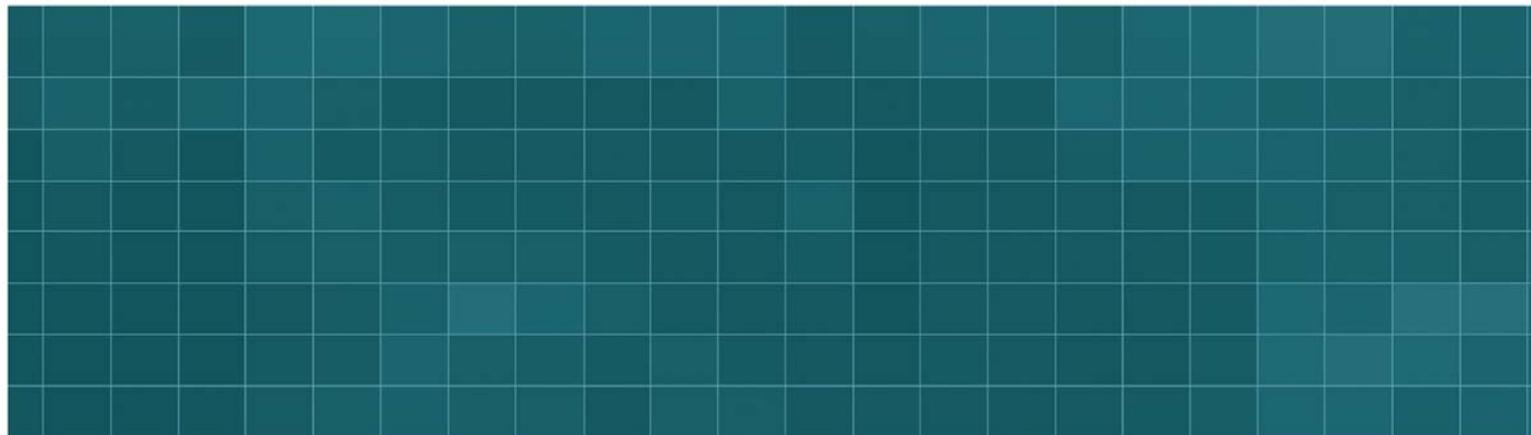


Antiviral Distribution and Dispensing
A Review of Legal and Policy Issues





Antiviral Distribution and Dispensing: A Review of Legal and Policy Issues

Sponsored by:

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Table of Abbreviations

ASTHO	Association of State and Territorial Health Officials	IOM	Institute of Medicine
CDC	Centers for Disease Control and Prevention	MACS	Multiagency Coordination Systems
CPA	Collaborative Practice Agreement	MIMAL	Model Intrastate Mutual Aid Legislation
DEA	Drug Enforcement Agency	MOU	Memorandum/Memoranda of Understanding
DHHS	Department of Health and Human Services	MRC	Medical Reserve Corps
EMAC	Emergency Management Assistance Compact	MSEHPA	Model State Emergency Health Powers Act
EPA	Environmental Protection Agency	NEA	National Emergencies Act
EPAP	Emergency Prescription Assistance Program	NIMS	National Incident Management System
EPDO	Emergency Prescription Drug Order	PDMA	Prescription Drug Marketing Act
ESAR-VHP	Emergency System for Advance Registration of Volunteer Health Professionals	PPE	Personal Protective Equipment
EUA	Emergency Use Authorization	PREP	Public Readiness and Emergency Preparedness
FDA	Food and Drug Administration	SLEP	Shelf-Life Extension Program
FEMA	Federal Emergency Management Agency	SNS	Strategic National Stockpile
HIPAA	Health Insurance Portability and Accountability Act	UEVHPA	Uniform Emergency Volunteer Health Practitioners Act
IND	Investigational New Drug	VHP	Volunteer Health Professional

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Disclaimer

Please note that information provided in this Report does not constitute legal advice. Always consult with legal counsel in your respective jurisdiction for specific legal guidance.

Executive Summary/Introduction

In partnership with CDC and NACCHO, ASTHO is conducting an in-depth assessment of antiviral distribution strategies within states based on the 2009-2010 H1N1 pandemic response, and investigating future, alternative distribution and dispensing methods that advance CDC's public-private partnership initiative by utilizing private actors to help distribute and dispense antivirals during future major pandemics. ASTHO's larger project includes a review of the distribution system used during the pandemic, an evaluation of the lessons learned, and identification of proposed improvements for distribution, dispensing, and tracking of antivirals, including alternative models utilizing wholesale drug distributors (hereinafter "distributors") and pharmacies. A key component of this larger project is an exploration of legal and policy issues related to antiviral distribution and dispensing for targeted treatment. Examining law and policy issues is essential because of their potential to affect national strategies for antiviral distribution differently across jurisdictions with divergent emergency, public health, and pharmacy practice laws.

Despite significant reforms of public health emergency laws in the last decade, legal responses to these types of emergencies across jurisdictions are disparate. Modern public health legal reforms offer a menu of legal options and flexibility for decision makers, but rarely prescribe specific actions that must be taken. Determining potential legal barriers and prioritizing options during public health emergencies are challenging for public health practitioners facing extreme pressures to distribute antivirals efficiently with limited time and resources.

This Report (1) identifies legal and policy issues implicated in a national strategy to distribute, dispense, and track antivirals, and (2) provides solutions to these issues (where possible) based on existing interpretations of law, practice, and lessons learned from prior emergencies, as listed in **Table 1. Summary of Primary Legal Issues and Solutions Relating to Antiviral Distribution and Dispensing**, and summarized below consistent with the Table of Contents. While the Report provides multiple examples of state (and other) laws, it does not provide an overarching assessment of state laws related to each of the key issues. State actors and their local counterparts may determine the need to assess their state legal infrastructure consistent with several key issues identified in this Report. **Appendix 1. Select Examples of Relevant State Laws Concerning Antiviral Distribution and Dispensing** provides an initial tabular guide of select legal issues states may seek to explore.

Part I. Setting the Stage discusses the need for extensive interjurisdictional coordination to successfully implement an antiviral distribution strategy during a major public health emergency. Collaborations across all levels of government can be enhanced through the use of advance agreements, Memoranda of Understanding (MOUs), and other compacts between multiple persons and entities, including: (1) CDC, states, and distributors; (2) pharmacies and distributors; (3) large chain and community pharmacies; (4) state, tribal, and local jurisdictions; and (5) physicians, pharmacies, and/or pharmacists. Depending on their binding effects or degrees of flexibility, these agreements offer an array of benefits in advance planning on key factors to ease distribution and dispensing of antivirals.

In **Part II. Real-time Responses**, the benefits of advance, interjurisdictional coordination are noted against a backdrop of changing laws and policies inherent in differing declarations of emergency, disaster, or public health emergency at all levels of government. During a major pandemic event varying declarations effectively change the legal landscape which requires a host of actors to assess and apply

new legal standards. Emergency laws can greatly facilitate the distribution and dispensing of antivirals, as discussed throughout the Report. They can also impede distribution strategies through the use of powers that may conflict with strategic initiatives. Ideally, public health authorities and emergency managers align with distributors, pharmacies, and health care entities to ensure patient access to antivirals nationally and regionally.

Part III. Moving the Product addresses the legal challenges encountered in moving antivirals from CDC's Strategic National Stockpile (SNS) through distributors to pharmacies that can dispense them to the public during a public health emergency. Federal law sets a legal floor for distributors, requiring them to obtain operators' licenses, provide detailed information on drug transactions, and control their storage facilities. States supplement these laws in many ways. In a declared emergency, distributors may be exempt from some federal or state legal requirements, which may, in part, ensure their ability to assure the real-time delivery and security of antivirals.

Part IV. Dispensing Antivirals evaluates the expanding roles and responsibilities of pharmacists and pharmacies in a declared emergency. Though many changes to pharmacy practice during a declared emergency also apply to hospital and other institutional pharmacists, the focus of the analysis is the role of community/retail pharmacists in the proposed antiviral distribution system. To facilitate public access to free antivirals, pharmacists may be called upon to dispense prescription drugs to large numbers of patients via an Emergency Prescription Drug Order (EPDO). State Medicaid policies may hamper reimbursement of minimal dispensing costs for out-of-state patients, potentially requiring waivers of Medicaid requirements. Pharmacists may dispense otherwise unapproved drugs pursuant to an Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA). Additional waivers of pharmacist licensing or prescription requirements by federal or state authorities may advance effective and efficient dispensing.

Part V. Meeting Surge Capacity focuses how to make sure there are adequate distributor and pharmacy personnel to get antivirals to patients. Industry losses of personnel during a major pandemic are highly predictable, whether due to illness or other reasons. Filling personnel gaps among distributors and pharmacies may be compromised by legal requirements relating to entity licensure and operation. These entities have engaged in advance planning to maintain continuity of operations despite personnel losses in emergencies. Yet, each may need to rely as well on vetted, trained volunteer health practitioners (VHPs). VHPs can provide essential services thanks to favorable laws supporting their efforts, including licensure reciprocity provisions allowing out-of-state volunteers to practice in-state during declared emergencies within specific limits.

Among the concerns of VHPs and pharmacy and distributor employees alike during public health emergencies is their potential for personal and professional liability. Distributors and pharmacies are also wary of their exposure to liability for their actions or omissions. Their collective concerns are principally addressed in **Part VI. Providing Incentives**. While liability claims may arise from multiple themes, an extensive array of liability protections helps to incentivize practitioners and entities to assist during emergencies. These include federal liability protections via the PREP Act (covering individual and entities providing countermeasures, such as antivirals, during emergencies), a bevy of state-based liability protections, and specific immunity provisions for VHPs and entities that provide or host them. Workers' compensation programs provide varying protections for employees and potentially VHPs from personal liability for harms they encounter in emergency response efforts.

Finally, **Part VII. Tracking Antivirals** describes specific legal issues related to the tracking of antivirals and other supplies during emergencies. Distributors, pharmacies, and pharmacists may be called on to provide real-time data to public health authorities to determine regional and national inventory levels and quantities of antivirals dispensed. Some of the data requested from pharmacists or pharmacies may include personally-identifiable health information about patients receiving the drugs, implicating health information privacy laws like the HIPAA Privacy Rule. Privacy laws, however, routinely allow use and disclosure of identifiable health data for public health purposes without individual authorization, especially during emergencies.

