, timely way?

If a portion of the available vaccine is shipped directly to pharmacies, what needs to be in place to make such **distribution** possible?

What needs to be in place to make sure rapid vaccine **administration** is possible?

What information do pharmacies need to provide—e.g., quantities/shipments, vaccine administration (patient information, vaccine lot numbers)?

What else is needed for smooth distribution and vaccine administration?

What recommendations would you make to ensure transparency in the decision making and timing of distribution?



In general, would pharmacy chains prefer to distribute vaccine themselves, using their existing medical distribution systems, or would they prefer to have vaccine distributed by the same system as other vaccine providers?

How would pharmacies assure USG that these systems could handle a weekly volume of vaccine of 7+ million doses?

#### *Coordination/Administration of Guidelines and Agreements; Communication Across Sectors*

What tools from public health would be helpful to pharmacies and public health in adhering to guidelines during a pandemic (e.g., memoranda of agreement, requirements to enter data into registries, policies/regulation about authority to vaccinate all ages during a pandemic, etc.)?

How would information about vaccine shipments, availability, priority groups, and vaccine administration best be communicated and shared between pharmacies and public health during a pandemic?

What formats would you recommend?

How would the distribution of vaccine across pharmacies and state/local public health be integrated into existing emergency operations centers or incident command systems?

#### *Communication With the Public*

What messages are critical to communicate to the public about vaccine availability in a pandemic scenario?

What messages would be effective in communicating with the public about who should go to different settings—pharmacies, public health clinics, or primary care providers?

How should those messages be communicated and by whom?

#### *Fiscal/Compensation Issues*

If pharmacies are required to provide vaccine to those uninsured and unable to pay out-of-pocket:

- How would pharmacies cover costs for administering vaccine?
- How would public health compensate pharmacies for the administration cost?

If pharmacies bill public health payers in advance, how would billing work?

Are there any mechanisms that should be in place other than the standard systems for billing health insurers, including Medicare and Medicaid (e.g., MOUs)?

Is there anything that could be done in advance to minimize the financial risk to pharmacies?





### *Tracking/Reporting*

Are registries an effective mechanism for tracking the administration of vaccines (e.g., do they capture all persons in your state? Do all providers, including pharmacists, have access to it in your state)? Why or why not?

Are there ways to streamline registry data entry for providers given the high volume of vaccine administered rapidly in this scenario (e.g., weekly instead of daily entry)?

Is there a minimum data set pharmacies need to provide to state programs?

What systems (for pharmacies) need to be in place to simplify reporting to state and local public health?

How would third-party reporting work for pharmacies? (What would need to be in place to make this work more effectively?)

What are the costs for third-party reporting (by chains, by independent pharmacies)?

### *Legal Issues*

What are some legal issues that could be anticipated during a pandemic (e.g., allowing pharmacies to provide vaccinations for adolescents or children during an emergency, instead of adults only; other liability concerns)?

### *Wrap-up*

If a protocol or guide were available to support smoother collaboration between public health and pharmacies in the event of pandemic influenza, what topics/tools would be most useful to you that are not currently available?

Are there existing guidelines (even for other topics) that you've found particularly useful/accessible?

Is there anything we haven't asked about (!) that would be relevant to improving pharmacy/public health collaboration in these types of scenarios?



WASHINGTON STATEWIDE PHARMACY-LOCAL HEALTH JURISDICTION  
MEMORANDUM OF UNDERSTANDING

This Washington Statewide Pharmacy-Local Health Jurisdiction Memorandum of Understanding (“MOU”) is made and entered into by the signatory Health Department or signatory Health District, or signatory County within the State of Washington that operates a public health department or division within its county government, (“Local Health Jurisdiction” or “LHJ”) and each signatory pharmacy entity licensed in the State of Washington (“Pharmacy”), individually, and with all other signatory LHJs and signatory Pharmacies.

ARTICLE I

PURPOSE

The purpose of this MOU is to utilize existing Pharmacy infrastructure to assist in addressing health and medical needs of an affected population during a Public Health Incident, Emergency or Disaster (“Incident”), using coordinated and standardized protocols statewide. The Washington State Department of Health (“DOH”) supports the development of this MOU.

ARTICLE II

DEFINITIONS

Local Health Jurisdiction: A signatory health department, health district, or county within the State of Washington that operates a public health department or division within its county government, pursuant to authority granted under Chapters 70.05, 70.08, 70.46 RCW or other applicable law. Each signatory party shall designate a representative for purposes of accepting requests for assistance and notice.

Pharmacy: A signatory to this MOU who meets the definition of a pharmacy as that term is defined in RCW 18.64.011.

Plan: a written Operation Plan or procedure developed pursuant to this MOU.

