In the fall of 2004, the United States faced a national shortage of influenza vaccine after a major vaccine manufacturer was unable to produce millions of doses of the vaccine due to potential contamination. Many public and private sector entities had far fewer doses of influenza vaccine to allocate than they had anticipated. In response, federal, state, and local public health officials, private vaccine distributors, and healthcare providers collaborated to distribute available doses of influenza vaccine. However, the existing legal framework through which allocations were made is murky. This article examines major legal issues regarding allocation strategies involving limited supplies of influenza vaccines, addressing in particular (1) existing legal requirements for allocating and distributing influenza vaccines among public health authorities and healthcare providers at the federal, state, and local levels; (2) the legal capacity of public health authorities to acquire existing vaccine supplies from healthcare providers; and (3) specific legal responses implemented by states in response to the 2004–2005 influenza vaccine shortage.

KEY WORDS: allocation, law, legislation, vaccine

In the fall of 2004, a national shortage of influenza vaccine was projected in the United States after Chiron Corporation, one of three major vaccine manufacturers, reported safety concerns related to the potential contamination of millions of doses of vaccine. Chiron was unable to fulfill domestic orders of the vaccine to public sector entities (eg, federal, tribal, state, and local public health agencies) and private sector distributors and healthcare providers. Because of the time-consuming and sophisticated nature of vaccine production, adequate production of additional doses of influenza vaccine by other manufacturers was not possible. As a result, the nation faced unexpected and unavoidable shortages of influenza vaccine during the 2004/2005 season in which the strain of influenza was projected to be more virulent than recent years (a forecast that fortunately proved inaccurate). Temporal delays in Chiron’s delivery of influenza vaccine during the 2005/2006 season have also been reported, but are not expected to significantly impact available supplies.

In response to the 2004/2005 influenza vaccine shortage, the federal Department of Health and Human Services (DHHS) and state and local governments scrambled to garner additional supplies. The federal Centers for Disease Control and Prevention (CDC) sought to ensure that existing supplies of vaccines were available for high-risk populations (eg, senior citizens, infants, and persons with chronic medical conditions). It allocated available vaccines according to the unmet needs of high-risk populations in each state. The Advisory Committee on Immunization Practices also released guidelines for state and local public health officials and others to consider in prioritizing and distributing limited vaccine supplies to the healthcare industry and to the public. These guidelines encouraged health departments and other vaccine providers...
to actively identify and vaccinate individuals who met the following priority guidelines:

- children aged 6–23 months;
- adults 65 years and older;
- individuals with underlying chronic medical conditions;
- pregnant women;
- residents of nursing homes and long-term-care facilities;
- healthcare workers with direct patient contact; and
- caregivers and other contacts of children younger than 6 months.6

Later, the Advisory Committee on Immunization Practices also recommended vaccination for additional priority groups (caregivers and other contacts of high-risk individuals, adults older than 50) if there was sufficient supply.7

Many states and localities responded by developing or initiating existing vaccine reallocation plans, administered mostly through their public health departments.8 These plans focused on distribution of unused influenza vaccines to high-priority individuals, usually consistent with CDC recommendations, within the state or locality. National public health organizations like the National Association of County and City Health Officials (NACCHO) helped coordinate vaccine reallocation efforts by collecting, organizing, and disseminating information about the availability of unused vaccines.9

Collectively, these legal and policy efforts helped ensure that available vaccines were distributed to those populations and individuals who needed them most. However, multiple legal issues concerns remain. The 2004/2005 influenza vaccine shortages required CDC and other federal government agencies, tribal, state, and local public health departments, and healthcare providers to revisit an increasingly recurring question: How should limited supplies of vaccines be allocated to ensure their proper distribution to providers and the public? This question may be viewed through multiple lenses (ethics,10 human rights,11 and public health sciences12). This article, however, examines legal and policy questions regarding allocation strategies involving limited supplies of influenza vaccines, addressing in particular (1) existing legal requirements for allocating influenza vaccines among public health authorities and healthcare providers at the federal, state, and local levels; (2) the legal capacity of governments to acquire existing vaccine supplies from healthcare providers to fill gaps in availability; (3) creation and adherence to vaccine distribution policies; and (4) state legal reforms addressing vaccine reallocation strategies.

