Prior to the declaration of a public health emergency, State and local planners should examine existing State public health and medical licensing laws, interstate emergency management compacts and mutual aid agreements, and other legal and regulatory arrangements to determine the extent to which they meet potential new threats. Waivers granted at any level are likely to be targeted to an affected area for a temporary and specified period of time. In the case of an evolving pandemic, it will therefore be important to have the flexibility to extend or expand such waivers as needed.

**Roles and Responsibilities**

The responsibility for preparing for, detecting, and responding to influenza outbreaks is shared by everyone. This includes private citizens, health care providers, the private sector, State, local, and tribal public health authorities, and the Federal Government. State, local, and tribal governments, the private sector, and the Federal Government all have important and interdependent roles in preparing for, responding to, and recovering from a pandemic. Effective management of the Nation's medical and public health response systems during a pandemic will require coordinated action by all segments of government and society.

State, local, and tribal governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the consequences of an outbreak. The Federal Government supports detection and response in many ways, including providing response personnel and expertise, response materiel, diagnostic reference services and testing support, and funding for certain response activities. It is anticipated that the potentially catastrophic nature of a pandemic may overwhelm local, State, and tribal capabilities. Federal agencies will be called upon to provide additional support, but even those resources may be overwhelmed at the peak of a pandemic.

**The Federal Government**

The Federal Government will use all capabilities within its authority to support the private sector and State, local, and tribal public health authorities in preparedness and response activities. It will increase readiness to sustain essential Federal public health and medical functions during a pandemic and provide public health and medical support services under the National Response Plan (NRP). It will be prepared to advise State, local, and tribal governments and the medical and public health communities at large on how to employ scarce medical resources, use and sequence community infection control measures, and address the medical challenges posed by pandemic influenza. It will perform surveillance for and monitor the progress of a pandemic on a national and international scale, support the development and production of medical countermeasures, and sponsor research on influenza viruses with pandemic potential. It will provide financial support and technical assistance to State, local, and tribal governments as they develop pandemic preparedness plans.

Department of Health and Human Services: HHS’s primary responsibilities are those actions required to protect the health of all Americans, including communication of information related to pandemic influenza, leading international and domestic efforts in surveillance and detection of influenza outbreaks, ensuring the provision of essential human services, implementing measures to limit spread, and providing recommendations related to the use, distribution, and allocation of countermeasures and to the provision of care in mass casualty settings. HHS will support rapid containment of localized outbreaks domestically and provide guidance to State, local, and tribal public health authorities on the use, timing, and sequencing of community infection control measures. HHS also supports biomedical research and development of new vaccines and medical countermeasures.
Department of Homeland Security: Pursuant to Homeland Security Presidential Directive 7 (HSPD-7), DHS coordinates overall domestic incident management and Federal response procedures under the NRP and National Incident Management System (NIMS). Under the NRP, DHS is responsible for coordinating the protection of the Nation’s critical infrastructure, and within the framework of Emergency Support Function #8 - Public Health and Medical Services (ESF #8) for the deployment of available NDMS medical, mortuary, and veterinary response assets.

Department of Defense: The primary responsibility of DOD is to preserve national security by protecting American forces, maintaining operational readiness, and sustaining critical military missions. DOD’s first priority with respect to protecting human health will be to ensure sufficient capability to provide medical care to DOD forces and beneficiaries. DOD can provide medical, public health, transportation, logistical, communications, and other support consistent with existing legal authorities and to the extent that DOD’s National Security preparedness is not compromised. Ideally, the human and technical resources of the National Guard should be balanced between support to the Governors of the individual States and the overall needs of national security.

Department of Veterans Affairs: VA provides health care, monetary benefits, and burial benefits to our Nation’s veterans. VA’s priority with respect to protecting human health is to deliver health care to enrolled veterans and beneficiaries. VA also has a mission to provide medical surge capacity for treatment of casualties arising from DOD operations and can provide other support to the extent that VA’s mission to serve veterans is not compromised.

Department of Labor: DOL’s primary responsibilities are those actions required to protect the health and safety of workers, including communication of information related to pandemic influenza to workers and employers, and other relevant activities.