Table 1. Summary of Primary Legal Issues and Solutions Relating to Antiviral Distribution and Dispensing

<u>Issues</u>	<u>Solutions</u>
<i>I. Setting the Stage ~ Pre-emergency Strategic Planning and Preparedness</i>	
1. Federal, tribal, state, and local jurisdictions face logistical and legal impediments to sharing personnel, supplies, and resources.	Advance contracts, compacts, and MOUs between jurisdictions and entities prior to an emergency can address and resolve anticipated needs.
2. Rigid contractual requirements may not allow sufficient flexibility for contingencies during emergencies.	Non-binding MOUs and compacts are flexible to promote collaboration and adjustment based on circumstances, but they may also reduce certainty as to specific performance.
<i>II. Real-time Responses ~ The Changing Legal Environment in Declared States of Emergency</i>	
3. Existing, routine laws and policies may thwart antiviral distribution and dispensing in emergencies.	Emergency, disaster, or public health emergency declarations change the legal landscape, often allowing for the waiver of inconsistent or conflicting laws.
4. No single declaration provides all necessary coverage, resources, or authorities.	Declarations are not mutually exclusive, thus allowing multiple types of declarations across all levels of government.
5. Distributors, pharmacists, public health practitioners, and emergency responders may be unsure of the legality of actions or omissions.	Practicing “legal triage” prior to and during declared emergencies through emergency planners, practitioners, and private entities helps prioritize legal issues, develop solutions, and communicate them to relevant actors in real-time.
6. Exercise of some emergency public health powers can impede distribution plans (closures, evacuations, curfews).	Emergency managers, public health officials, and others work with distributors and pharmacies to limit impact on distribution and dispensing.
<i>III. Moving the Product ~ The Challenges of Antiviral Distribution Across Jurisdictions</i>	
7. Federal and state regulations concerning wholesale distributors could impede emergency antiviral distribution.	While the Prescription Drug Marketing Act and federal/state regulations could restrict distributions, federal and state laws may exempt emergency response efforts, and advance agreements may address remaining conflicts.
8. State and local governments may need to obtain distributors’ licenses to assist in distribution of antivirals.	Federal and state laws may exempt emergency response from the definition of wholesale distribution (negating the need for a license), but licenses could be obtained in advance if required.
9. Distributors may be liable for losses or damages to antivirals in transit.	Advance agreements may identify standards for liability. Otherwise, there is no liability generally for losses in transit absent failure to exercise reasonable care under the circumstances..
10. Large quantities of overstock and expired antivirals need to be removed and destroyed.	CDC may work contractually with states to coordinate removal and disposal to avoid antiviral diversion or environmental hazards.
11. Antivirals may reach their expiration date during an emergency.	FDA can authorize continued use of expired antivirals based on testing via the federal Shelf-Life Extension Program.
<i>IV. Dispensing Antivirals ~ Roles and Responsibilities of Pharmacists</i>	
12. Individuals may lack the ability to obtain a prescription in an emergency.	States can waive prescription requirements or allow widespread dispensing under EPDOs, or an EUA can waive prescription requirement at the federal level. Alternate models (e.g.,

	telepharmacy, nurse triage lines) may expedite issuance of prescriptions to patients without face-to-face contact with healthcare providers.
13. Counseling, labeling, and other needs may be difficult to meet in an emergency.	Federal and state requirements can be relaxed or waived during a declared emergency via executive, legislative, or agency orders, or by pharmacy boards.
14. Pharmacists may need to compound antivirals to address needs or shortages.	General compounding authority, waivers of existing legal restrictions, or EUAs can facilitate pharmacists' compounding.
15. Pharmacies may charge administration fees that are prohibitive for patients or that vary widely across a community.	Agreements or contracts with CDC or other agencies providing antivirals may stipulate maximum fees (e.g., capped at the current Medicare rate).
16. Dispensing costs may need to be reimbursed, including through other states' Medicaid programs for displaced residents.	Agreements or contracts with CDC or other agencies providing antivirals may allow separate charges for dispensing fees. Medicaid reimbursement restrictions in many states may be waived. Pharmacies may need to register with other states' Medicaid agencies, but can and should do so in advance.
17. Uninsured patients may need coverage to pay dispensing fees for antivirals.	The Emergency Prescription Assistance Program or similar state programs may provide coverage to uninsured recipients.
18. Appropriate antivirals may not yet be approved by FDA or may not be approved for a specific use.	FDA can issue an EUA to allow dispensing of qualifying products from any source during the emergency and can prioritize pre-emergency advance submissions, subject to FDA restrictions.
19. Legal restrictions on antiviral dispensing may vary depending on the source of the product.	Advance agreements and federal/state coordination on dispensing priorities can clarify relevant distinctions among differing caches.
V. Meeting Surge Capacity ~ Ensuring and Empowering Personnel	
20. Wholesale distributors face workforce gaps during an emergency due to predictable losses of personnel. These losses could lead to business failures or inability to meet contractual or other obligations.	Pandemic business continuity plans may include staffing shifts exposure controls, and training requirements to alleviate personnel losses. In the event of business failure or inability to meet contractual obligations, "escape clauses" in contracts with distributors may allow transfer of unused stockpiled medicines to other distributors.
21. More pharmacists/technicians may be needed to assist with dispensing during an emergency.	The Uniform Emergency Volunteer Health Practitioners Act, state pharmacy board waivers, or standard license reciprocity provisions can permit sharing of licensed health personnel across state lines.
22. Delays in waivers or other permissions could impede rapid deployment and use of VHPs.	Most states allow automatic, limited recognition of out-of-state licenses for qualified volunteers in declared emergencies.
VI. Providing Incentives for Participation ~ Liability and Other Protections	
23. Meeting the routine medical standard of care is difficult during an emergency.	In an emergency, a "crisis" standard of care may apply, allowing legal adaptation to changing circumstances and increased demand.
24. Pharmacists, technicians, and volunteers may need to act beyond their scope of practice in an emergency.	Emergency laws, CPAs, and waivers of pharmacy/medical board restrictions can allow administration of drugs, adjustment or issuance of prescriptions, or other functions by qualified

	personnel.
25. Individuals and entities participating in emergency response could be subject to malpractice or other liability claims.	Absent gross negligence or willful/criminal acts, many actors and entities are protected from liability claims under a variety of laws (e.g., PREP Act, VPA, MSEHPA, MIMAL, UEVHPA, EMAC).
26. Patients injured through the administration of antivirals during an emergency may require compensation.	The federal PREP Act establishes funds for compensating individuals injured during administration of medical countermeasures, including dispensing antivirals.
27. Emergency volunteers could be injured during response efforts, and require compensation.	The UEVHPA and corresponding state laws extend basic workers' compensation protections to licensed, vetted emergency volunteers.
VII. Tracking Antivirals ~ Supplies, Prescriptions, and Patients	
28. Real-time tracking and reporting of antiviral distribution and dispensing are uncommon in non-emergencies and so may be unfamiliar.	Public health reporting requirements may be legally authorized under various emergency laws or under an MOU or contract with distributors or pharmacists that clarifies responsibilities.
29. Public health agencies may need identifiable health information to uncover circumstances affecting the public's health.	Public health reporting laws may require reporting of unusual trends, types, or rates of prescription and diseases or conditions of public health importance using identifiable health data.
30. Reporting of identifiable health information by pharmacists to public health authorities implicates privacy concerns.	Disclosures of identifiable health information to public health authorities are expressly permitted under the HIPAA Privacy Rule and multiple state laws.
31. Pharmacists are not well-positioned to aggregate large amounts of patient data.	CDC may utilize de-identified patient data collected by data processing agencies to limit the need for pharmacists to directly aggregate identifiable or non-identifiable health data..

I. **Setting the Stage ~ Pre-emergency Strategic Planning and Preparedness**

Underlying the implementation of an antiviral distribution strategy during a major, public health emergency are advanced planning and emergency preparedness activities. The federal government, all states, and many tribal and local governments routinely plan for pandemic influenza or other mass, communicable disease scenarios. Resulting plans and preparedness activities focus in part on the ability of public and private sectors to distribute large quantities of medicines, supplies, and services to meet patient surge capacity. Adjustments to these plans based on lessons learned following the 2009-2010 H1N1 pandemic as well as newly-emerging distribution strategies are always in flux. Together with other legal tools to plan and agree on key concerns of law and policy, these efforts can help resolve multiple interjurisdictional and other issues prior to an emergency event.

Interjurisdictional Coordination

As noted in the Executive Summary/Introduction, one of the central lessons from the H1N1 pandemic and prior emergency events, as well as a pivotal component of CDC's new antiviral distribution strategy, is the need for strong interjurisdictional coordination across local, county, tribal, and state borders when considering the transfer of resources from CDC's SNS and other caches between public and private actors. While logistical and other obstacles to the seamless sharing of personnel exist, supplies, medicines, data, and other resources across boundaries, numerous legal avenues support interjurisdictional exchanges that can ensure efficient sharing during declared emergencies (see **Part II** for a discussion of emergency declarations).

Advance Agreements, Memoranda, and Compacts

Among the legal tools to improve antiviral management strategies are a series of advance agreements, MOUs, compacts, or policy statements executed prior to or concurrently with emergency events. These agreements or statements can provide meaningful paths and options among and between multiple actors and entities. Examples include agreements between:

(1) **CDC, states, and wholesale drug distributors** ~ Contractual agreements between governmental entities such as CDC and states with distributors are currently being considered by CDC to facilitate antiviral distribution. These legally-binding agreements may set terms for distributors'¹ roles during an emergency, including delivery, storage, and security requirements and post-emergency return procedures. An existing agreement between the New York State Department of Health and distributors, for example, includes terms reinforcing federal and state requirements (such as chain of custody documentation), packaging and storage procedures, segregation of government assets from commercial inventory, and returning of unused or expired drugs.²

(2) **Pharmacies and distributors** ~ Agreements between pharmacies and distributors (whether private corporations or state or local governments) typically leave to pharmacies decisions about moving antivirals from distribution points or within their network. Pharmacies may choose to enlist distributors as transportation agents. For example, the Texas Department of State Health Services, in a 2009 agreement, planned for delivery of antivirals to a central chain pharmacy location, but required pharmacies to get the drugs to appropriate locations with potential assistance from a private sector distributor.³

(3) States and private sector entities (including large chain or community pharmacies) ~ Many states have existing agreements in place to facilitate distribution of antivirals from state stockpiles (either originating in the SNS or purchased by the state itself) through various entities, including community retail pharmacies.⁴ Concerning these latter agreements, common provisions include restricting dispensing within the state, limiting pharmacy “dispensing fees” (with waivers for recipients unable to pay), and inventory reporting requirements.⁵ Such agreements could be adapted and used as models for new agreements to address the use of SNS antivirals supplied directly from CDC to distributors and pharmacies. Additional state agreements with non-profit entities such as charitable organizations, academic centers, and pharmacy schools may help ensure the availability of essential volunteer personnel or other resources to distribute or dispense antivirals. For example, pharmacy school faculty, staff, and students led coordination efforts to distribute 33,000 doses of H1N1 vaccine on the Auburn University campuses and to off-campus employees in 2009 on behalf of the Alabama Department of Health.⁶

(4) State, tribal, and local jurisdictions ~ Interjurisdictional agreements between state, tribal, or local governments take many forms, including legislatively authorized compacts. With Congressional support, for example, all fifty states, Puerto Rico, Guam, the U.S. Virgin Islands, and the District of Columbia have ratified the Emergency Management Assistance Compact (EMAC),⁷ a mutual aid agreement that provides for interjurisdictional movement of goods, services, personnel, and resources in response to a declared emergency or disaster. EMAC includes provisions on implementation, responsibilities, limitations, licenses and permits, liability, supplementary agreements, compensation and reimbursement, evacuation, and severability. Though not implicated extensively in response to the H1N1 pandemic, EMAC was used extensively in response to Hurricane Katrina in 2005. The State of Florida, for example, provided 2,000 Tetanus and Diphtheria vaccines to Louisiana and Mississippi, along with numerous other resources and personnel via EMAC.⁸ Tribal and local governments may agree to similar cooperative compacts to enable sharing of resources within and outside their jurisdictions.