**Influenza Vaccine Allocation and Distribution**

Although influenza vaccines are allocated in the United States in many ways, there are no legal mechanisms that specifically and comprehensively regulate the channels through which vaccines are procured. Each year, the Food and Drug Administration (FDA) determines which strains of the influenza virus should be included in the season’s influenza vaccine. The FDA then licenses selected vaccine manufacturers and closely regulates vaccine production.13 In 2004, three vaccine manufacturers (Aventis Pasteur, Chiron, and MedImmune) were initially licensed by the FDA to produce an adequate supply of the influenza vaccine for the nation. Approximately 109 million influenza vaccine doses were ordered to account for roughly 90 million high-risk individuals.14

During a typical year, these manufacturers accept direct orders for the influenza vaccine from government agencies and healthcare providers (eg, hospitals, health maintenance organizations, clinics, and physician practices). They also allocate a significant portion of vaccines to more than 25 influenza vaccine distributors in the United States, including STAT Pharmaceuticals, Moore Medical, GIV, Edwards Medical Supply, and Nationwide Medical.15 Various allocation channels for influenza vaccine are described in Figure 1.

The federal government is a large purchaser of influenza vaccine each year. The CDC, for example, issues contracts for millions of doses purchased with funds from the Section 317 Immunization Grant Program, the Vaccines for Children Program, and grantee funds. The federal Occupational Safety and Health Agency, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs also buy significant amounts of influenza vaccine.16,17

As shown in Figure 1, the CDC makes influenza vaccine doses available to state and local public health departments, which typically distribute vaccines according to their own standards. State and local health departments can also place direct orders with vaccine distribution companies to increase their supply. These departments provide influenza vaccines directly to individuals (with the assistance of healthcare workers) through in-school immunization programs, immunization clinics in retail stores, workplace settings, community organizations, universities, and community health centers. State and local public health departments may also supply vaccines to pharmacies and healthcare providers (private practitioners, nursing homes, hospitals, and long-term-care facilities) to supplement the influenza vaccines purchased directly through manufacturers or distributors. Providers often reallocate some of the vaccines they receive to other
healthcare providers or organizations when supplies are low.\textsuperscript{18}

Prior to the beginning of the 2004–2005 influenza season, the CDC released vaccine distribution recommendations that many state and local public health departments and healthcare providers used as guidance when ordering and distributing vaccines.\textsuperscript{19} The CDC’s policy, however, is not legally binding. State and local governments can deviate from this guideline in the distribution of influenza vaccine to meet the needs of their specific populations. In 2004–2005, many states and localities implemented regulatory mechanisms for distributing vaccines.\textsuperscript{20,21} Although these regulations varied in scope (Table 1), they typically (1) established clear allocation channels to provide certain percentages of vaccines to healthcare organizations and providers within the state and (2) attempted to ensure that vaccines were distributed to as many high-risk individuals as possible.

For the 2005–2006 influenza season, four vaccine manufacturers are licensed to produce the influenza vaccine (sanofi pasteur, Chiron Corporation, GlaxoSmithKline, and MedImmune). The number of doses that will actually be available and the timing of distribution are impossible to predict precisely. In anticipation of a potential distribution delay or vaccine shortage, the CDC recommended that until October 24, 2005, only priority groups will receive the influenza vaccine. Thereafter, all individuals are eligible to receive the influenza vaccine.\textsuperscript{22} Many state and local public health authorities issued statements encouraging compliance with the CDC’s recommendations.\textsuperscript{23}

\section*{Reallocating Influenza Vaccine During Shortages}

Although this system for allocating and distributing influenza vaccine works well when supplies are adequate, it is challenged when supplies dwindle. In the event of a limited vaccine supply due to public health emergencies or other factors, federal, state, and local governments may lack sufficient legal capacity to acquire and reallocate available vaccines.\textsuperscript{13} Public health authorities may be unable to allocate vaccines appropriately or efficiently to achieve the greatest possible reductions in influenza morbidity and mortality. Resulting drops in public confidence in the
## TABLE 1  ● State reallocation and distribution legal responses to the 2004/2005 influenza vaccine shortage