State, Local, and Tribal Entities

State, local, and tribal entities should have credible pandemic preparedness plans that address key response issues and outline strategies to mitigate the human, social, and economic consequences of a pandemic. They will initiate the request for the delivery and be primarily responsible for the distribution of medical countermeasures released from national stockpiles. States should be prepared to face challenges in the availability of essential commodities, demands for health care services that exceed existing capacity, and public pressure to enforce infection control measures in ways that may hinder the delivery of emergency services and supplies and exacerbate the economic repercussions of the pandemic. States, localities, and tribal entities should work to improve communication between public health departments and both private sector partners, such as health care facilities, community- and faith-based organizations, and clinical laboratories that are likely to be involved in the response to a pandemic. State, local, and tribal public health departments should coordinate their planning efforts with local Federal health care facilities.

The Private Sector and Critical Infrastructure Entities

The private sector will play an integral role in preparedness before a pandemic begins and should be part of the national response. Businesses and corporations, especially those within sectors constituting the Nation’s critical infrastructure, should develop continuity of operations plans that provide for workforce health protection and ensure that essential functions and vital services can be performed in the setting of significant absenteeism. Businesses and corporations should be prepared for public health interventions and recommendations that may increase absenteeism. Elements of the private sector concerned with
health care should be prepared to support local, State, national, and international efforts to contain or mitigate a pandemic.

**Individuals and Families**

Private citizens must recognize and understand the degree to which their personal actions will govern the course of a pandemic. The success or failure of infection control measures is ultimately dependent upon the acts of individuals, and the collective response of 300 million Americans will significantly influence the shape of the pandemic and its medical, social, and economic outcomes (see *Individual, Family, and Community Response to Pandemic Influenza* between Chapters 5 and 6). Individuals will, in general, respond to a pandemic and to public health interventions in ways that they perceive to be congruent with their interests and their instinct for self-preservation, and public health authorities should tailor their risk communication campaigns and interventions accordingly. Institutions in danger of becoming overwhelmed will rely on the voluntarism and sense of civic and humanitarian duty of ordinary Americans. The talents and skills of individuals will prove crucial in our Nation’s response to a pandemic.

**Actions and Expectations**

6.1. Pillar One: Preparedness and Communication

Preparedness and transparency are critical elements of the Strategy and the foundation of efforts to detect, contain, limit, delay, and mitigate a pandemic. Activities that should be undertaken before a pandemic to ensure preparedness and to communicate expectations and responsibilities to all levels of government and society are described below.

*a. Planning for a Pandemic*

6.1.1. Continue to work with States, localities, and tribal entities to establish and exercise pandemic response plans.

6.1.1.1. The Federal Government shall, and State, local, and tribal governments should, define and test actions and priorities required to prepare for and respond to a pandemic, within 6 months. Measure of performance: completion and communication of national, departmental, State, local, and tribal pandemic influenza response plans; actions and priorities defined and tested.

6.1.1.2. HHS, in coordination with DHS, shall review and approve State Pandemic Influenza plans to supplement and support DHS State Homeland Security Strategies to ensure that Federal homeland security grants, training, exercises, technical, and other forms of assistance are applied to a common set of priorities, capabilities, and performance benchmarks, in conformance with the National Preparedness Goal, within 12 months. Measure of performance: definition of priorities, capabilities, and performance benchmarks; percentage of States with plans that address priorities, identify capabilities, and meet benchmarks.

6.1.1.3. DHS, in coordination with HHS, DOJ, DOT, and DOD, shall be prepared to provide emergency response element training (e.g., incident management, triage, security, and communications) and exercise assistance upon request of State,
6.1.2. **Build upon existing domestic mechanisms to develop medical and veterinary surge capacity within or across jurisdictions to match medical requirements with capabilities.**

6.1.2.1. All health care facilities should develop and test infectious disease surge capacity plans that address challenges including: increased demand for services, staff shortages, infectious disease isolation protocols, supply shortages, and security.

6.1.2.2. HHS, in coordination with DHS, DOD, and VA, shall develop a joint strategy defining the objectives, conditions, and mechanisms for deployment under which NDMS assets, U.S. Public Health Service (PHS) Commissioned Corps, Epidemic Intelligence Service (EIS) officers, and DOD/VA health care personnel and public health officers would be deployed during a pandemic, within 9 months. Measure of performance: interagency strategy completed and tested for the deployment of Federal medical personnel during a pandemic.