(5) Physicians and pharmacists ~ Nearly all states’ pharmacy laws authorize collaborative practice agreements (CPAs) through which physicians may work closely with pharmacists and share a series of patient care tasks. Pharmacists’ roles may include assessing or screening patients, ordering and evaluating drug therapy-related tests, choosing and overseeing drug regimens, counseling and educating patients, and administering medications.⁹ With capable pharmacists following defined protocols, CPAs can extend the reach of patient care by pharmacists. As seen during the H1N1 pandemic, CPAs can be an effective tool, especially when built on a nationally-vetted model typically issued by CDC or states. A CPA template developed in Washington State for influenza outbreaks, for example, allowed pharmacists to issue prescriptions for antivirals and included extensive guidance on patient evaluation, prophylaxis, referrals, adverse reactions, training, documentation and reporting, and dosage and administration.¹⁰ Resources for developing such agreements at the local level are also available.¹¹

Contractual vs. Informal Approaches

Contractual and informal approaches offer opportunities to set terms or facilitate understandings of key issues to guide allocations of limited antiviral supplies. Some agreements may embrace a legal contractual approach. Others, such as MOUs or compacts, may be intentionally worded

so as not to be construed as binding contracts. This is an important distinction because of the potential legal significance of each approach.

Though sometimes used interchangeably, MOUs and contracts are different. In the emergency preparedness context, MOUs or compacts may be entered into among state or local governments to help formalize cooperative plans to address emerging threats. For example, the International Emergency Management Assistance Memorandum of Understanding^{12,13} provides guidance among six New England states and five Canadian provinces on coordinating emergency response efforts, but is not necessarily legally binding like a formalized international treaty. In this limited context, MOUs are distinct from contracts or other legal documents principally because these types of MOUs do not include legal requirements to act. Rather, they typically provide guidance for when signatories choose to respond to requests, and potentially set parties' expectations regarding circumstances that may inhibit action.

In other settings, however, MOUs may constitute contractually binding agreements if three legal conditions are met: (1) there is an offer (e.g., to provide resources); (2) there is an acceptance of the offer (e.g., a requester indicates its need for the resource and accepts terms related to its sharing); and (3) something of value (e.g., money, personnel, supplies) is exchanged to secure the deal (which is known legally as "consideration").¹⁴ Absent congressional action (such as pursuant to EMAC), there may be limitations on the potential legal enforceability of MOUs between states.

Agencies across jurisdictions, disciplines, and levels of government may also develop Multiagency Coordination Systems (MACS) to guide and harmonize their responses. MACS establish dispatch procedures, command structure, support activities, and other advance strategies. MACS can be less formal than MOUs or contracts while still serving the interests of response and resource transfer. However, complex and unanticipated situations can stretch the capabilities of such arrangements.¹⁵

Unlike generalized agreements or policies on principles, binding contracts necessitate specific actions and impose potential liabilities between parties. Unless skillfully drafted, contracts may not be preferred during emergencies because of the need for considerable flexibility. Non-contractually binding agreements, such as MOUs and MACS, enable parties to align and collaborate during emergencies without rigid requirements. Their downside is that they may not legally require any party to share or distribute antivirals with another in accordance with preset plans.

Benefits of Advance Planning

Whether framed as binding contracts or non-binding agreements, these advance arrangements offer numerous benefits. They present an opportunity to craft and spell out terms of collaboration (instead of waiting until an emergency is declared and such negotiations become compromised).¹⁶ To be effective, these agreements must either allow for considerable flexibility (thus reducing certainty as to actual distribution plans) or attempt to reflect actual emergency conditions through which decisions will be made. Either objective can be difficult. Even skilled legal drafters working with public health partners providing excellent input may: (1) miss the mark as to the actual needs for rapid antiviral distribution and reallocation during emergencies; (2) complicate matters by failing to recognize the changing legal standards in declared emergencies (see **Part II**); (3) add to confusion through overly-legalistic language; or (4) fail to provide needed flexibility for variable conditions.

Unnecessarily complicated legal language in antiviral distribution and dispensing agreements may be difficult to understand. One contract, for example, contains the following language: “Now, therefore, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows”¹⁷ Though this reflects common language in many formal contracts, it could easily be rewritten to say “As both parties acknowledge the legal existence of the contract, they agree to” Considerable efforts to clarify legal drafting in these types of contracts and agreements facilitates understanding and execution.

In summary, binding legal contracts can be effective in setting antiviral distribution and dispensing strategies. Overly-legalistic language can obscure guidance on how to share resources during emergencies. MOUs or other agreements that do not accurately reflect actual demands or legal conditions, or are too complicated to execute, can actually impede efficient strategies.

II. *Real-time Responses* ~ The Changing Legal Environment in Declared States of Emergency

In non-emergencies, existing laws and policies offer reasonable guidance on the legality of various decisions and actions in distributing and dispensing antivirals. Things change, however, during pandemics or other major emergencies requiring rapid responses to protect the public’s health. The legal environment transforms during declared states of emergency, disaster, or public health emergency at the federal, tribal, state, or local levels. These declarations trigger an array of special powers designed to facilitate public- and private-sector response efforts.¹⁸ For example, emergency laws:

- (1) offer flexible powers to respond rapidly;
- (2) encourage response efforts by limiting liability;^{19,20}
- (3) smooth shifts in situational standards of care;²¹
- (4) allow alterations of professional scopes of practice;²² and
- (5) may permit waiver of legislative or regulatory provisions that impede effective responses.

These changes in the legal environment can significantly impact response during an emergency, including distribution and dispensing of antivirals.

Emergencies and Disasters

The extent of legal variations during emergencies depends heavily on the type of emergency declared. The federal government, every state, and many tribal governments, territories (e.g., American Samoa), and local governments²³ may declare either general states of “emergency” or “disaster” in response to crises that affect the public’s health.

Federal Emergency Declarations. The President, for example, can declare a state of emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (“Stafford Act”)²⁴ upon request of any state governor when federal assistance is needed “to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe.”²⁵ The President can also declare a state of emergency pursuant to the National Emergencies Act (NEA)²⁶ for incidents requiring a

national response, like the 2009-2010 H1N1 pandemic.²⁷ These types of emergency declarations typically authorize emergency management agencies, like the Federal Emergency Management Agency (FEMA) and partners to coordinate emergency responses, as well as activate programs such as the Emergency Prescription Assistance Program (discussed in **Part IV**).

In addition, the federal Department of Health and Human Services (DHHS), pursuant to the Public Health Service Act,²⁸ may also declare states of “public health emergency.”²⁹ Pursuant to this declaration, DHHS can mobilize resources, waive specified federal requirements related to Medicare or Medicaid reimbursement, temporarily set aside certain provisions of the HIPAA Privacy Rule, and conduct other emergency response activities.

Some of DHHS’ emergency powers may only be authorized with a further declaration of a national emergency by the President. For example, during the 2009-2010 H1N1 pandemic, DHHS immediately declared a state of public health emergency on April 26, 2009, just days after initial cases in Mexico were confirmed. However, only months later on October 23, 2009 did President Obama declare a state of emergency allowing for broader waivers of federal regulatory requirements (e.g., specific provisions of the State Children’s Health Insurance Program and the Emergency Medical Treatment and Labor Act).³⁰ While some members of Congress are considering legislative fixes to expand DHHS’ public health emergency powers without the need for a subsequent national emergency declaration, at present coupling these two types of declarations may be essential to empower DHHS to act to the fullest, lawful extent.

State and Territorial Declarations. All states and territories have the legal authority to declare states of emergency or disaster, including in relation to crises that impact the public’s health (e.g., pandemics, bioterrorism events, widespread food borne illnesses). According to the Network for Public Health Law, twenty-six states and D.C. have legislatively crafted “public health emergencies,” or like terms, as part of their laws,³¹ based largely on the Model State Emergency Health Powers Act (MSEHPA).³²

Developed by the *Centers for Law and the Public’s Health* in response to calls for legislative reforms following the anthrax exposures in the Fall of 2001,³³ MSEHPA’s model statutory language incorporates a series of flexible measures to facilitate emergency responses under a high threshold definition of “public health emergency,” defined as:

An occurrence or imminent threat of an illness or health condition that is (1) believed to be caused by . . . bioterrorism, the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin; and (2) poses a high probability of . . . a large number of deaths in the affected population; a large number of serious or long-term disabilities in the affected population; or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.³⁴

Public health emergency declarations empower public health officials and private entities to focus on the public health aspects of emergencies, including the need to distribute and dispense resources like antivirals efficiently to prevent avoidable morbidity and mortality. While all states initiated their pandemic flu response plans in response to the spread of H1N1, only twelve formally declared states of

emergency, disaster, or public health emergency over the first six months of the pandemic. It is worth noting that these dozen states' combined populations included over one-half of the U.S. populace. Equally noteworthy is the false premise that all states and territories will proximately declare states of emergency in response to a relatively slow-moving pandemic event. What is more predictable is that these declarations will be staggered over months as state and territorial officials assess the need for such declarations, if at all.

In states or territories that do not formally declare states of emergency, public health officials must rely on other legal techniques and maneuvers embedded within agreements, MOUs, contracts, or existing public health laws to facilitate the distribution and dispensing of antivirals. This accentuates the need for adequate advance planning (discussed in **Part I**) that is not overly-reliant on declarations of emergency to change the legal landscape. In many jurisdictions, distribution and dispensing of antivirals may have to proceed consistent with routine laws and policies unless and until the legal environment can change pursuant to an emergency declaration.

Dual Declarations

One interjurisdictional dilemma arises when federal and state governments may not decide collectively to formally declare states of emergency. Another dilemma arises, however, when federal and some state governments may declare both states of “emergency” or “disaster” and “public health emergency” in response to a major pandemic. These dual declarations are possible because the statutory constructs underlying them are not mutually exclusive. In fact, they often share common components. In Delaware, for example, a *disaster* can be declared when any of a number of man-made or natural events causes “substantial damage to property or the environment, and/or hardship, suffering, injury or possible loss of life;”³⁵ an *emergency* can be declared in any situation that requires government efforts to save lives, to protect property, public health, and safety, or to decrease the threat of a disaster;³⁶ and a *public health emergency* can be declared for an event involving bioterrorism, an infectious agent, or the release of a chemical that poses a high probability of numerous deaths, disabilities, or widespread exposure to a dangerous agent.³⁷ An influenza pandemic could trigger all three declarations simultaneously.³⁸ The potential for overlapping declarations within and across jurisdictions can lead to confusion as divergent public and private actors, each mobilized or authorized to act under a different declaration that invokes different powers and chains of command, seek to respond in duplicative, overlapping, and at times inconsistent ways.

Practicing “Legal Triage”

Though a critical component of emergency responses, emergency laws do not always ensure best practices. The challenges of real-time legal decision-making in declared emergencies are substantial. Framed in broad language, shaped by political realities, and subject to fluctuations on the frontlines of response efforts, emergency laws tend to offer a menu of legal powers and options, but not definitive guidance on how to use them. Lacking affirmative legal direction, emergency responders may unknowingly act outside of legal boundaries. Worse yet, they may fail to act to protect the public's health because of erroneous legal advice, liability fears, fiscal concerns, or other perceived legal ramifications.

