HRSA Guidance on Preparations for the 2nd Phase of the Novel H1N1 Influenza Pandemic (Fall 2009 – Winter 2010 Flu Season)

This guidance was originally issued on **8/14/2009**.
This guidance was updated through **9/15/2009**. Updated information is preceded with Updated: shown in red print.

Check back at www.hrsa.gov/h1n1/ for more recent updates.

Content area that has been updated:

- Acquiring Countermeasures, 6
- Acquiring Countermeasures, 8.
- Collaborations – Working with Others, 15.
- Collaborations – Working with Others, 17.
- Collaborations – Working with Others, 18.
- Workforce Considerations, 25.
- Workforce Considerations, 27.
- Communications Strategies, 30, a.
- Reporting, 35.

Background

This guidance is intended primarily for HRSA-funded direct service grantees, their subgrantees, and contractors although other HRSA grantees may also find the information useful. Grantees with subgrantees may wish to share this guidance with their subgrantees/contractors. In addition to HRSA grantees, this guidance may also be of interest to eligible 340B entities (see www.hrsa.gov/opa/introduction.htm) and our cooperative agreement partners to the extent that the information in this guidance may apply to them.

The purpose of this guidance is to convey information to HRSA grantees that they can use to help plan and prepare for the coming 2nd Phase Novel H1N1 pandemic during the Fall 2009 – Winter 2010 flu season. HRSA encourages its grantees to review their existing Emergency Preparedness and Continuity of Operations (COOP) Plans and to incorporate pandemic influenza preparation measures, such as those suggested below, into those plans as appropriate and necessary.

On June 11, 2009, the World Health Organization (WHO) signaled that a global pandemic of Novel H1N1 influenza A was underway by raising the worldwide pandemic alert level to Phase 6, its highest level. This action reflected the increasing geographic spread of new H1N1 infections to new countries and regions, not an increasing severity of illness caused by the virus. At the time, more than 70 countries had reported cases of Novel H1N1 Influenza infections during that 1st phase of the pandemic.

Since the WHO declaration of a pandemic, the Novel H1N1 virus has continued to spread, with the number of countries reporting cases of Novel H1N1 infections nearly doubling. The Southern Hemisphere's annual flu season has begun and countries there are reporting that the new H1N1 virus is spreading and causing illness along with the regular seasonal influenza viruses. In the United States, significant Novel H1N1 illness has continued into the summer, with localized and sometimes intense outbreaks occurring. The United States continues to report the largest number of Novel H1N1 cases of any country worldwide. However, most people who have become ill from confirmed H1N1 infection have recovered without requiring medical treatment. (See www.cdc.gov/h1n1flu)

While last spring's emergence of the Novel H1N1 influenza virus was less serious than originally anticipated, the possibility in the fall of mutation, antiviral resistance, or increased virulence makes it necessary for grantees to plan ahead and implement prudent preparedness measures, especially for populations at highest risk.

In some instances this guidance links to websites that are not government-owned or government-sponsored if these websites provide government information and/or services in a way that is not available on an official government website and the additional information is consistent with the intended purpose of a HRSA.gov web site. HRSA provides these non-government websites as a public service only. The U.S. government, including HRSA or any of its employees, neither endorses nor guarantees in any way the external organizations, services, advice, or products included in these website links. Furthermore, the U.S. government neither controls nor guarantees the accuracy, relevance, timeliness or completeness of the information contained in non-government website links. Please be aware that HRSA.gov's privacy protection may not be available at these external links.

This guidance relies on information from a wide variety of sources. It is the best information available to HRSA at the time this guidance is released. However, H1N1 preparedness is expected to continue evolving as we get closer to the fall flu season and more information becomes available. HRSA will post any major changes to this guidance to its website at www.hrsa.gov/h1n1

The guidance is organized into thematic groups however the numbering of the guidance sections is continuous for ease of reference.

HRSA H1N1 GUIDANCE

Planning

1. HRSA encourages its grantees to plan for the coming flu season in coordination with State and local public health authorities. Ten important steps outpatient facilities can take to prepare for Novel H1N1 can be found at www.cdc.gov/h1n1flu/10steps.htm.

2. HRSA encourages its grantees to work with their States to determine how they might partner in preparedness and response efforts to promote surge capacity and assist with keeping less severely ill persons from overtaxing emergency departments. States, territories, and certain large metropolitan areas recently received H1N1 preparedness funding from the Federal government from two sources: $90 million in U.S Department of Health and Human Services (HHS) Hospital Preparedness Program (HPP) grants and the $260 million in Centers for Disease Control and Prevention (CDC) Public Health Emergency Response (PHER) Grants. See www.hhs.gov/news/press/2009pres/07/20090710a.html . In the past, some of these States, territories, and cities have made some of the funding from these mechanisms available to HRSA funded programs including entities with HRSA cooperative agreements. HRSA funded entities should work with their public health departments to determine the availability of any H1N1 preparedness funding from these sources.