6.1.2.3. HHS, in coordination with DHS, DOT, DOD, and VA, shall work with State, local, and tribal governments and leverage Emergency Management Assistance Compact agreements to develop protocols for distribution of critical medical materiel (e.g., ventilators) in times of medical emergency within 6 months. Measure of performance: critical medical material distribution protocols completed and tested.

6.1.2.4. HHS, in coordination with DOD and VA, in collaboration with medical professional and specialty societies, within their domains of expertise, shall develop guidance for allocating scarce health and medical resources during a pandemic, within 6 months. Measure of performance: guidance developed and disseminated.

6.1.2.5. HHS shall package and offer to the States and Territories the core operating components of an ESAR-VHP system within 6 months and encourage all States and tribal entities to implement the ESAR-VHP program by providing technical assistance and orientations at State and territory request to implement and operate Federal guideline (ESAR-VHP) compliant systems within 12 months. Measure of performance: guidance and technical assistance, as requested, provided to States to implement ESAR-VHP capability, compliant with Federal guidelines, in all States and U.S. territories.

6.1.2.6. HHS, in coordination with the USA Freedom Corps and Citizen Corps programs, shall continue to work with States and local communities to expand the Medical Reserve Corps program by 20 percent within 12 months. Measure of performance: increase number of Medical Reserve Corps units by 20 percent, from 350 to 420 units.

local, and tribal communities and public health entities within 6 months. Measure of performance: percentage of requests for training and assistance fulfilled.
6.1.2.7. HHS, in coordination with DHS, DOD, VA and the USA Freedom Corps and Citizen Corps programs, shall prepare guidance for local Medical Reserve Corps coordinators describing the role of the Medical Reserve Corps during a pandemic, within 3 months. Measure of performance: guidance materials developed and published on Medical Reserve Corps website (www.medicalreservecorps.gov).

6.1.2.8. DHS, in coordination with the USA Freedom Corps, shall direct other Citizen Corps programs to prepare guidance detailing appropriate pandemic preparedness activities for each program, within 3 months. Measure of performance: guidance materials developed and published on Citizen Corps website and component program websites.

b. Communicating Expectations and Responsibilities

6.1.3. Work to ensure clear, effective, and coordinated risk communication, domestically and internationally, before and during a pandemic. This includes identifying credible spokespersons at all levels of government to effectively coordinate and communicate helpful, informative messages in a timely manner.

6.1.3.1. HHS, in coordination with DHS, DOS, DOD, VA, and other Federal partners, shall develop, test, and implement a Federal Government public health emergency communications plan (describing the government’s strategy for responding to a pandemic, outlining U.S. international commitments and intentions, and reviewing containment measures that the government believes will be effective as well as those it regards as likely to be ineffective, excessively costly, or harmful) within 6 months. Measure of performance: containment strategy and emergency response materials completed and published on www.pandemicflu.gov; communications plan implemented.

6.1.3.2. HHS, in coordination with DHS, shall develop, test, update and implement (if necessary) a multilingual and multimedia public engagement and risk communications strategy within 6 months. Measure of performance: risk communication material completed and published on www.pandemicflu.gov and other venues; State summit meetings held.

6.1.3.3. HHS, in coordination with DHS, DOD, and the VA, and in collaboration with State, local, and tribal health agencies and the academic community, shall select and retain opinion leaders and medical experts to serve as credible spokespersons to coordinate and effectively communicate important and informative messages to the public, within 6 months. Measure of performance: national spokespersons engaged in communications campaign.

6.1.4. Provide guidance to the private sector and critical infrastructure entities on their role in the pandemic response, and considerations necessary to maintain essential services and operations despite significant and sustained worker absenteeism.

6.1.4.1. State, local, and tribal public health and health care authorities, in collaboration with DHS, HHS, and the Department of Labor (DOL), should coordinate emer-
ergency communication protocols with print and broadcast media, private industry, academic, and nonprofit partners within 6 months. Measure of performance: coordinated messages from communities identified above.