Public Health Incident, Emergency, or Disaster (“Incident”): Any occurrence, or threat thereof, whether natural or caused by man, in war or in peace, to which an LHJ may respond pursuant to its authority



under chapter 70.05, 70.08 or 70.46 RCW, or other applicable law, and that, in the judgment of the LHJ, results or may result in circumstances sufficient to exceed the day to day operational capabilities of immediate local or regional public health response.

### ARTICLE III

#### PARTICIPATION

The Pharmacies have a desire to assist the LHJs in addressing health and medical needs of an affected population during an Incident. The LHJs and Pharmacies agree that this MOU, however, does not create a legal duty to do so. The LHJs and Pharmacies agree that any and all actions taken pursuant to this MOU shall be voluntary and in each LHJ's and Pharmacy's sole discretion.

### ARTICLE IV

#### HOW TO INVOKE ASSISTANCE

An LHJ may request assistance of a Pharmacy by contacting the designated representative of that Pharmacy. The provisions of this MOU shall only apply to requests for assistance made by and to such designees. Requests may be verbal or in writing. If verbal, the request shall be confirmed in writing as soon as possible to the extent practical. LHJs intend to activate community-wide mass vaccination and dispensing plans, to include delivery of medications by Pharmacy with Pharmacy's agreement, only (a) after a declaration of "Public Health Emergency" made by the Secretary of the Department of Health and Human Services under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C.A. §247d-6d, or (b) a locally or state declared emergency, under chapter 38.52 RCW, requiring a public health and medical response, or (c) the issuance of an event mission number by the Emergency Management Division of the State Military Department for a public health and medical response.

### ARTICLE V

#### EFFECT OF DECLARATION OF EMERGENCY

The LHJs and Pharmacies recognize that state or federal declarations of emergency, or orders related thereto, may supersede the arrangements made or actions taken pursuant to this MOU. Nothing in this MOU should be construed as independent of or bypassing established emergency management procedures, the provisions of county or state declarations of emergencies, or any conditions for the distribution and dispensing of the Strategic National Stockpile (SNS) or administration of vaccines established by the federal or state governments.

### ARTICLE VI

#### RESPONSIBILITIES OF LOCAL HEALTH JURISDICTIONS



Local Health Jurisdictions responsibilities includes:

- Coordinate with DOH and/or signatory pharmacies to ensure statewide consistency with screening forms, tracking, training and other Pharmacy requirements if applicable.
- Provide planning and technical assistance to Pharmacy, including but not limited to, supply lists, fact sheets, dispensing algorithms, and applicable requirements
- Provide statewide consistent medical screening forms to Pharmacy as a guidance for implementing dispensing operations
- Provide technical assistance and training, as mutually agreed upon by LHJ and Pharmacy
- Activate community-wide mass vaccination and dispensing plans as necessary
- Notify Pharmacy that community dispensing plans should be implemented
- Request appropriate amounts and type of medication or vaccine, and available supplies, from local, state or federal sources, including use of SNS resources
- Facilitate a discussion with Pharmacy regarding the most appropriate locations for distribution
- Request DOH to deliver, or have delivered medications to distribution centers as determined by the local health jurisdiction in consultation with the DOH and Pharmacy
- Provide Pharmacy with statewide consistent medical protocols regarding the Pharmacy's response including, but not limited to, dosing and follow-up procedures
- Provide Pharmacy with releasable information regarding the public health emergency situation
- Manage public information activities with regard to the overall health and medical response across the LHJ's jurisdiction
- Provide educational materials, if appropriate, to Pharmacy for the purposes of distributing to all persons in emergencies impacting the public's health
- Make arrangements to retrieve or dispose of any unused medications from Pharmacy facilities and collect documentation forms in coordination with DOH
- Provide guidance and criteria to Pharmacy for tracking levels of activity, supplies and inventory, as applicable to the response and consistent across signatory LHJ jurisdictions



If no statewide mission number has been issued by the State Emergency Management Division, Pharmacy and Local Health Jurisdiction agree that prior to invoking this Agreement during emergencies, Local Health Jurisdiction, through the local department of emergency management, will request the issuance of a mission number from the Washington Military Department, Emergency Management Division.

## ARTICLE VII

### RESPONSIBILITIES OF PHARMACIES

Pharmacies' responsibilities include:

- Coordinate with DOH and/or signatory LHJs to insure statewide consistency with screening forms, tracking, training, and other Pharmacy requirements
- Comply with Pharmacy standards in effect during the Incident
- Identify the approximate number of medication doses that could be administered by Pharmacy in a specified time period and communicate that information to the LHJ
- Identify Pharmacy sites to receive medication deliveries and communicate site locations to the LHJ
- Communicate to LHJs each site location's scope of Pharmacy practice regarding affected populations, e.g., convey age or prescriptive authority limitations
- Receive and store medication deliveries, consistent with federal, state or local government requirements, at Pharmacy-identified facilities during Incidents
- Ensure that Pharmacy site locations serve the general public
- At Pharmacy's discretion, ensure that its own employees, including those employed by its parent company, and their families, are cared for consistent with public health recommendations
- Conduct medical screening of individuals receiving medications, based on guidance provided by LHJ, to identify potential contraindications and complications, and assure dispensing and administration consistent with federal, state and local government requirements
- In the absence of the issuance of an emergency use authorization, or a declared emergency triggering RCW 38.52.180 (6) waiving license requirements for registered emergency workers, prescribe and dispense medications under a collaborative agreement with a licensed health care prescriber or lawful health order issued by a local health officer