Through what has been called “*legal triage*,”³⁹ emergency planners, public health practitioners, and private entities (e.g., wholesale distributors, pharmacies), and their legal counsel must prioritize legal issues and solutions in real-time emergencies to further legitimate public health responses. Legal triage requires responders to make critical legal decisions that balance communal and individual interests in emergencies where facts may be unclear, resources are scarce, and communal well-being is at serious risk. Responders must expeditiously:

- identify legal issues that may facilitate or impede public health efforts in real-time;
- assess and monitor changing legal norms during emergencies;
- craft innovative, legally-sound solutions to reported barriers to public health response efforts;
- explain legal conclusions through tailored communications to responders and the public; and
- revisit the utility and efficacy of their legal guidance with the goal of improving public health outcomes.⁴⁰

Only through these types of real-time actions in declared emergencies may critical issues of law and policy be addressed sufficiently to promote the efficient distribution and dispensing of antivirals in furtherance of the public’s health

Legal Limits to Moving Antivirals

Despite the expansiveness of emergency legal authority, there are limits to what public and private actors can do to distribute and dispense antivirals.⁴¹ A diverse range of laws (e.g., constitutional provisions, statutes, regulations, cases, and contracts) may constrain governmental and private actors during declared emergencies. In addition to significant logistical challenges, a thicket of laws may potentially impede the transfer of antivirals from manufacturers or government stockpiles to patients. Some of these impediments may be rooted in inviolable constitutional norms such as equal protection or the ability of government to “take” property (including antivirals) with compensation from private entities (e.g., hospitals, clinics, pharmacies) to further communal purposes.

Emergency laws activated during a severe pandemic may thwart antiviral distribution plans through, for example:

- (1) closures of businesses, , schools, or roads;
- (2) issuance of evacuation orders that shift populations away from antiviral supplies or dispensing sites;
- (3) implementation of expedited authority to “take” (with compensation) antivirals from private sector entities for public purposes; or
- (4) implementation of broad curfews that impair individuals’ abilities to access antivirals at pharmacies or other locations.

Other legal issues may arise as a function of pre-existing contractual laws or procedures that constrain relationships along the antiviral supply chain, as discussed in **Part I**. Though potentially posing impediments to emergency response efforts, few of these legal obstacles are intractable.⁴² Through advance planning and artful, well-communicated interpretations in real-time, specific legal concerns underlying the distribution and dispensing of antivirals can be alleviated. Emergency laws themselves become the tool through which widespread movement and dispensing of antivirals is possible.

III. ***Moving the Product* ~ The Challenges of Antiviral Distribution Across Jurisdictions**

In non-emergencies, drugs move quickly and safely from manufacturers to distributors to pharmacies and other points of dispensing along well-defined and legally-regulated paths. In a declared emergency, however, moving antivirals from CDC's SNS or other government stocks through distributors to pharmacies for dispensing may be legally problematic due to existing legal norms that require detail processes and security assurances related to the movement of drugs, as well as other reasons discussed below. The situation is further complicated by potential concurrent distribution and dispensing activities of state and local health departments utilizing their own caches of antivirals or additional products from SNS. Widespread antiviral distributions face an array of federal and state regulations designed to regulate routine movements of drugs between drug manufacturers, distributors, and pharmacies on a just-in-time basis. This section lays out specific federal and state regulatory requirements underlying the distribution of drugs, and offers a series of proposed solutions to perceived legal barriers.

Federal Regulation of the Distribution of Antivirals or Other Prescription Drugs

The Prescription Drug Marketing Act⁴³ (PDMA) and corresponding federal regulations⁴⁴ govern the wholesale distribution of prescription drugs at a national level. PDMA requires distributors to: (1) provide the recipient of the drugs with a statement identifying the date of each prior purchase or trade and the name and address of each party involved; and (2) be licensed in each state where they operate pursuant to minimum regulatory requirements for personnel, storage, handling, and record-keeping.

While the PDMA and federal regulations set a legal floor for distributors, additional state- or local-based requirements for licensure or operation procedures may implicate real-time distribution of SNS or other antivirals through distributors during a national pandemic. Differences in state and local regulations may be addressed using a combination of MOUs or contracts (discussed in **Part I**), and federal guidance and protocols. Waiver of some state regulations under declarations of emergency, as noted in **Part II**, may also alleviate interjurisdictional impediments resulting from divergent regulations.

Real-time Distribution of Antivirals

Federal law requires that all drugs distributed by a distributor be accompanied by a general statement (a.k.a. "pedigree") specifying all transactions involving the drug. The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy suggest that the pedigree additionally include the name and address of the principle seller, the business address of each prior owner, and a certification of accuracy.⁴⁵ Some states, including Arizona,⁴⁶ Georgia,⁴⁷ Illinois,⁴⁸ and Texas,⁴⁹ require the name and address of each location from where the drug was shipped. Georgia law specifies that failing to provide a pedigree is unlawful. In transferring antivirals from SNS to distributors, CDC might not be able to provide the address of every location from which the drug has been shipped due to national security restrictions. CDC has indicated that federal pedigree requirements have not been required in prior distributions from the SNS, which presumably would preempt additional state requirements which supplement federal standards. Absent this type of exception in future pandemics, adhering to federal or state pedigree requirements may be required.

PDMA-related federal regulations concerning distributors' facilities also require that they be temperature- and humidity-controlled, properly lit, feature "quarantine areas" for adulterated drugs, and use appropriate security to limit access to drugs on site.⁵⁰ Some states, such as California, also require alarm systems and restrictions on persons present in the facility.⁵¹ Distributors must also maintain written procedures (1) requiring the oldest approved stock be distributed first; (2) concerning the handling of drug withdrawals and recalls; and (3) on the security and ongoing operations of the facility in the event of disaster or emergency.⁵² Collectively, these regulatory requirements could delay or hamper rapid movement of antivirals in emergencies.

Fortunately, there are legal solutions addressing these concerns. PDMA, as well as the Model Rules for Licensure of Wholesale Distributors, defines "wholesale distribution" to exclude the sale, purchase, or trade of prescription drugs for emergency medical reasons.⁵³ States like Illinois,⁵⁴ Texas,⁵⁵ and Wisconsin⁵⁶ have similar provisions. Broadly interpreted, these exceptions could exempt distributors moving antivirals during a national emergency from many requirements, including the need to provide pedigree information. Colorado's Board of Pharmacy determined that distribution of antivirals from the SNS in response to H1N1 in 2009 did not constitute wholesale distribution and thus did not require wholesale registration.⁵⁷ Additionally, transfers of drugs between retail pharmacies to alleviate temporary shortages are specifically excluded from the definition of "wholesale distribution" under PDMA.⁵⁸ Texas authorizes its state health commissioner to exempt specific purchases of drugs by state agencies or political subdivisions from pedigree or similar requirements if substantial costs may result.⁵⁹

Distributor Licensing. One additional issue relates to state-based requirements for distributor licensing. During the 2009 H1N1 pandemic, some state Attorneys General required state or local governments to become licensed as distributors before handling antivirals or other medications. This requirement is unnecessary during a declared emergency. As noted above, transfers of antivirals or other drugs for emergency medical reasons are not considered "wholesale distributions" and thus should not require a distributor's license pursuant to PDMA, the Model Rules of Licensure of Wholesale Distributors, and many state pharmacy laws. Still, acknowledging the realities of real-time emergency response and consequences of potential delays due to inter-agency conflicts, some state and local governments anticipating the need to distribute antivirals directly may consider becoming licensed as distributors in advance of the emergency. Some local governments, however, may find that the costs of obtaining and maintaining distributor licensure are too significant or prohibitive to justify advance licensing.

Risks of Loss for Antivirals in Transit

While PDMA does not specifically state that distributors are responsible for risks of loss for drugs in their possession (perhaps leaving this issue for contractual resolution), requirements at the federal⁶⁰ and state⁶¹ level suggest that a security breach could result in investigation or de-licensing. Distributors' security concerns may be mitigated by the use of just-in-time delivery systems to minimize the need for significant storage of antivirals between their receipt from CDC and delivery to pharmacies.

Potential risks for antivirals lost or damaged in transit are another concern. Antivirals from the SNS remain CDC property (unless CDC indicates otherwise). Title to the product would likely not pass to distributors since CDC may be responsible for reclaiming unused SNS supplies after an emergency has abated. Forthcoming, proposed contracts between CDC and distributors may clarify liability terms under

various circumstances, potentially tying prospective responsibility to PREP Act covered countermeasures (explained in more detail in **Part VI**). Absent a contrary contractual provision, distributors may not be liable for losses in transit resulting from the nature of the property, disasters or accidents, or intervening criminal acts of others.⁶² They may be responsible, however, for damages to antiviral stocks stemming from their own failures to exercise reasonable care under the circumstances.⁶³

Removing and Disposing of Overstock and Expired Assets

Generally, pharmacies dispose of their excess or expired stock through “reverse distributors,” which are licensed and highly regulated by the federal government, in particular the Drug Enforcement Agency (DEA), because they often handle controlled substances. Reverse distributors are distinct from wholesale distributors that originally deliver the product to the pharmacies. In some cases, the drugs are returned to the manufacturer through reverse distributors, but more often the products are destroyed due to expiration. Pharmacies, wary of absorbing the expense of returning drugs, may enter agreements with a manufacturer or distributor to offset or reimburse a portion of the costs.

During the 2009/2010 H1N1 outbreak, CDC worked closely with providers and states to return or dispose of overstock of Tamiflu[®] and Relenza[®].⁶⁴ The federal Environmental Protection Agency (EPA) may also oversee specific aspects of disposal consistent with environmental health and safety laws. Since antivirals, unlike some vaccines, do not contain thimerosal or any other “hazardous” substance (as defined by federal law), their disposal may not implicate certain environmental requirements. Federal oversight of the return of excess antiviral stocks may be essential to ensure national standards and direct receipt by federal or state public health authorities. It may also help preclude potential diversion of drugs onto the “black market,” as happened with Ciprofloxacin (used to treat anthrax) following the terrorist attacks of September 11, 2001.⁶⁵

Shelf-Life Extension Program

Drugs that have exceeded their stated expiration date typically must be pulled from the market and destroyed. Expired antivirals, however, may not require immediate removal or disposal. On the basis of lot testing, FDA is authorized under the Shelf-Life Extension Program (SLEP) to extend the expiration date beyond that originally established by the drug’s manufacturer. Products reaching their expiration dates may in some cases be retained by distributors, government entities, or pharmacies on the premise that they may be used under a forthcoming EUA. EUAs, discussed more extensively in **Part IV**, may allow previously unapproved uses of the drug or extended uses beyond the drug’s original expiration date so long as approved storage conditions and other conditions are met.⁶⁶

IV. *Dispensing Antivirals* ~ Roles and Responsibilities of Pharmacists

Pursuant to a well-defined regulatory environment and in collaboration with other health care professionals, pharmacists provide an array of health services to the public in addition to dispensing prescription medications. During declared emergencies, the boundaries of a pharmacist’s practice and responsibilities may adjust to meet surge capacity. Whether employed by a community pharmacy, hospital, or other entity, pharmacists may be allowed to dispense drugs not yet fully approved by FDA, screen patients directly to assess whether they should receive a drug, or practice outside their normal scope of practice under broad waivers of pharmacy board requirements. Advance understanding of and

planning for these potential changes, in conjunction with governmental guidance, can obviate confusion and liability concerns that could impede the role of pharmacists and pharmacies in effectively dispensing antivirals in real-time emergencies.