6.1.4.2. DOT, in cooperation with HHS, DHS, and DOC, shall develop model protocols for 9-1-1 call centers and public safety answering points that address the provision of information to the public, facilitate caller screening, and assist with priority dispatch of limited emergency medical services, within 12 months. Measure of performance: model protocols developed and disseminated to 9-1-1 call centers and public safety answering points.

c. Producing and Stockpiling Vaccines, Antiviral Medications, and Medical Material

6.1.5. **Encourage and subsidize the development of State-based antiviral stockpiles to support response activities.**

6.1.5.1. HHS shall encourage and subsidize the development of State, territorial, and tribal antiviral stockpiles to support response activities within 18 months. Measure of performance: State, territorial, and tribal stockpiles established and antiviral medication purchases made toward goal of aggregate 31 million treatment courses.

6.1.6. **Ensure that our national stockpile and stockpiles based in States and communities are properly configured to respond to the diversity of medical requirements presented by a pandemic, including personal protective equipment, antibiotics, and general supplies.**

6.1.6.1. HHS, in coordination with DOD, VA, and State, local, and tribal partners, shall define the mix of antiviral medications to include in the Strategic National Stockpile (SNS) and State stockpiles and develop recommendations for how the different agents are to be used, within 6 months. Measure of performance: development of policy concerning the selection, relative proportions, and use of antiviral medications in SNS and State stockpiles.

6.1.6.2. HHS, in coordination with DOD, VA, and State, local, and tribal partners, shall define critical medical material requirements for stockpiling by the SNS and States to respond to the diversity of needs presented by a pandemic, within 9 months. Measure of performance: requirements defined and guidance provided on stockpiling.

6.1.6.3. DOD, as part of its departmental implementation plan, shall conduct a medical materiel requirements gap analysis and procure necessary materiel to enhance Military Health System surge capacity, within 18 months. Measure of performance: gap analysis completed and necessary materiel procured.

6.1.6.4. HHS, DOD, VA and the States shall maintain antiviral and vaccine stockpiles in a manner consistent with the requirements of FDA’s Shelf Life Extension Program (SLEP) and explore the possibility of broadening SLEP to include equivalently maintained State stockpiles, within 6 months. Measure of performance:
compliance with SLEP requirements documented; decision made on broadening SLEP to State stockpiles.

6.1.7. Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient antiviral medications and vaccine for front-line personnel and at-risk populations, including military personnel.

6.1.7.1. HHS, in coordination with DHS, DOJ, VA, and in collaboration with State, local, and tribal partners, shall determine the national medical countermeasure requirements to ensure the sustained functioning of medical, emergency response, and other front-line organizations, within 12 months. Measure of performance: more specific definition of sectors and personnel for priority access to medical countermeasures and quantities needed to protect those groups; guidance provided to State, local, and tribal governments and to infrastructure sectors for various scenarios of pandemic severity and medical countermeasure supply.

6.1.7.2. HHS shall establish and maintain stockpiles of pre-pandemic vaccines adequate to immunize 20 million persons against influenza strains that present a pandemic threat, as soon as possible within the constraints of industrial capacity. Measure of performance: procurement of 20 million courses of pre-pandemic vaccine against influenza strains presenting a pandemic threat.

6.1.7.3. HHS in collaboration with State/local partners shall procure and allocate sufficient stockpiles of countermeasures to ensure continuity of critical medical and emergency response operations, within 18 months, within the constraints of industrial capacity. Measure of performance: sufficient quantities of antiviral medications and other countermeasures procured and distributed between SNS and State stockpiles.

6.1.7.4. DOD shall establish stockpiles of vaccine against H5N1 and other influenza subtypes determined to represent a pandemic threat adequate to immunize approximately 1.35 million persons for military use within 18 months of availability. Measure of performance: sufficient vaccine against each influenza virus determined to represent a pandemic threat in DOD stockpile to vaccinate 1.35 million persons.

6.1.8. Establish domestic production capacity and stockpiles of countermeasures to ensure sufficient vaccine to vaccinate the entire U.S. population within 6 months of the emergence of a virus with pandemic potential.