- Maintain accurate records of medications dispensed, administered, and remaining inventory
- Maintain and inventory the local, state or federal stock of medications, vaccines and supplies and physically separate them from the regular inventory. The local, state and federal stock cannot be used in place of commercial pharmacy stock at any time. Pharmacy stock may be used as a substitute for the local, state or federal stock and Pharmacy may seek reimbursement for this action, if available, in accordance with the then current state or federal guidance
- Track contact information of individuals receiving medications
- Communicate information regarding medications dispensed, administered, and contact information to local health jurisdiction as required by local health jurisdiction
- Provide education materials, supplied by local health jurisdiction to all individuals receiving medications
- Secure any unused medications until a time when LHJ can make arrangements for retrieval or disposal
- Participate, as appropriate, in LHJ-sponsored mass vaccination or medication dispensing or administration training and exercises
- Register and maintain qualifications of all Pharmacy personnel working under this Agreement as Emergency Workers within the Local Health Jurisdiction pursuant to Chapters 38.52 RCW et seq., Chapters 118-04 WAC et seq., and any other applicable statute, regulation or law in order to obtain immunity from liability and the benefits of workers compensation protection to the extent allowed by law.

## ARTICLE VIII

### COST AND PAYMENT

Local Health Jurisdiction shall provide the medications that are to be dispensed or administered by Pharmacy as specified in this Agreement at no cost to Pharmacy. Pharmacy shall dispense or administer these medications to patients or customers at no charge to the patient or customer except for an administrative fee not to exceed the lesser of that reimbursed by the Medicare Part D schedule, or emergency federal or state current guidance at the time. Pharmacy agrees to waive this fee if required by then current federal or state guidance. Pharmacy may also, in its discretion, waive this fee for patients or customers who demonstrate an inability to pay.

All other costs incurred by either Local Health Jurisdiction or Pharmacy through implementation of this Agreement shall be borne by each respective agency.

## ARTICLE IX



## IMMUNITY, INDEMNIFICATIONS AND LIMITATIONS

The Parties acknowledge that if this Agreement has been triggered after a federal public health emergency declaration by the Secretary of the Department of Health and Human Services under the PREP Act, immunity under state and federal law will extend to covered persons involved in dispensing, distributing, and administering countermeasures/prophylaxis under 42 U.S.C.A. §247d-6d. Immunity under the PREP Act does not apply to willful misconduct or acts conducted outside the scope of the declaration.

The Parties further acknowledge that if this Agreement has been triggered after a locally or state declared emergency under chapter 38.52 RCW or after the issuance of an event mission number by the Emergency Management Division of the Military Department, immunity and indemnification are provided under RCW 38.52.180 for activities within the scope of assigned responsibilities and under the direction of the local emergency management organization. Immunity and indemnification does not apply to gross negligence, willful or wanton misconduct, or acts outside the scope of the assigned responsibilities or not under the direction of the local emergency management organization.

The Parties agree to assert immunity as applicable to any action against one or more of them. The Parties acknowledge that the indemnification and defense provisions herein do not abrogate any statutory immunity.

If this Agreement has been triggered in circumstances when there is not a federal public health emergency declaration or issuance of a state event mission number, or to the extent immunity and indemnification under 42 U.S.C.A. §247d-6d or RCW 38.52.180 are determined by a court of general jurisdiction in the State of Washington to be inapplicable, each party agrees to be responsible and assume tort liability for its own wrongful acts or omissions, or those of its officers, agents or employees to the fullest extent required by law, and agrees to save, indemnify, defend and hold other parties harmless from any such tort liability. In the case of a determination of negligence or wrongful acts by the Local Health Jurisdiction and one or more Pharmacy, any damages allowed shall be levied in proportion to the percentage of fault attributable to each party, and each party shall have the right to seek contribution from the other parties.

Notwithstanding anything to the contrary in this Agreement, once the Local Health Jurisdiction has delivered the inventory to the Pharmacy, the LHJ will retain the risk of loss with respect to the inventory unless the loss is the result of the Pharmacy's negligence, gross negligence or intentional act or failure to act.