In-state Dispensing

A pharmacist must be licensed to dispense prescription drugs to patients in any state in which the pharmacist practices. In non-emergencies, pharmacists may generally only dispense prescription drugs pursuant to a valid prescription issued by a licensed and authorized health care practitioner. During a declared public health or other emergency, pharmacists may also dispense medications pursuant to an Emergency Prescription Drug Order (EPDO), or similar provisions under other nomenclatures. An EPDO would typically be issued by a state health officer or local public health officer, depending on applicable statutes. Upon issuance, it allows pharmacists to dispense designated prescription drugs for treatment or prophylaxis to a large number of patients without individual prescriptions when widespread dispensing is required.⁶⁷

Alternative models (e.g., telepharmacy, nurse triage lines, CPAs) for obtaining prescriptions without face-to-face contact with a health care provider may ensure that patients are able to receive prescriptions more efficiently. As a result, dispensing antivirals to these patients through pharmacists or public health authorities (e.g., operating under a CPA) can be expedited. .

Other techniques may accelerate dispensing of antivirals to patients. State boards of pharmacy may permit dispensing of drugs in emergency situations or make exceptions to existing regulations.⁶⁸ For example, in response to the Joplin tornado in May 2011, the Missouri Board of Pharmacy suspended several rules to:

- recognize out-of-state licenses for pharmacists/practitioners aiding relief efforts;
- dispense emergency refills of prescriptions; and
- omit required prescription label information, such as patient address, when unavailable due to emergency conditions.⁶⁹

While prescriptions may be filled in mass pursuant to an EPDO or other interventions during a declared emergency, pharmacists may be required to conduct a prospective drug use review and patient counseling to the extent possible under the circumstances.⁷⁰ Patient counseling is required in almost every state and under Medicaid for patients with new prescriptions. In some states, a pharmacist's offer to counsel is sufficient. A few states allow counseling by non-pharmacists.⁷¹ A prospective drug use review includes evaluation of the prescription and the patient's record for allergies, contraindications, reasonable use directions, proper utilization, and potential interactions.⁷² In a declared emergency, patient records may be inaccessible and pharmacists may lack time to devote to each individual patient seeking antivirals. While drug use reviews and patient counseling under such circumstances are likely to be minimal at best, this does not legally inhibit widespread dispensing because pharmacists are only required to conduct these activities to the extent possible.⁷³

Labeling. Generally, federal regulations require prescription drug labels containing, among other items:

- dispenser's name and address;
- serial number and date of prescription or filling;
- prescriber's name, indications and usage instructions;
- contraindications, warnings, overdose and abuse information; and
- dosage and administration information.⁷⁴

SNS antivirals are pre-labeled consistent with federal requirements. States, however, may mandate that labels contain additional information in some circumstances, such as the patient's name⁷⁵ and the brand or generic name and strength of the drug.⁷⁶ Printed warnings and appropriate manufacturer labeling of antivirals help to inform recipients on how to avoid improper uses of the drugs. These sorts of labeling requirements may hold up efficient, large-scale dispensing of antivirals as pharmacists attempt to properly affix labels to each package with the recipient's name or other data. As in the Joplin, Missouri example above, state labeling requirements may be waived or altered in an emergency to the degree they stall dispensing of essential antivirals to prospective patients. At the federal level, FDA may allow appropriate exceptions or alternatives to federal labeling requirements for products held by SNS.⁷⁷

Compounding. Authority to compound prescription medications is typically reserved to licensed pharmacists, pharmacist-supervised technicians, and practitioners.⁷⁸ During a pandemic, these individuals may need to tailor drugs to recipients' needs or address shortages. For example, to manage shortages of Tamiflu® for Oral Suspension and for recipients with difficulty swallowing capsules, providers were instructed on how to compound the oral suspension from 75mg capsules during the 2009-2010 H1N1 pandemic.⁷⁹ Waivers (discussed in **Part IV**) to allow out-of-state pharmacists or other providers to participate in emergency responses may broaden compounding authority, as a component of the practice of pharmacy, in a declared emergency.

Compounding is generally regulated by states as part of their broader regulation of the practice of pharmacy. The extent of FDA involvement is unsettled. FDA has not issued formal regulations explicitly distinguishing between manufacturing and traditional compounding activities, though some courts have noted authority for the agency to do so.⁸⁰ However, FDA has expressed concern about pharmacist bulk compounding activities that more closely resemble larger-scale manufacturing of unapproved new drugs. Compounding in bulk in anticipation of forthcoming prescriptions that may exceed limited quantities and outside an established pharmacist-patient relationship may draw ire from the FDA's enforcement branch.⁸¹ Federal courts have concurred as to FDA's authority to regulate or prohibit bulk compounding⁸² even though pharmacists' ability to advertise these activities may be protected under the First Amendment.⁸³

Inter-state Dispensing and Reimbursement

During a pandemic where antivirals may be limited, individuals may seek to acquire them in any jurisdiction in which they are available, including outside their state of residence. Large chain or other pharmacies may have no issue dispensing antivirals to out-of-state patients requesting the drugs at their locations. A problem may arise, however, related to reimbursement for dispensing fees for persons covered under state Medicaid programs or others who lack the ability to pay.

Under federal Medicaid regulations, state Medicaid programs must pay for services provided to their residents while in another state to the same extent they would pay for the services if provided in-

state, so long as the service is medically necessary or is customarily provided out-of-state in the recipient's location (e.g., close to a state border).⁸⁴ However, providers (including pharmacists) often must be registered with the state Medicaid agency from which they seek reimbursement, even if already registered in the state where the service was actually provided. As a result, some providers avoid billing an out-of-state Medicaid agency due to potentially burdensome and duplicative registration procedures. Instead they attempt to obtain payment from patients directly. Patients who pay out-of-pocket often are not eligible to receive reimbursement from their home state's Medicaid agency.⁸⁵ To avoid these issues, providers may seek to register in advance with Medicaid agencies in their bordering states, at least, prior to an emergency to avoid delays or burdens for providers or patients.

Costs. While antivirals available through SNS supplies are likely to be provided to the public at no cost, pharmacies may legitimately charge dispensing fees (e.g., up to \$10-12 per transaction). These fees could be prohibitive for some Medicaid or uninsured patients who might need to purchase antivirals out of state. If these patients are unable to receive coverage or reimbursement, distribution schemes could be compromised absent some other mechanism to waive or reimburse such fees. For example, some states, concerning their own antiviral supplies, provide pharmacies with the drugs at no cost, but set maximum administrative fees that pharmacies may charge to dispense and require pharmacies to waive the fee for patients expressing an inability to pay.⁸⁶ In a national distribution plan, maximum fees (e.g., capped at the current Medicare rate) or allowable fee ranges could be stipulated by agreement or contract with CDC or other agencies providing antivirals to limit costs to patients and reduce potential variation in fees across communities.

Almost all state Medicaid agencies reimburse pharmacies using a formula that presupposes a margin for dispensing fees in the cost of the drug itself with no adjustment for labor costs, overhead, or profit. Alabama and Oregon are the only states that calculate dispensing fees separately. As a result, the status quo reimbursement plan in most states would not reimburse pharmacists for dispensing costs for free antivirals from SNS. These states may need to change or waive their Medicaid reimbursement policies during declared emergencies. Alternatively, other paths for governmental reimbursement to patients or pharmacies are needed to ensure that they do not bear an undue share of the costs of dispensing the drugs.

Emergency Prescription Assistance Program

One alternative means of coverage for prescription drugs in an emergency is the federal Emergency Prescription Assistance Program (EPAP), which provides access to drugs and durable medical equipment for individuals who lack any type of insurance coverage – private or public – during declared emergencies or major disasters.⁸⁷ Operationalized through specific software designed to instantly check for a patient's insurance status in real-time, EPAP is activated in response to an emergency or major disaster declaration under the Stafford Act or a declaration of an Incident of National Significance⁸⁸ (although this type of declaration may no longer be valid according to DHS).⁸⁹ Eligible individuals can present at any enrolled pharmacy⁹⁰ and receive at no cost a one-time, thirty-day supply of medication to treat an acute condition or replace medication or medical equipment lost due to the emergency or in transit to a shelter facility.⁹¹ Costs sharing through the EPAP are generally split between the federal (75%) and state (25%) governments.

A potential impediment to use of EPAP is that pharmacists technically are required to check for other insurance coverage at the point of sale.⁹² This may be impractical in the throes of an emergency when time, personnel, and communications are limited. Furthermore, EPAP only covers individuals with a valid prescription from a licensed practitioner, a current prescription bottle, a prescription phoned in by a licensed practitioner, or proof of an existing prescription order.⁹³ It does not cover individuals lacking a prescription, such as those potentially exposed to flu who seek antivirals during a pandemic. An EPDO issued to enable widespread dispensing, however, could be considered an existing prescription, thus enabling coverage for these individuals under EPAP. Other state-based programs may also aid in covering the uninsured and other groups. As of June, 2011, a majority of U.S. states and territories had some form of supplemental pharmaceutical coverage or assistance for seniors, the disabled, the uninsured, or other groups through a variety of programs. According to data collected by the National Conference of State Legislatures:

- Twenty-nine states and territories offer direct use of state funds to subsidize part of prescription drug costs;⁹⁴
- Twenty-four states and territories offer programs designed to fill gaps in Medicare coverage;⁹⁵ and
- Fifteen states offer discount prescription drug plans.⁹⁶

Many states offer more than one type of program, and programs may apply to all state residents⁹⁷ or may be limited to certain groups (e.g., seniors) or those with specific diseases or conditions (e.g., HIV/AIDS).⁹⁸

Emergency Use Authorizations

During a DHHS-declared public health emergency⁹⁹ FDA can issue an EUA to allow emergency use of necessary drug products. EUAs were used during the 2009-2010 H1N1 pandemic to allow unapproved uses of zanamivir (Relenza®) and oseltamivir (Tamiflu®) for treatment and prophylaxis of young children and hospitalized patients.¹⁰⁰ EUAs permit the dispensing of a product that is either not yet approved for use or that is approved but is being sought for an unapproved use.¹⁰¹ The latter type of EUA approval is more likely in the context of antiviral distribution due to the potential for unapproved drugs to trigger the need for an Investigational New Drug (IND) application.¹⁰² However, FDA guidance indicates that only an EUA application, and not an IND application, would likely be required based on information that should already be available regarding the safety and efficacy of EUA candidate products.¹⁰³ Although an EUA can only be issued after an emergency is declared, FDA regularly evaluates pre-emergency submissions to expedite the issuance of EUAs.¹⁰⁴ Per the FDA, CDC is the most appropriate requester for an EUA; state and local jurisdictions should work through CDC, rather than submitting simultaneous requests for the emergency uses of the same products.¹⁰⁵