6.1.8.1. HHS shall work with the pharmaceutical industry toward the goal of developing, within 60 months, domestic vaccine production capacity sufficient to provide vaccine for the entire U.S. population within 6 months after the development of a vaccine reference strain. Measure of performance: domestic vaccine manufacturing capacity in place to produce 300 million courses of vaccine within 6 months of development of a vaccine reference strain during a pandemic.
6.1.9. Establish domestic production capacity and stockpiles of countermeasures to ensure antiviral treatment for those who contract a pandemic strain of influenza.

6.1.9.1. HHS shall, to the extent feasible, work with antiviral drug manufacturers and large distributors to develop agreements supporting the Federal procurement of available stocks of antiviral drugs both during the pre-pandemic and pandemic periods, within 12 months. Measure of performance: new antiviral medications procured by SNS, within the constraints of industrial capacity; Federal contracts in place with antiviral drug manufacturers and distributors.

6.1.9.2. HHS, in collaboration with the States, shall purchase sufficient quantities of antiviral drugs to treat 25 percent of the U.S. population, with reserve of 6 million treatment courses for outbreak containment within 18 months, within the constraints of industrial capacity. Measure of performance: 50 million treatment courses of antiviral drugs procured by SNS; States and tribes make stockpile purchases toward aggregate 31 million treatment course goal.

6.1.9.3. DOD shall procure 2.4 million treatment courses of antiviral medications and position them at locations worldwide within 18 months. Measure of performance: aggregate 2.4 million treatment courses of antiviral medications in DOD stockpiles.

6.1.10. Facilitate appropriate coordination of efforts across the vaccine manufacturing sector.

6.1.10.1. HHS, in coordination with the private sector, shall assess the ability of U.S.-based pharmaceutical manufacturing facilities to contribute surge capacity and to retrofit existing facilities for pandemic vaccine production. This assessment will be completed within 6 months and should inform efforts to expand vaccine capacity. Measure of performance: completed assessment.

6.1.10.2. HHS, in coordination with DHS, DOD, VA, DOC, DOJ, and Treasury, shall assess within whether use of the Defense Production Act or other authorities would provide sustained advantages in procuring medical countermeasures, within 6 months. Measure of performance: analytical report completed on the advantages/disadvantages of invoking the Defense Production Act to facilitate medical countermeasure production and procurement.

6.1.11. Address regulatory and other legal issues to the expansion of our domestic vaccine production capacity.

6.1.11.1. HHS shall assess its existing authorities and develop a plan of action to address any regulatory or other legal issues related to the expansion of domestic vaccine production capacity within 12 months. Measure of performance: regulatory and legal issues identified in assessment.

6.1.11.2. HHS shall develop a protocol and decision tools to implement liability protections and compensation, as authorized by the Public Readiness and Emergency Preparedness Act (Pub. L. 109-148), within 6 months. Measure of performance: publication of protocol and decision tools.
6.1.12. Expand the public health recommendations for domestic seasonal influenza vaccination and encourage the same practice internationally.

6.1.12.1. HHS shall collaborate with health care providers, industry partners, and State, local, and tribal public health authorities to develop public information campaigns and other mechanisms to stimulate increased seasonal influenza vaccination, within 12 months. Measure of performance: domestic vaccine use increased relative to historical norms.

d. Establishing Distribution Plans for Medical Countermeasures, Including Vaccines and Antiviral Medications

6.1.13. Develop credible countermeasure distribution mechanisms for vaccine and antiviral agents prior to and during a pandemic.

6.1.13.1. HHS, in coordination with DHS, DOD, VA, and DOJ, and in collaboration with State, local, and tribal partners and the private sector, shall ensure that States, localities, and tribal entities have developed and exercised pandemic influenza countermeasure distribution plans, and can enact security protocols if necessary, according to pre-determined priorities (see below) within 12 months. Measures of performance: ability to activate, deploy, and begin distributing contents of medical stockpiles in localities as needed established and validated through exercises.

6.1.13.2. HHS, in coordination with DOD, VA, States, and other public sector entities with antiviral drug stockpiles, shall coordinate use of assets maintained by different organizations, within 12 months. Measure of performance: plans developed for coordinated use of antiviral stockpiles.