<table>
<thead>
<tr>
<th>State</th>
<th>Legislative, regulatory, executive, or other state action</th>
<th>Brief description</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>Order to Control Influenza Vaccination, State Health Officer</td>
<td>Orders all healthcare providers to vaccinate only high-risk individuals. Requires that healthcare providers cooperate with local health officers to facilitate redistribution efforts.</td>
</tr>
<tr>
<td>Connecticut</td>
<td>42 Conn Gen Stat ch 743h Emergency Executive Order</td>
<td>Allows the governor to impose price restrictions in the event of an emergency shortage of any essential healthcare product. Prevents price gouging.</td>
</tr>
<tr>
<td>Delaware</td>
<td>House Bill 51 (introduced February 4, 2005) Order to Control Influenza Vaccination, State Department of Health</td>
<td>Would improve patient’s access to influenza vaccines and allow pharmacists to work closely with physicians to improve health outcomes.</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>22 DC Municipal Reg ch 2, § 219–220</td>
<td>Requires that influenza vaccine be distributed to high-risk individuals. Noncompliance results in criminal charges and fines.</td>
</tr>
<tr>
<td>Florida</td>
<td>Emergency Rule, State Department of Health</td>
<td>Authorizes redistribution of influenza vaccine within the state to accommodate all high-risk individuals. Requires compliance with CDC redistribution regulations. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Hawaii</td>
<td>Influenza Vaccine Priority Guidelines, State Department of Health</td>
<td>Issues priority guidelines regarding vaccine distribution to high-risk individuals. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Iowa</td>
<td>Public Health Bulletin, State Department of Public Health</td>
<td>Provides that influenza vaccine only be distributed to high-risk individuals. Requires that bulletins be posted at all vaccine distribution sites.</td>
</tr>
<tr>
<td>Kansas</td>
<td>Guidance on Priority Groups, State Department of Health and Environment</td>
<td>Defines high-risk individuals according to CDC categories. Encourages healthcare providers to prioritize vaccine distribution.</td>
</tr>
<tr>
<td>Maine</td>
<td>Updated Guidance on Influenza, State Department of Health</td>
<td>Recommends that vaccine be distributed only to high-risk individuals. Requires that state-supplied vaccines be distributed accordingly. Encourages redistribution within the state. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Maryland</td>
<td>Call for Prioritization of Influenza Vaccine, Governor</td>
<td>Adopts CDC recommendations for prioritization of influenza vaccine to high-risk individuals. Encourages preventive measures to avoid infection. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Influenza Vaccine Initiatives, State Public Health Commissioner</td>
<td>Directs that vaccine be distributed only to high-risk individuals. Organizes redistribution within the state. Encourages preventive measures.</td>
</tr>
<tr>
<td>Michigan</td>
<td>Public Health Order, State Department of Community Health</td>
<td>Limits the distribution of influenza vaccine to high-risk groups as defined by the CDC. Noncompliance results in civil penalty.</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Public Health Notice, State Department of Health</td>
<td>Establishes priorities for the distribution of the influenza vaccine to high-risk groups. Requires that notice be displayed at all vaccine distribution sites. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Missouri</td>
<td>Executive Order, the Governor of Missouri</td>
<td>Requires healthcare providers to comply with high-risk vaccination recommendations. Encourages redistribution within the state. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Nebraska</td>
<td>Health Alert Network: Priority Guidelines, State Department of Health and Human Services</td>
<td>Implements guidelines for specifically defining high-risk groups to receive influenza vaccination.</td>
</tr>
</tbody>
</table>
ability of governmental authorities or the private sector to deliver influenza vaccine threatens future vaccine efforts. DesRoches and her colleagues surmised from survey data following the 2004–2005 influenza vaccine shortage that “...it may be difficult to convince the general public that there will be an ample supply of the vaccine...” in future years.

In atonement, some suggest a need for national uniformity in the allocation of influenza vaccine. In recent years, federal legislation has been proposed to regulate and standardize the vaccine distribution process. For example, the Flu Protection Act of 2005 would require the federal government to contract directly with vaccine manufacturers to purchase additional doses if necessary, and encourage states to develop a contingency plan for vaccine distribution to high-risk populations in the event of a shortage. To date, such legislation has not been enacted.

In response to the 2004/2005 influenza vaccine shortages, lacking national legislative fixes, governments developed or revamped vaccine reallocation policies to distribute vaccines to populations. In 2004, the CDC considered the vaccine needs of high-risk population within each state to determine the number of vaccines required for high-risk individuals. The Wisconsin Emergency Order, State Department of Health and Family Services, reserves 25% of supply for redistribution. Noncompliance results in court proceedings. This action is limited to the 2004–2005 influenza season.

In the event of a shortage, the CDC indicates Centers for Disease Control and Prevention. This action is limited to the 2004–2005 influenza season. The New Mexico Health Order, State Department of Health, limits distribution of influenza vaccines to high-risk individuals. Requires that orders be posted at all vaccine distribution sites. Noncompliance results in court proceedings. This action is limited to the 2004–2005 influenza season.