Potential unapproved uses which could be permitted under an EUA may include distribution and dispensing of prescription-only products without a prescription and/or by non-licensed providers (i.e., non-pharmacists).¹⁰⁶ FDA has opined that an EUA to this effect would preempt state laws that require a prescription or mandate dispensing by a licensed pharmacist.¹⁰⁷ FDA also suggests that an EUA permitting temporary storage under conditions that do not conform to product label requirements would also preempt contrary state law.¹⁰⁸

To issue an EUA, FDA's Commissioner must conclude that:

- (1) a disease or other condition specified in the declaration poses a risk of serious or life-threatening disease or condition;
- (2) it is reasonable to believe that the drug may be effective in diagnosing, treating, or preventing the disease or condition;
- (3) known and potential benefits of use of the product outweigh the known and potential risks; and
- (4) no adequate, approved, and available alternative exists to address the disease or condition.¹⁰⁹

The EUA may remain in effect for the duration of a declared emergency (up to one year unless revoked). Both the EUA and the declaration are renewable if justified.¹¹⁰ An EUA for post-exposure prophylactic doxycycline for *B. anthracis* (anthrax), for example, was issued in 2008 and subsequently renewed in 2009 and 2010 in response to continuing national security concerns.¹¹¹ Once issued, the EUA takes effect nationally irrespective of any additional state legal action in support of the authorization.¹¹²

FDA's Commissioner can set conditions on activities carried out under an EUA to protect the public's health, including ensuring that health care professionals and patients are informed of risks, benefits, and alternatives, and that adverse events are monitored through manufacturers, practitioners, or public health authorities.¹¹³ Potential conditions for distribution and administration of approved products for unapproved uses are limited in that they cannot be more restrictive than conditions on the approved use of the product. Additionally, EUA provisions do not override federal authority to manage and use SNS products.¹¹⁴

EUAs and Labeling. EUAs may also impact product labeling. A manufacturer may be permitted to change the label on a product under an EUA to note (1) a permitted use (e.g., treatment of young children) under the EUA but not under the drug's original FDA approval or (2) an extension of the product's expiration date. Dispensing may also be permitted for drugs not provided in unit-of-use containers or with labels that do not contain all of the typically required information (e.g., name of dispenser, name of patient).¹¹⁵ However, if the manufacturer chooses not to alter the label, distributors, and pharmacists may not alter or cover the manufacturer's original label.¹¹⁶ If a manufacturer does not alter the label on an antiviral to account for permissible uses under an EUA, distributors and pharmacists may circulate a drug for a use that is explicitly contraindicated on the label. The EUA would allow the use, but clear guidance would be required to avoid confusion or conflict among distributors, pharmacists, and recipients. If the manufacturer does alter the label, it may conflict with existing state dispensing laws. Whether state labeling laws would be preempted by an EUA remains unsettled,¹¹⁷ but a label that was acceptable under existing state law and was not altered under an EUA would presumably be permitted. Thus, distributing and dispensing antivirals with original labeling appears to be legally viable.

Legal Distinctions Concerning Varying Caches of Antivirals

During an emergency, a distributor or pharmacy may possess multiple caches of the same antiviral obtained from different sources – stock purchased from the manufacturer for routine distribution and dispensing needs, stock supplied for emergency needs from state or local government

stockpiles, or stock from the SNS in response to the specific emergency. Although the drug in each inventory may be exactly the same, the supply source of the drug can be legally relevant to how it is dispensed due to issues of ownership, oversight, and costs.

Agreements and MOUs concerning distribution and dispensing of drugs from state and local stockpiles typically require distributors and pharmacies to segregate stockpile drugs from purchased drugs. These agreements also often limit allowable dispensing fees that may be charged by pharmacies (and may require the fee be waived when a recipient cannot pay), require reporting of dispensed quantities, and mandate return of unused quantities upon demand. Agreements governing use of stockpile drugs may restrict distributions and priority of dispensing.¹¹⁸ Such restrictions might not apply, however, to drugs obtained previously in the regular course of business unless the agreement so provides. In contrast, an EUA or other expansion of permissible use for a product could apply regardless of a product's source.¹¹⁹ Depending on the precise language of the agreement or MOU, a pharmacy may be permitted to use its own stock of antivirals to supplement an exhausted supply of stockpile drugs, although the same terms of reimbursement may not be available to the pharmacy. Conversely, SNS or other stockpile drugs may not be used to supplement depleted commercial supplies.¹²⁰

Guidance from CDC or state public health officials regarding how to share government-supplied antivirals between geographic areas or distinct populations may also determine how a particular supply is to be distributed or dispensed. Public health officials may request that guidelines be followed voluntarily, or attempt to enforce them through contractual or other legal routes (e.g., refusals to reimburse for improper dispensing, licensure reviews). Distributors or pharmacists that fail to adhere to mandatory requirements may be found later to be in breach of contract or face potential investigations, licensure sanctions, fines, or other recourse.

Waivers of Existing State Pharmaceutical Board Requirements

During declared emergencies, state governments can provide broad waivers for existing medical board or pharmacy board requirements to facilitate emergency distribution and dispensing of antivirals.¹²¹ Depending on their legal framework, states may be able to waive provisions such as those that:

- require licensure as a distributor for any entity moving prescription drugs;
- limit prescription distribution authority to licensed pharmacists;
- mandate patient counseling during dispensing;
- stipulate contents of prescription drug labels beyond federal requirements;
- constrain pharmacist compounding activities;
- restrict personnel at distributor facilities; or
- permit only health care workers with in-state licenses to practice within the state.

These waivers are directly tied to formal declarations of emergency. As discussed in **Part II** above, a jurisdiction may have to issue an emergency declaration for these waivers to be authorized or take effect. Such declarations may (1) set different requirements for issuance of waivers, and (2) permit different types of legal provisions to be waived (e.g., pharmaceutical board rules, state regulations, statutory law). Assessing and understanding the legal options for waivers consistent with the legal framework in a particular state are key to effectuating appropriate emergency responses. Among the

majority of states choosing not to declare a formal state of emergency in response to the H1N1 pandemic, there may have been fewer legal opportunities to waive regulations or board practices in real-time. Still, other solutions not requiring emergency declarations, such as the use of MOUs or CPAs, may smooth the distribution and dispensing of antivirals.

V. Meeting Surge Capacity ~ Ensuring and Empowering Personnel

During a pandemic influenza emergency, meeting patient surge capacity at hospitals, clinics, and other treatment or medication dispensing locations is an enormous challenge. Large-scale distribution and dispensing of antivirals raise unique issues related to surge capacity. Wholesale distributors must be capable of pushing antiviral stocks out to pharmacies or other locations determined by public health authorities. Pharmacies must collaborate with distributors, public health authorities, and clinicians to receive and dispense antivirals to patients on a timely basis.

To fulfill CDC's antiviral distribution strategy, distributors and dispensers must execute these core functions in a real-time setting that may deplete available personnel in related and other key industries (e.g., shipping, transportation, law enforcement). Execution of various public health powers (e.g., evacuations, transportation closures, curfews, noted in **Part II**) may interfere with the flow of antivirals to patients and others at risk. Ensuring adequate access and availability of antivirals through distributors and pharmacies may be daunting, but specific legal options prior to and during the declaration of emergencies help greatly.

Advance Personnel Planning Among Distributors

As discussed in **Part III**, wholesale distributors' ability to routinely transport drugs is furthered by available, well-trained employees who work daily to track drug requests and deliver products safely and efficiently. During emergencies, even a slight loss of personnel (e.g., managers, data processors, deliverers) among the major distributors could impact their performance. Loss of personnel due to illness, familial needs, or other reasons is especially problematic since many highly-trained and licensed personnel in the wholesale drug distribution industry are not easily replaced. Significant losses of employees could lead to temporary business failures or inability to meet contractual or other obligations. "Escape clauses" embedded within CDC contracts with distributors may allow for the transfer of unused stockpiled products to other distributors or pharmacies to expedite distributions even in the event of business failures.

PDMA regulations require that each state ensure that all personnel employed by a distributor "have appropriate education and or experience to assume responsibility for positions related to compliance with state licensing requirements."¹²² Arizona requires that distributors have a designated representative who is present at the facility during normal business hours.¹²³ Distributors in New York involved in the repacking of drugs must have a pharmacist present during business hours.¹²⁴ California requires distributors to maintain a list and summary of qualification of all officers, directors, managers, and other persons involved in the distribution, storage or handling at all times.¹²⁵ These varying legal requirements concerning personnel could stymie distributors' operations if key employees are unable to perform their roles during a pandemic.

Federal and state laws governing the core requisites for distributors' personnel may be put aside via waivers upon the declaration of a federal or state-based emergency, at least among those jurisdictions (described in **Part IV**) that issue such declarations. Reliance on legal waivers is tenuous, however, necessitating distributors' advance planning for continuity of operations despite major losses of personnel. One of the largest wholesale distributors, Cardinal Health, for example, has plans for how to meet product demands during an emergency. While the details are not public, Cardinal Health's emergency operations plans include the purchase of personal protective equipment (PPE) for employees, staffing alternatives to accommodate decreases in workforce, and processes for telecommuting and flexible hours to decrease employee exposure to communicable disease.¹²⁶ Emergency plans of another major distributor, AmerisourceBergen, provide for alternate deliveries and services at all its facilities as needed due to a closure of a warehouse, corporate office, or packaging facility.¹²⁷

Licensure Reciprocity for Pharmacists

Pharmacists face different issues from distributors on the frontlines of emergency responses. Because of their direct exposure to infected patients, pharmacists and their employees may face increased risks of acquiring pandemic flu even with the use of PPE and other universal precautions. Losses of core pharmaceutical personnel in the throes of the pandemic are predictable. Collectively these losses may impede rapid dispensing of antivirals to patients and negatively impact the public's health.

Like distributors, large and small pharmacies nationally have planned for these scenarios, including how to dispense products efficiently in collaboration with clinicians through CPAs (discussed in **Part I**). Large chain pharmacies may have the capacity to move pharmacists and other personnel from one location to another to fill personnel gaps within states. Smaller pharmacies can temporarily share employees as well, although this may be uncommon due to the need for specific training on each pharmacy's practices and systems. For pharmacists licensed in the same state but working at different locations, temporary reassignments implicate no particular legal concerns (other than the risks a pharmacist may face directly in regards to exposure to disease through patients or the community). Transferring pharmacists across state lines, however, presents a different legal issue.

Normally pharmacists licensed in one state may not practice in another jurisdiction without violating each state's licensure laws. Most states do not offer temporary licensure for pharmacists, although licensing boards may allow them to apply for reciprocal licensure provided they demonstrate knowledge of state law and/or have been admitted to practice in another state for a specified period of time prior to application.¹²⁸ Pharmacists licensed in other states may also practice telepharmacy (i.e., provision of pharmacist care via telephone or internet communications) so long as they register with the state in which their service is received. Pharmacies located outside a state may also be licensed to provide services to patients within the state.¹²⁹

Each of these legal options may help fill personnel gaps, but also leads to lengthy delays that impede the flow of antivirals to patients in emergencies. To help bypass regulatory tie-ups, most states allow for an automatic, limited recognition of out-of-state licenses among pharmacists and other medical personnel during declared emergencies. The Model State Pharmacy Act contemplates temporary recognition of out-of-state licensure during a declared public health emergency, permitting

pharmacists licensed in other states to dispense in areas affected by the emergency if the pharmacy board can verify current licensure in good standing and involvement in a legitimate relief effort.¹³⁰ Certified pharmacy technicians and pharmacy interns registered or licensed in other states are similarly permitted to assist pharmacists during an emergency.¹³¹ Licensure reciprocity provisions, especially related to volunteers (discussed below), effectively allow out-of-state pharmacists to dispense drugs as if they possessed a license in the state where an emergency is declared (at least for the duration of the emergency). Reciprocity can greatly assist the sharing of licensed pharmacists across jurisdictions to meet regional, state, or local dispensing needs.