6.1.13.3. HHS, in collaboration with State, territorial, tribal, and local health care delivery partners, shall develop and execute strategies to effectively implement target group recommendations described below, within 12 months. Measure of performance: guidance on strategies to implement target group recommendations developed and disseminated to State, local, and tribal authorities for inclusion in pandemic response plans.

6.1.13.4. HHS, in coordination with DOD, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall assist in the development of distribution plans for medical countermeasure stockpiles to ensure that delivery and distribution algorithms have been planned for each locality for antiviral distribution. Goal is to be able to distribute antiviral medications to infected patients within 48 hours of the onset of symptoms within 12 months. Measure of performance: distribution plans developed.

6.1.13.5. HHS, in coordination with DHS, DOS, DOD, DOL, VA, and in collaboration with State, local, and tribal governments and private sector partners, shall develop plans for the allocation, distribution, and administration of pre-pandemic vaccine, within 9 months. Measure of performance: department plans developed and guidance disseminated to State, local, and tribal authorities.
to facilitate development of pandemic response plans.

6.1.13.6. DOT, in coordination with HHS, DHS, State, local, and tribal officials and other EMS stakeholders, shall develop suggested EMS pandemic influenza guidelines for statewide adoption that address: clinical standards, education, treatment protocols, decontamination procedures, medical direction, scope of practice, legal parameters, and other issues, within 12 months. Measure of performance: EMS pandemic influenza guidelines completed.

6.1.13.7. HHS, in coordination with DHS, DOT, DOD, and VA, shall work with State, local, and tribal governments and private sector partners to develop and test plans to allocate and distribute critical medical materiel (e.g., ventilators with accessories, resuscitator bags, gloves, face masks, gowns) in a health emergency, within 6 months. Measure of performance: plans developed, tested, and incorporated into department plan, and disseminated to States and tribes for incorporation into their pandemic response plans.

6.1.13.8. DOD shall supply military units and posts, installations, bases, and stations with vaccine and antiviral medications according to the schedule of priorities listed in the DOD pandemic influenza policy and planning guidance, within 18 months. Measure of performance: vaccine and antiviral medications procured; DOD policy guidance developed on use and release of vaccine and antiviral medications; and worldwide distribution drill completed.

6.1.13.9. HHS, in coordination with DOD, VA, and in collaboration with State, territorial, tribal, and local partners, shall develop/refine mechanisms to: (1) track adverse events following vaccine and antiviral administration; (2) ensure that individuals obtain additional doses of vaccine, if necessary; and (3) define protocols for conducting vaccine- and antiviral-effectiveness studies during a pandemic, within 18 months. Measure of performance: mechanism(s) to track vaccine and antiviral medication coverage and adverse events developed; vaccine- and antiviral-effectiveness study protocols developed.

6.1.13.10. DOJ, in coordination with HHS, DHS, DOS, and DOC, shall lead the development of a joint strategic plan to ensure international shipments of counterfeit vaccine and antiviral medications are detected at our borders and that domestic counterfeit drug production and distribution is thwarted through aggressive enforcement efforts. Measure of performance: joint strategic plan developed; international and domestic counterfeit drug shipments prevented or interdicted.

6.1.14. Prioritize countermeasure allocation before an outbreak, and update this prioritization immediately after the outbreak begins based on the at-risk populations, available supplies, and the characteristics of the virus.

6.1.14.1. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOJ, DOL, VA, Treasury, and State/local governments, shall develop objectives for the use of, and strategy for allocating, vaccine and antiviral drug stockpiles during pre-pandemic and pandemic periods under varying conditions of countermeasure supply and pandemic severity within 3 months. Measure of performance:
clearly articulated statement of objectives for use of medical countermeasures under varying conditions of supply and pandemic severity.

6.1.14.2. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, Treasury, and State/local governments, shall identify lists of personnel and high-risk groups who should be considered for priority access to medical countermeasures, under various pandemic scenarios, according to strategy developed in compliance with 6.1.14.1, within 9 months. Measure of performance: provisional recommendations of groups who should receive priority access to vaccine and antiviral drugs established for various scenarios of pandemic severity and medical countermeasure supply.