## ARTICLE X

### INFORMATION SHARING

Pharmacy will provide Local Health Jurisdiction with information Local Health Jurisdiction deems necessary for documentation of the actions taken and services provided under this Agreement, all of



which is available under the public health exemption of HIPAA, 45 CFR §164.512(b), and the Health Care Information Act, RCW 70.02.050 (2)(a).

Local Health Jurisdiction will advise Pharmacy of the information needed to protect the public health and to prevent or control disease, injury or disability and will only request the information necessary to protect the public health and to prevent or control disease, injury or disability.

## ARTICLE XI

### TERM AND TERMINATION

This Agreement shall become effective immediately upon its execution by any one Pharmacy and one Local Health Jurisdiction. After the first two such executions, this Agreement shall become effective as to any other Pharmacy or Local Health Jurisdiction upon its execution by such Pharmacy or Local Health Jurisdiction. The Agreement shall remain in effect as between each and every Pharmacy and Local Health Jurisdiction until participation in this Agreement is terminated by a withdrawing Pharmacy or Local Health Jurisdiction by written notice to all of the other signatories to the Agreement. Termination of participation in this Agreement by a withdrawing Pharmacy or Local Health Jurisdiction shall not affect the continued operation of this Agreement as between the remaining Pharmacies and Local Health Jurisdictions so long as at least one Pharmacy and one Local Health Jurisdiction remain.

Either Local Health Jurisdiction or Pharmacy may terminate this Agreement for convenience with written notification to all of the other signatories to the Agreement no less than thirty (30) calendar days in advance of the termination date.

## ARTICLE XII

### AMENDMENTS

No provision of this Agreement may be modified, altered or rescinded by any individual Pharmacy or Local Health Jurisdiction without the unanimous concurrence of the other Pharmacies and Local Health Jurisdictions. Modifications to this Agreement must be in writing and will become effective upon the approval of the modification by all Pharmacies and Local Health Jurisdictions. Modifications must be signed by each Pharmacy and Local Health Jurisdiction.

## ARTICLE XIII

### INDEPENDENT CAPACITY

The employees or agents of Pharmacy or Local Health Jurisdiction who are engaged in whole or in part in the performance of this Agreement shall continue to be employees or agents of that party and shall not be considered for any purpose to be employees or agents of any other party to this Agreement.





#### ARTICLE XIV

##### SEVERABILITY

If any provision of this Agreement or any document incorporated by reference shall be held invalid, such invalidity shall not affect the other provisions of this Agreement which can be given effect without the invalid provision, if such remainder conforms to the requirements of applicable law and the fundamental purpose of this Agreement, and to this end the provisions of this Agreement are declared to be severable.

#### ARTICLE XV

##### NO THIRD PARTY BENEFICIARIES

This Agreement is entered into solely for the mutual benefit of the parties to this Agreement. This Agreement is not entered into with the intent that it shall benefit any other person and no other such person shall be entitled to be treated as a third-party beneficiary of this Agreement.

#### ARTICLE XVI

##### DISPUTE RESOLUTION

If a dispute between any parties to this Agreement arises out of or related to this Agreement, or the breach thereof, the parties agree to endeavor to settle the dispute in an amicable manner by direct communication between or among each other before terminating the Agreement.



## ARTICLE XVII

### NOTICES

Whenever this Agreement provides for notice to be provided by one party to another, such notice shall be in writing and directed to the designated representative of the party.

## ARTICLE XVIII

### SURVIVORSHIP

The following clauses survive the termination of this Agreement:

- IX. Immunity, Indemnification, and Limitations
- XIV. Severability
- XV. No Third Party Beneficiaries

## ARTICLE XIX

### OTHER OR PRIOR AGREEMENTS

If a Pharmacy and Local Health Jurisdiction have a prior written agreement that relates to the subject matter of this Agreement, namely, using existing Pharmacy infrastructure to assist in addressing health and medical needs of an affected population during an Incident, including but not limited to mass dispensing of antibiotics, antiviral medications or vaccines to the general public during times of health and medical disasters, then, at such time that said Pharmacy and said Local Health Jurisdiction both execute this Agreement, such prior written agreement between them shall become null and void and of no further force and effect.

Notwithstanding the above provision in this Article XIX, any Pharmacy and/or Local Health Jurisdiction may enter into other agreements with other Pharmacies and/or Local Health Jurisdictions provided such other agreements govern subject matter not governed by this Agreement

## ARTICLE XX

### GOVERNING LAW

This Agreement shall be interpreted, construed and enforced in accordance with the laws of the State of Washington.

## ARTICLE XXI

### EXECUTION IN COUNTERPARTS



This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For purposes hereof, a facsimile copy of this Agreement, including the signature pages hereto, shall be deemed to be an original.

IN WITNESS WHEREOF, this Agreement has been executed and approved and is effective and operative as to each Pharmacy and each Local Health Jurisdiction as herein provided.

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Signature

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Print Name and Title

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Date:



ENDNOTES

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