Deployment and Use of Volunteer Health Practitioners

Even large chain pharmacies may temporarily lack essential personnel during a widespread disease outbreak such as pandemic flu. Pharmacies may have to rely on volunteer health practitioners (VHPs) to rapidly dispense drugs. VHPs may include trained pharmacists, technicians, and assistants who are licensed, vetted, and registered through existing state-based ESAR-VHP systems, Medical Reserve Corps (MRC) units, the American Red Cross, or other legitimate volunteer systems. Volunteers also include other licensed medical personnel (e.g., physicians, nurses, public health workers) and even unlicensed personnel willing to assist where needed, including execution of specific screening or other functions pursuant to CPAs. While VHPs have been deployed and used extensively in prior emergencies such as Hurricane Katrina,¹³² their roles in response to the H1N1 pandemic were more limited given the relatively mild surge in patients in most jurisdictions.

Multiple emergency laws and policies support the deployment and use of registered VHPs. (note that these same laws do not typically apply to “spontaneous volunteers,” or those personnel who are not registered with volunteer databases and are not responding through specific governmental efforts).¹³³ The nearly dozen states passing provisions of the Uniform Emergency Volunteer Health Practitioners Act (UEVHPA)¹³⁴ may take a broad view of who constitutes a VHP and ascribe a series of permissive legal avenues to facilitate their services. Under the UEVHPA, pharmacists registered via ESAR-VHP and MRC automatically qualify as VHPs. Pharmacists employed by a large pharmacy chain with locations in multiple states may also be viewed as VHPs if they are brought in to assist in stores or mobile emergency pharmacies in the areas affected by the emergency declaration.¹³⁵ By expanding the pool of who may constitute a VHP, UEVHPA encourages voluntarism to meet emergency responses and specifically grants licensure reciprocity and other benefits, including clarifications over the scope of practice and liability protections (discussed in **Part VI**), to the volunteers and the entities that support them.

VI. *Providing Incentives for Participation ~ Liability and Other Protections*

Emergencies require public health departments and health care systems to deal with significant increases in the demands for their services coupled with resource shortages (e.g., equipment, supplies, pharmaceuticals, personnel).¹³⁶ As part of the essential personnel responsible for distributing and dispensing antivirals, pharmacists, health care providers, and VHPs may be concerned about their potential liability. Distributors, pharmacies, and other entities may similarly be apprehensive about their potential exposure to legal claims for their acts or omissions. Risks of exposure to liability can greatly deter individuals and entities from participating in emergency response efforts or volunteering their services.¹³⁷

Crisis Standard of Care

Assessing potential liability claims arising during emergencies can be complicated. Prior and ongoing work of an Institute of Medicine (IOM) committee describes how the level of patient care in emergencies is likely to fall along a continuum from “conventional” to “contingency” to “crisis.”¹³⁸ A crisis standard of care is necessitated by the need to quickly adapt to changing circumstances and increased demand during emergencies.¹³⁹ As noted in an original Letter Report of the IOM committee, under a crisis standard persons with the greatest needs tend to receive available care first until everyone requiring services can be assessed and initially treated.¹⁴⁰ Implementing a crisis standard of care requires choices and actions that may otherwise be legally questioned in non-emergencies. A pharmacist with limited supply of SNS antivirals, for example, may have to dispense the drugs to two or three classes of persons pre-determined by CDC to be most at risk of a particular strain of flu. Others viewed as having less risks of harm may be excluded from initial access to the antivirals, even though they may be first in line at the pharmacist’s counter.¹⁴¹ Decisions like these may further the public’s health consistent with a crisis standard of care, but may not be viewed favorably by legal or political actors or the public. Resulting legal and policy challenges may be assessed under different legal standards that are inconsistent with a crisis standard of care, resulting in uncertainty over potential liability.¹⁴²

Scope of Practice Limitations

An important distinction exists between the standard of care and potential scope of practice limitations. As noted in **Part IV**, all states’ laws regulating pharmacists set criteria for the scope of the pharmacist’s practice. Scope of practice laws clearly include provisions authorizing pharmacists to dispense drugs and medications with a valid prescription. Many additional activities may also be included within a pharmacist’s scope of practice in different states. In most states, for example, a pharmacist is permitted to screen prospective patients, administer drugs or vaccines, or monitor patients’ ongoing compliance within limits set by a CPA or other laws.¹⁴³ In Kansas, pharmacy students and licensed assistants may assist in dispensing of prescription medications under the direct supervision of a licensed pharmacist.¹⁴⁴ However, states may strictly limit such personnel to tasks not requiring the exercise of professional judgment.¹⁴⁵

Differences in the scope of practice among pharmacists, technicians, and students across states may impact the extent of services these persons may provide. During a declared emergency, however, pharmacy boards or other regulatory bodies may effectively change, alter, or waive scope of practice requirements of pharmacists and other licensed personnel to promote emergency response efforts. UEVHPA Section 8 acknowledges these potential alterations, and clarifies further that an out-of-state pharmacist (or other) volunteer is limited to those services within the altered scope of practice in the host state that are also consistent with the pharmacist’s abilities under his or her home state’s routine scope of practice.

Risks of Liability

Potential liability claims against public and private sector practitioners and entities can result from alleged civil, criminal, and constitutional violations underlying their emergency response efforts.¹⁴⁶

Liability may arise from claims of medical malpractice, discrimination, invasions of privacy, or specific violations of federal or state laws. Persons may be adjudged liable not only for what they did, but also for what they failed to do. For example, Tenet Health Systems, which operated Memorial Medical Center in New Orleans during Hurricane Katrina, recently settled claims brought by injured patients for \$25 million. The patients' claims were grounded not only in negligence for Tenet's substandard response efforts, but also for its failure to properly plan and prepare for the emergency itself.¹⁴⁷ While many legal causes of action against practitioners or entities are unfounded or lacking merit, high profile cases like this raise the specter of liability risks for many health care providers and entities.

Liability Protections - Generally

There is no single, national liability protection for all emergency responders and actors. There are, however, numerous legal protections limiting civil liability during a declared emergency. These include emergency laws (e.g., MSEHPA,¹⁴⁸ Model Intrastate Mutual Aid Legislation (MIMAL),¹⁴⁹ UEVHPA¹⁵⁰), interstate compacts (e.g., EMAC¹⁵¹), sovereign immunity provisions protecting governmental employees, volunteer protection acts, and Good Samaritan protections. While these protections may offer immunity or indemnification from liability, they do not safeguard all actions or persons in emergencies. For example, none of these liability provisions, explained below, protect individuals from liability for gross negligence or willful, wanton, or criminal acts.¹⁵²

Federal Liability Protections - PREP Act

DHHS' declarations pursuant to the federal Public Readiness and Emergency Preparedness (PREP) Act¹⁵³ provide specific liability protections for individuals and entities implementing medical countermeasures.¹⁵⁴ PREP Act liability protections were utilized to immunize various actors administering vaccines during the 2009-2010 H1N1 pandemic. Under the PREP Act, limited immunity from tort liability is extended to "covered persons" (e.g., the United States, countermeasure manufacturers, drug distributors, pharmacies, and state and local program planners) involved in medical countermeasure development, distribution, and administration pursuant to a PREP Act declaration through HHS (which can be issued retroactively as needed). This includes the distribution and dispensing of antivirals through CDC's SNS or other caches. The Act also establishes a compensation fund for individuals injured from the administration or use of covered countermeasures.

Though beneficial, PREP Act liability protections are limited. Like other liability protections, the PREP Act does not cover willful misconduct, which includes actions and omissions that are (1) intended to achieve a wrongful purpose, (2) lacking legal or factual justification, or (3) in disregard of known or obvious risks that potential harm will outweigh potential benefit.¹⁵⁵ For example, a recent lower court decision in New York, currently on appeal, suggests that PREP Act liability protections do not immunize a local school system or health practitioner that vaccinated a minor student during the H1N1 pandemic without parental consent.¹⁵⁶ At present, there appears to be no other reported litigation regarding the scope of PREP Act liability protections. However, FDA has indicated that use of drugs that is inconsistent with product approval and FDA regulations may not be covered by PREP Act protections absent an EUA (discussed in **Part IV**).¹⁵⁷

Volunteer Liability Protections

As discussed in **Part V**, meeting patient surge capacity requires the deployment and use of trained, vetted VHPs, including physicians, nurses, pharmacists, and their assistants. To the extent that VHPs act on their own volition to respond to emergencies, they enjoy special liability protections (as contrasted with health care employees) in part to incentivize their services. There are multiple paths to protecting volunteers from liability depending on their status and jurisdiction. These include:

- **UEVHPA** ~ provides liability protections for VHPs (including pharmacists) who register with a volunteer registration system (e.g., ESAR-VHP, MRC), as well entities who support their deployment and use. At least thirteen states have passed versions of the UEVHPA to date.¹⁵⁸
- **Federal Volunteer Protection Act of 1997** (VPA) ~ shields volunteers of nonprofits or governmental entities from liability if the volunteer acts within the scope of the volunteer's activities for the nonprofit or governmental entity and is duly licensed or certified in the state where the activity occurred. Unfortunately, the VPA defines "volunteer" narrowly as someone performing services for a nonprofit or government entity that does not receive any compensation (other than reasonable expense reimbursement) or any other item of value in excess of \$500 per year.¹⁵⁹ Similar laws at the state level may provide protections for a broader class of volunteers.
- **MSEHPA** ~ covers out-of-state emergency health care providers (including pharmacists) appointed by a state or local public health authority to respond to the emergency. Providers are protected from liability resulting from medical care or treatment related to the public health emergency. Twenty-two states have passed similar laws based on this model provision.
- **EMAC** ~ Article VI offers liability protections to state or local employees who are sent by one state to render aid and assistance for a disaster or emergency in another state. Some states may "deputize" private sector pharmacists as state agents for the limited duration of an emergency to garner EMAC liability protections for the practitioners.¹⁶⁰
- **Sovereign Immunity Statutes** ~ these laws protect most governmental employees acting within the scope of employment from tort liability. Some states extend these protections to volunteers by treating them as state employees with respect to their volunteer response efforts. Some sovereign immunity statutes protect volunteers by classifying them as employees of the state (e.g., New Jersey)¹⁶¹ or by expressly including unpaid individuals performing state functions under immunity protections (e.g., Maryland).¹⁶²
- **Good Samaritan Acts** ~ every state features "Good Samaritan" laws that immunize individuals who render aid at the scene of an emergency, generally in the absence of an emergency declaration.¹⁶³ These statutes typically cover individual rescuers who do not have a pre-existing duty to provide aid. Consequently, volunteers who provide care in a health care setting or during declared emergencies are usually not protected under these laws.¹⁶⁴ States such as Florida, however, statutorily extend their Good Samaritan protections to volunteers during declared emergencies.¹⁶⁵

Workers' Compensation

In addition to external liability risks arising from negligence or other claims from patients or others negatively affected by emergency response efforts, emergency responders may risk injury or deaths as a result of their work-related functions. Whether individuals are covered for these liability risks is subject to workers' compensation laws. Workers' compensation is a no-fault insurance program provided by employers and administered by the government. Through workers' compensation, individuals (or their families) receive limited benefits for work-related injuries and deaths. While the federal government and every state have enacted workers' compensation statutes, there is considerable variation in coverage.¹⁶⁶

Generally, employers are responsible for employees' injuries that arise out of or occur in the course of employment. By definition, this may exclude volunteers because volunteers are not employees. During declared emergencies, states like Alabama, Illinois, Minnesota, Ohio, and Wisconsin extend their workers' compensation coverage to specific emergency response volunteers.¹⁶⁷ Under UEVHPA, volunteers who otherwise lack workers' compensation coverage are automatically deemed state employees and thus eligible for benefits. Thus, depending on the state and scope of its workers' compensation laws, registered volunteers responding to an emergency through organized efforts can receive basic workers' compensation protections.¹⁶⁸

VII. Tracking Antivirals ~ Supplies, Prescriptions, and Patients

Normally, distributors and pharmacists do not systematically track pharmaceuticals other than through their data collection to maintain appropriate inventory. During an emergency, however, they may be called upon to report information to permit tracking of the distribution and dispensing of SNS or other antivirals.