6.1.14.3. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, and VA, shall establish a strategy for shifting priorities based on at-risk populations, supplies and efficacy of countermeasures against the circulating pandemic strain, and characteristics of the virus within 9 months. Measure of performance: clearly articulated process in place for evaluating and adjusting pre-pandemic recommendations of groups receiving priority access to medical countermeasures.

6.1.14.4. HHS, in coordination with DHS and Sector-Specific Agencies, DOS, DOD, DOL, VA, and Treasury, shall present recommendations on target groups for vaccine and antiviral drugs when sustained and efficient human-to-human transmission of a potential pandemic influenza strain is documented anywhere in the world. These recommendations will reflect data from the pandemic and available supplies of medical countermeasures. Measure of performance: provisional identification of priority groups for various pandemic scenarios through interagency process within 2-3 weeks of outbreak.

e. Advancing Scientific Knowledge and Accelerating Development

6.1.15. Ensure that there is maximal sharing of scientific information about influenza viruses between governments, scientific entities, and the private sector.

6.1.15.1. HHS shall develop capability, protocols, and procedures to ensure that viral isolates obtained during investigation of human outbreaks of influenza with pandemic potential are sequenced and that sequences are published on GenBank within 1 week of confirmation of diagnosis in index case, within 6 months. Measure of performance: viral isolate sequences from outbreaks published on GenBank within 1 week of confirmation of diagnosis.

6.1.15.2. HHS shall increase and accelerate genomic sequencing of known human and avian influenza viruses and shall rapidly make this sequence information publicly available, within 6 months. Measure of performance: increased throughput of genomes sequenced (versus FY 2005 baseline) and decreased time interval between completion of sequencing and publication on GenBank.

6.1.15.3. HHS shall develop protocols and procedures to ensure timely reporting to Federal agencies and submission for publication of data from HHS-supported
influenza vaccine, antiviral medication, and diagnostic evaluation studies, within 6 months. Measure of performance: study data shared with Federal agencies within 1 month of analysis and publication of clinical trial data following completion of studies.

6.1.16. **Accelerate the development of cell culture technology for influenza vaccine production and establish a domestic production base to support vaccination demands.**

6.1.16.1. HHS shall continue to support the advanced development of cell-culture based influenza vaccine candidates. Measure of performance: research grants and/or contracts awarded to develop cell-culture based influenza vaccines against currently circulating influenza strains with pandemic potential within 6 months.

6.1.16.2. HHS shall support the renovation of existing U.S. manufacturing facilities that produce other FDA-licensed cell-based vaccines or biologics and the establishment of new domestic cell-based influenza vaccine manufacturing facilities, within 36 months. Measure of performance: contracts awarded for renovation or establishment of domestic cell-based influenza vaccine manufacturing capacity.

6.1.17. **Use novel investment strategies to advance the development of next-generation influenza diagnostics and countermeasures, including new antiviral medications, vaccines, adjuvant technologies, and countermeasures that provide protection across multiple strains and seasons of the influenza virus.**

6.1.17.1. HHS shall continue to support the development and clinical evaluation of novel vaccines and vaccination strategies (e.g., adjuvants, alternative delivery systems, common epitope vaccines). Measure of performance: research grants and/or contracts awarded to support the development of influenza vaccines (including polyvalent influenza vaccines), adjuvants and dose-sparing strategies, and more efficient delivery systems within 12 months, leading to initiation of phase I and II clinical trials to evaluate influenza vaccines and vaccination strategies.

6.1.17.2. HHS shall collaborate with the pharmaceutical, medical device, and diagnostics industries to accelerate development, evaluation (including the evaluation of dose-sparing strategies), licensure, and U.S.-based production of new antiviral drugs and diagnostics. Development activities should include design of preclinical and clinical studies to collect safety and efficacy information across multiple strains and seasons of circulating influenza illness, and advance design of protocols to obtain additional updated information to support revisions in product usage during circulation of novel strains and evolution of pandemic spread. Such collaborations should involve early and frequent discussions with the FDA to explore the use of accelerated regulatory pathways towards product approval or licensure. Collaborations concerning diagnostic tests should include CDC to facilitate access to pandemic virus samples for validation testing and ensure that the test is one that can be used to promote and protect the public health during an influenza pandemic. Measure of performance: initiation of clinical trials of new influenza antiviral drugs and diagnostics.