TABLE 1  State reallocation and distribution legal responses to the 2004/2005 influenza vaccine shortage (Continued)

<table>
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<th>State</th>
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</tr>
</thead>
<tbody>
<tr>
<td>New Mexico</td>
<td>Public Health Order, State Department of Health</td>
<td>Limits distribution of influenza vaccines to high-risk individuals. Requires that orders be posted at all vaccine distribution sites. Noncompliance results in court proceedings. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>New York</td>
<td>New Standard of Care, State Health Department</td>
<td>Adopts CDC vaccine distribution guidelines as the new “standard of care” within the state. Noncompliance with the guidelines could lead to regulatory action by the state health department.</td>
</tr>
<tr>
<td>North Carolina</td>
<td>N.C.A.C. § 41A.0201: Control Measures for Communicable Diseases</td>
<td>Makes CDC recommendations regarding which high-risk groups should receive influenza vaccination an enforceable rule within the state.</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Executive Proclamation, Governor</td>
<td>Encourages healthcare providers to comply with high-risk distribution recommendations. Encourages redistribution within the state to high-risk individuals. Compliance is not legally enforceable.</td>
</tr>
<tr>
<td>Oregon</td>
<td>Influenza Vaccine Education and Prioritization Plan, State Department of Human Services</td>
<td>Provides vaccine distribution guidelines for healthcare providers and creates strategy for vaccine redistribution within the state. Noncompliance results in civil penalty. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td></td>
<td>Influenza Outbreak Plan, State Department of Health</td>
<td>Outlines statewide influenza response plan, including role of state Department of Health and vaccine reallocation to high-risk populations. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>South Carolina</td>
<td>Public Health Advisory, State Department of Health and Environmental Control</td>
<td>Adopts CDC’s high-risk distribution guidelines. Encourages use of live vaccine for healthy, high-risk individuals. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Texas</td>
<td>House Bill 2060 (introduced March 4, 2005)</td>
<td>Relates to establishing a committee to study influenza vaccine shortage in the state.</td>
</tr>
<tr>
<td>Vermont</td>
<td>Health Order, State Department of Health</td>
<td>Limits vaccine distribution to high-risk individuals. Requires that all private purchasers reserve 25% of supply for redistribution. Noncompliance results in criminal penalty.</td>
</tr>
<tr>
<td>Virginia</td>
<td>Senate Bill 707 (signed by the governor on March 28, 2005)</td>
<td>Prohibits individuals from selling or administering influenza vaccine at unconscionable prices during an influenza vaccine shortage, as declared by the governor.</td>
</tr>
<tr>
<td>Washington</td>
<td>Distribution Plan, State Department of Health</td>
<td>Creates state and local distribution plan for vaccine doses reallocated to the state through the CDC to ensure distribution to high-priority populations. This action is limited to the 2004–2005 influenza season.</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Emergency Order, State Department of Health and Family Services</td>
<td>Limits vaccine distribution to high-risk individuals. Requires that the “emergency order” be posted at all vaccination sites. Noncompliance results in court proceedings.</td>
</tr>
</tbody>
</table>

*CDC indicates Centers for Disease Control and Prevention.
to be initially allocated from available vaccines at sanofi pasteur. Allocations were made in each state on the basis of a calculated percentage of unmet needs.26 Once vaccines were provided to each state from the limited supply available, responsibility for reallocating the vaccines was largely vested in state and local public health authorities. Each state then determined how the reallocated vaccines would be made available within the state. Some states purchased all of the vaccines and then distributed them to the public and private sectors. Other states allowed public and private entities to purchase the vaccines directly. Many states implemented some plan, regulation, policy, or legislation regarding influenza vaccine allocation or distribution in the event of a limited supply.