Distributor Tracking to Pharmacies

Distributors commonly track their drug deliveries to account for stock consistent with federal and state requirements, which may also require reporting of antivirals. In an emergency, additional reporting might be necessitated. For example, CDC may require tracking of specific orders and supplies to examine disease trends or to evaluate distribution strategies. States supplying distributors with antivirals from their own stockpiles (either obtained previously from the SNS or purchased independently by the state) may establish reporting requirements through MOUs or contracts with distributors to avoid duplicative or unjust sharing of resources during an emergency. Emergency laws authorizing rapid implementation of public health reporting requirements may further allow state public health agencies to collect these data with the assistance of wholesale distributors, pharmacists, and other commercial data companies.

Public Health Reporting Requirements for Pharmacists and Pharmacies

Pharmacists are required to maintain prescription records for 2-7 years after dispensing depending on the jurisdiction.¹⁶⁹ However, pharmacists rarely report identifiable patient information outside of their own patient records, subject to some exceptions. For example, many state public health reporting laws may require pharmacists to track and report any increases or unusual trends, types, or

rates of prescriptions,¹⁷⁰ or diseases or conditions under similar rules as other health professionals like physicians, nurses, or laboratory clinicians.¹⁷¹ These largely state-based reporting requirements do not implicate any specific legal concerns because they are standard, routine measures designed to gather data for legitimate public health purposes. In emergencies, when pharmacists may dispense antivirals without prescriptions (either under a waiver or EPDO) or initiate prescriptions themselves (e.g., under a CPA), enhanced public health reporting by pharmacists could be essential and legally required to accurately assess public health trends.

Privacy and Security Concerning Sharing of Identifiable Health Information

Pharmacists may be reticent to divulge identifiable health information to state or local public health authorities, even during an emergency. Like other health practitioners, pharmacists are generally prohibited from using or disclosing individually identifiable health information inconsistently with legal privacy principles pursuant to the HIPAA Privacy Rule¹⁷² and numerous, additional federal, state, or local laws. While the Privacy Rule limits how pharmacists, health care providers, and other “covered entities” can use or disclose individually identifiable health information without individual authorization, it specifically allows disclosures to governmental public health authorities (or entities under their direction) for public health purposes (e.g., surveillance, epidemiologic investigation, or intervention).¹⁷³ The Privacy Rule also includes a special exception to allow reporting of such data to governmental authorities when needed to respond to emergencies.

Neither the HIPAA Privacy Rule nor other privacy laws apply to uses or disclosures of non-identifiable health data or de-identified health information (information that does not permit identification of an individual). These data may be used or disclosed for any purpose to anyone without privacy restrictions. To track antiviral distribution and dispensing, and to limit the need for pharmacists and pharmacies to aggregate data, CDC anticipates collaborating with data companies such as IMS Health, an information services company already currently tracking more than 80% of global pharmaceutical sales activity. For the purposes of CDC’s anticipated data requests, IMS Health collects only de-identified patient data.¹⁷⁴ In this capacity the use and disclosure of its data, or similar non-identifiable data held by pharmacists, do not implicate privacy laws.

Conclusion

Multiple legal and policy challenges must be addressed in developing a national strategy to distribute, dispense, and track antivirals. This Report has sought to identify and explain the legal pathways that can facilitate implementation of this strategy through existing distribution and pharmacy channels. Particularly during an emergency, legal concerns and logistical hurdles may inhibit effective and timely response. Through focused, advance planning, understanding of existing law, and critical application of specific emergency laws and policies, many foreseeable impediments can be avoided or mitigated to effectively and efficiently distribute and dispense antivirals. Equipped with sufficient legal knowledge, public and private sector actors can select from an array of legal tools and solutions to successfully implement a national antiviral distribution strategy.

Appendix 1. Select Examples of Relevant State Laws Concerning Antiviral Distribution and Dispensing

The table below provides 3 brief examples of existing statutory and regulatory provisions that may impact emergency response and antiviral distribution in 7 key areas of state laws: (1) Emergency Declarations; (2) Pedigree Requirements; (3) Distributor Licensure Requirements; (4) Prescription Labeling; (5) Prescription Assistance; (6) Liability Protections; and (7) Workers’ Compensation for VHPs. The examples below provide illustrative statutory or regulatory options in each area, and not to suggest the appropriateness, sufficiency, or quality of the cited provisions. Users should consult with legal counsel regarding current laws (e.g., statutes, regulations, case law, and other sources) in their own jurisdictions regarding these and other legal topics discussed in this Report.

Types	1. Emergency Declarations ¹	2. Pedigree Requirements ²	3. Distributor Licensure Requirements ³	4. Prescription Labeling ⁴	5. Prescription Assistance ⁵	6. Liability Protections ⁶	7. Workers’ Compensation for VHPs ⁷
Example A	Defines and authorizes Governor to declare a state of “public health emergency.” <u>CONN. GEN. STAT. ANN. § 19a-131(8).</u>	Name and address of each location from which a drug is shipped must be documented. <u>225 ILL. COMP. STAT. ANN. 120/57.</u>	Entity moving prescription drugs for emergency medical reasons is exempted from definition of “wholesale distributor.” <u>TEX. HEALTH & SAFETY CODE ANN.</u>	Patient’s name must appear on the prescription drug label if stated in the prescription. <u>MD. CODE ANN., CRIM. LAW § 5-701(c)(4).</u>	Prescription drug cost assistance provided to state residents who meet eligibility criteria and are not covered by other programs. <u>WYO. STAT. ANN.</u>	Sovereign immunity protects volunteers by classifying them as employees of the state. <u>N.J. STAT. ANN. § 59:1-3.</u>	Emergency volunteers are defined as state employees for purposes of workers’ compensation protections during declared emergencies. <u>MINN. STAT. §</u>

1 “Emergency Declarations” include legally defined public health emergencies and other emergency declarations available to state officials.

2 “Pedigree Requirements” include state prescription drug pedigree requirements that supplement or exceed federal standards.

3 “Distributor Licensure Requirements” include state-based requirements or exceptions to distributor licensure as applied to state or local governments attempting to move drugs during declared emergencies or other similar circumstances.

4 “Prescription Labeling” includes state prescription drug label content mandates that exceed federal requirements.

5 “Prescription Assistance” includes legally-authorized, state-based programs that defray prescription drug costs through subsidies, Medicare gap coverage, or discount plans.

6 “Liability Protections” include statutory or regulatory liability protections for health care workers, volunteers, or entities during a declared emergency.

7 “Workers’ Compensation for VHPs” includes state workers’ compensation laws that apply coverage to volunteer health practitioners in a declared emergency.

Types	1. Emergency Declarations ¹	2. Pedigree Requirements ²	3. Distributor Licensure Requirements ³	4. Prescription Labeling ⁴	5. Prescription Assistance ⁵	6. Liability Protections ⁶	7. Workers' Compensation for VHPs ⁷
			<u>§ 431.401(11)(B).</u>		<u>§ 42-4-118.</u>		<u>12.22.</u>
Example B	Defines and authorizes Governor to declare a state of "emergency," including as the result of an epidemic. <u>ARIZ. REV. STAT. ANN. §§ 26.301, 26.303.</u>	Pedigree must include, among other data: name, address, phone number, and email address (if available) of each owner and wholesale distributor. <u>GA. CODE ANN. § 26-4-202.</u>	Definition of "wholesale distribution" of prescription drugs does not include transfer or distribution for emergency medical reasons. <u>WIS. STAT. ANN. § 450.01(23)(b).</u>	Patient's and prescriber's names, pharmacy name and address, and other information must appear on prescription drug labels. <u>CAL. BUS. & PROF. CODE § 4076.</u>	Reduces prescription drug costs for state residents over 65 and disabled residents (age 18-64) via direct state payments to pharmacies with required (but capped) patient copays. <u>CONN. GEN. STAT. § 17b-491.</u>	Sovereign immunity protects unpaid persons performing state functions. <u>MD. CODE ANN., CTS. & JUD. PROC. § 5-522(B); MD. CODE ANN., STATE GOV'T § 12-101.</u>	Workers' compensation benefits are available to persons acting at the request of a public official, agency, or political subdivision during an emergency. <u>OHIO REV. CODE ANN. § 4123.025.</u>
Example C	Defines and authorizes the Governor or Legislature to declare a "state of emergency" following a "disaster," including an epidemic. <u>W. VA. CODE § 46A-6J-2.</u>	Pedigree must include, among other data: name, address, phone number, and email address (if available) for each owner and wholesale permittee in the distribution chain. <u>ARIZ. REV. STAT.</u>	"Wholesale distribution" does not include transfer or distribution for emergency medical reasons. <u>225 ILL. COMP. STAT. ANN. 120/15.</u>	Prescription drug labels must include patient's and prescriber's names, and the pharmacy name and address, among other information. <u>OHIO ADMIN. CODE 4729-5-16.</u>	No-cost prescription drug discount program available to all state residents regardless of income, age, or insurance status. <u>WASH. REV. CODE § 70.14.060.</u>	Good Samaritan protection extends to volunteer health care professionals acting during declared emergencies. <u>FLA. STAT. ANN. § 768.13.</u>	Volunteers performing emergency management services are eligible for workers' compensation coverage. <u>ALA. CODE § 31-9-16.</u>

Types	1. Emergency Declarations ¹	2. Pedigree Requirements ²	3. Distributor Licensure Requirements ³	4. Prescription Labeling ⁴	5. Prescription Assistance ⁵	6. Liability Protections ⁶	7. Workers' Compensation for VHPs ⁷
		<u>ANN. § 32-1984.</u>					

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