Table 1 comprehensively lists the states in which major legislative or regulatory changes were proposed or made in response to the 2004–2005 influenza vaccine shortage. These laws generally sought to ensure that any unused vaccines were reallocated within and outside of the state to high-risk individuals before being provided to the general public. During the 2004–2005 influenza season, 27 states and the District of Columbia took some form of direct legal action in response to the influenza vaccine shortage. While much of the state action is enduring, providing for vaccine distribution and allocation in the event of any future vaccine shortage, legal action taken by 12 states (Delaware, Florida, Hawaii, Maine, Maryland, Mississippi, Missouri, New Jersey, Oregon, Rhode Island, South Carolina, and Washington) was limited to the 2004–2005 influenza season. At least five states (Connecticut, New Jersey, North Carolina, Texas, and Virginia) and the District of Columbia proposed or enacted legislation or regulations to ensure distribution to high-risk populations or to create a more efficient allocation process. For example, Connecticut enacted a statute that allows the governor to (1) impose price restrictions on vaccines (to prevent price gouging) in the event of an emergency, and (2) require healthcare providers to administer vaccines to high-risk populations before providing vaccines to the general public.27 North Carolina revised its administrative regulations to specifically enforce CDC recommendations regarding which high-risk groups should receive influenza vaccination across the state.28

Other states issued “executive orders” to guide vaccine allocation through their governors (Connecticut, Maryland, Missouri, and Oklahoma) or state Departments of Health (California, Delaware, Florida, Hawaii, Indiana, Kansas, Maine, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New Mexico, New York, Oregon, Rhode Island, South Carolina, Vermont, Washington, and Wisconsin). In Vermont, a state health department “emergency order” required that all private vaccine purchasers (typically healthcare providers and pharmacies) reserve 25 percent of their vaccines for reallocation within the state. Noncompliance could result in criminal penalties.29 The New York State Department of Health issued an order to adopt CDC guidelines as the “standard of care” for vaccine distribution within the state.30 The governor of Oklahoma issued an “executive proclamation” encouraging vaccine administration to high-risk individuals, although compliance was not legally enforceable.31

Like state and local public health agencies, private healthcare providers typically created vaccine reallocation plans to guide distribution of their limited supplies.32 While the federal government does not directly regulate the resale or reallocation of vaccines by healthcare providers, their plans must comply with FDA’s “good manufacturing” regulations under the “emergency medical reasons” exemption (§503(c)(3)(B)(iv)) of the 1938 Food, Drug, and Cosmetic Act.33 Under normal conditions, this act prohibits the sale, purchase, or trade of drugs between hospitals or healthcare entities. However, the act does not prohibit the reallocation of drugs or vaccines for “emergency medical reasons” defined to include:

- “transfers of a prescription drug between healthcare entities or from a healthcare entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules;
- sales to nearby emergency medical services, that is, ambulance companies and fire fighting organizations in the same state or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons;
- provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and
- transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.”34

Any healthcare entity that reallocates vaccine pursuant to the emergency medical reason exception must maintain information about the brand name, the manufacturer and distributor, the lot number, the number of doses transferred, and the recipient of the redistributed doses. In addition, transfers must abide by the FDA’s requirements regarding proper handling, storage, and shipping.35

National public health organizations also helped in the coordination of reallocation efforts by gathering information regarding vaccine availability and needs. NACCHO, for example, created a clearinghouse and database to share model local reallocation and
redistribution plans. NACCHO’s Influenza Vaccine Reallocation Plan Database describes reallocation plans developed by local public health departments and provides information regarding statewide coordination of vaccination distribution. Its Influenza Vaccine Availability List, on which local health departments posted requests for vaccine or provided information on amounts they had available to share, helped to link states and localities needing additional vaccinations with those that have vaccinations available for reallocation.

**Recommendations and Conclusions**

Federal, state, and local efforts in response to the influenza vaccine shortage of 2004–2005 helped ensure that the majority of available vaccine doses were allocated and distributed to high-risk individuals through collective efforts and legal authorizations found in legislative or regulatory provisions, executive orders, and health department plans. State and local governments used existing or new legal approaches to set affirmative parameters for the allocation and distribution of their limited vaccine supplies, often consistent with CDC recommendations. Despite the lack of comprehensive federal regulatory authority, the public health and healthcare systems managed to timely link high-risk individuals with influenza vaccines in most cases. In October and November 2004, 13 million doses of influenza vaccine allocated for high-risk individuals were distributed to public and private healthcare providers. All unfilled public health orders were completed by early November, and 8 million doses were allocated to states according to the CDC’s priority plan by the end of 2004. In all, 95 percent of the 58 million influenza vaccine doses that were available in 2004/2005 were successfully distributed through public and private efforts. (Remaining doses were presumably unused.) According to data gathered by the CDC in February 2005, vaccination coverage among adults in priority groups approximated 42 percent while coverage among adults in nonpriority groups was 8.8 percent. This suggests that a vast majority of the vaccine doses were distributed to high-priority groups. Yet, several challenges remain relating to the coordination and distribution of influenza vaccines under existing and proposed legislative structures.

**Ensuring distribution to high-priority groups**

In previous years during vaccine supply disruptions, mass immunizations in a variety of settings (eg, grocery stores, schools) became controversial when some healthy persons were vaccinated before high-risk individuals. Facing potential significant vaccine deficits during the 2004–2005 influenza season, the public health system and vaccine providers focused on the prioritization of vaccine to high-risk groups. Only after fears over widespread vaccination shortages dissipated later in the 2004–2005 season were high-risk distribution priorities ultimately lifted in some jurisdictions. Still, even at the height of concern over shortages, some individuals who were not listed among CDC’s priority groups received vaccination through private sector entities or others. As mentioned above, nearly 9 percent of adults in nonpriority groups had received an influenza vaccine as of February 2005, even though (1) CDC recommendations regarding prioritization of vaccine to high-risk groups remained intact and (2) more than 55 percent of individuals in high-risk groups were never vaccinated. During exigencies, failures to justly allocate and distribute influenza vaccines may contribute to increased morbidity and mortality.

**Tangential implications of influenza vaccine legislation and regulations**

Legislation and regulations granting federal, state, and local authorities additional powers and duties related to a vaccine shortage implicate several legal issues. First, liability and accountability concerns could evolve from decisions regarding distribution priority and the administration of vaccines in nontraditional settings. Rationing of healthcare services, supplies, or medications will inevitably result in the denial of vaccines to some worthy recipients. Governmental authorities must ensure that denials are not based on factors such as race, ethnic origin, income status, or other discriminatory categories.

Second, when it is necessary to distribute and administer limited vaccines quickly (to make up for delays in shipments or availability of the vaccines), public health and healthcare authorities must maximize the capabilities of the healthcare workforce. The need to meet surge capacities in some jurisdictions may require the use of volunteer healthcare professionals, which raises a host of legal issues concerning licensure portability, personal liability, and workers’ compensation. Finally, federal, state, or local requirements that private sector vaccine purchasers reallocate a portion of their vaccine supply could lead to a finding of a constitutional taking. A constitutional taking can result from the direct acquisition or regulation of private property for public use, including the protection of the public’s health. Takings are authorized by the Fifth Amendment to the US Constitution and by many state constitutions, but require due process and just compensation be paid to private sector entities from whom the property (eg, purchased vaccine doses) was taken. It is not known how many
takings of influenza vaccine occurred in the 2004–2005 influenza season, although it is believed to be few.

Coordination between public and private vaccine purchasers

Existing government distribution plans cannot guarantee the proper allocation of existing vaccine supplies largely because government does not possess all, or even a majority of, vaccine supplies. For example, the public sector was responsible for purchasing only 36 percent of the total doses of influenza vaccine that were ultimately distributed in 2003.42 As noted in Figure 1, private sector entities directly contract with vaccine manufacturers or distributors to obtain vaccines. While states like Vermont required private sector vaccine purchasers to reserve a portion of their supplies for redistribution, other states do not similarly authorize this potential taking. Absent the declaration of a general state of emergency or public health emergency (which may authorize the rapid acquisition of needed medical treatments, supplies, or pharmaceuticals)43 or other legal maneuvers, states may be limited in their abilities to quickly reacquire private sector supplies of vaccine under existing legal methods.

Interjurisdictional sharing among states and localities

National coordination of vaccine supplies across state and local jurisdictions helped streamline reallocation of available vaccines and facilitated interstate exchanges. These efforts are commendable, but may not be sufficient in future incidents of significant vaccine shortages. Fair distribution of vaccine supplies across the country is addressed through CDC policies, but future shortages may require state or local governments to increasingly prioritize the sharing of supplies across jurisdictions to serve the public’s health when federal supplies are exhausted. Most states’ vaccine reallocation laws or plans, however, tend to focus on the distribution of vaccines solely within the state. Compacts or other agreements between states (such as the Emergency Management Assistance Compact,44 which 49 states have adopted) may facilitate interjurisdictional reallocations that state-specific legislation or regulation do not address.45

REFERENCES


34. 21 CFR §203.3(m).


42. Centers for Disease Control and Prevention. Estimated influenza vaccine doses paid for with public funds by payer category and agency/entity [nonpublic information available through the corresponding author]. 2003.