3. HRSA encourages grantees to regularly review resources available at www.flu.gov , the One-Stop Access to U.S. Government information on Novel H1N1, avian, and pandemic influenza viruses. More H1N1-specific information is available at www.cdc.gov/h1n1flu or en Español at www.cdc.gov/h1n1flu/espanol/

    a. To learn about other updates made to the CDC H1N1 Flu Website in the past 24 hours, please check the "What's New" page at www.cdc.gov/h1n1flu/whatsnew.htm

    b. Checking for updates at the CDC “What’s New” page allows you to get up-to-the-minute information at your convenience with less repetition and reduces the volume of incoming messaging so you can focus efforts on response to the outbreak.

    c. Grantees should also consider signing up through www.emergency.cdc.gov/rss/ for CDC Really Simple Syndication (RSS) feeds to receive automatic updates from the CDC’s Clinician Outreach Communications Activity (COCA) directly on the desktop or through an Internet browser or e-mail.

    d. Grantees should be monitoring health alert network (HAN) messaging from their State or local health department via www2a.cdc.gov/han/Index.asp

4. HRSA encourages its grantees to review their State’s pandemic flu plan which can be found at www.pandemicflu.gov/plan/states/stateplans.html

Acquiring Countermeasures

5. HRSA suggests to its grantees that they arrange to receive or acquire, through public or private sources, sufficient quantities of countermeasures (antivirals, vaccine [when it becomes available – see Item 8 below], N95 disposable respirators, surgical masks, eye protection,

gowns, hand sanitizer, etc.) consistent with evolving Federal recommendations. In addition, grantees should arrange to receive or acquire, through public or private sources, sufficient quantities of countermeasures (antivirals, vaccine [when it becomes available – see Item 8 below], surgical masks, hand sanitizer, etc.) to cover symptomatic patients exhibiting influenza-like illness (ILI).

a. Grantees should closely monitor evolving Federal plans to provide H1N1 vaccine to States for distribution to public health providers. Providers should review the following websites, which can assist in planning:
www.flu.gov/vaccine/antiviral_employers.html and
www.pandemictoolkit.com/tamiflu-supplyordering/tamiflu-store.aspx .
www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm?s_cid=ccu081009_CDCQandA_e

b. HRSA grantees should coordinate with their State Department of Health and their State's Strategic National Stockpile (SNS) Coordinator to be sure they are included in the State's plan for distribution of countermeasures (other than vaccine) from State cache's and Federal SNS allocations to States.

6. HRSA suggests that in acquiring N95 disposable respirators, grantees should take into account the need for individualized medical clearance and fit testing for staff and be aware of CDC's "Interim Recommendations for Facemask and Respirator Use to Reduce Novel Influenza (H1N1) Virus Transmission". See www.cdc.gov/h1n1flu/masks.htm and https://www.osha.gov/SLTC/respiratoryprotection/standards.html. Updated: On 9/1/2009 the Institute of Medicine (IOM) released a letter report entitled "Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A" that reiterated the need for healthcare providers to use N95 disposable respirators in healthcare settings. A free download of the IOM Report is available through
http://books.nap.edu/catalog.php?record_id=12748

7. Under certain circumstances, HRSA grantees participating in the 340B Drug Pricing Program may purchase antivirals at reduced cost www.hrsa.gov/opa/introduction.htm.

8. Current planning assumptions are that Novel H1N1 vaccine will be purchased by the U.S. Government and made available to vaccinators at no cost. Grantees should monitor the situation closely in case there are any adjustments to this planning assumption. The current plan is for syringes, needles, sharps containers and alcohol swabs to also be provided free of charge. Vaccine will be allocated to States, proportionally by population. State health departments (and a few separately funded large city health departments) will direct their allocation to local health departments and other vaccination partners.
www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm . A number of States have already established registries for providers to request H1N1 vaccine allocations and HRSA grantees are encouraged to work closely with their States to make their needs known and register with their State public health authorities to receive H1N1 vaccine. Additional information on preparing for vaccination with H1N1 vaccine can be found at:
www.cdc.gov/h1n1flu/vaccination/provider/preparing.htm. CDC has recently (8/28/09) posted a listing of whom providers can contact in the State/Jurisdiction if they are interested in providing H1N1 vaccination. These contacts can be found at:
www.cdc.gov/h1n1flu/vaccination/statecontacts.htm?s_cid=ccu083109_VaccinePOC_e.

Although providers will receive the vaccine free of charge, reimbursement for administration of the H1N1 vaccine is currently being worked on by health care financing authorities. Since most HRSA grantees have diversified funding streams, they will need to consider the policies of each payor or grantor. For Medicare patients seen at Federally Qualified Health Centers (FQHCs), the Centers for Medicare & Medicaid Services (CMS) have traditionally paid for 100% of the cost of the influenza vaccine and its administration once a year. Updated: The possibility of two to four influenza vaccinations this year (one seasonal trivalent and one H1N1 monovalent for adults or two seasonal trivalent and two H1N1 monovalent for children under 9 years of age that are planned as of 9/11/09* raises reimbursement questions that have yet to be answered. States are expected to pay their established rates for vaccines provided to Medicaid patients. Private insurers have expressed their intention to pay for H1N1 vaccination of their covered individuals. For additional information see the America's Health Insurance Plans' (AHIP) response available at www.cdc.gov/h1n1flu/vaccination/provider/preparing.htm . Finally, since vaccine for uninsured patients seen by HRSA grantees is expected to come from the Federal government at no cost via State public health authorities, administration of H1N1 vaccine to a grantee's existing uninsured patients is expected to be covered under the existing grant award. Reimbursement for administration of H1N1 vaccine to any new uninsured surge patients a grantee may see has yet to be determined but grantees are encouraged to work with public health authorities to see if funding may be available to address surge needs. Updated : *Vaccine trial results from Australia and the United States made public on 9/11/09 indicated that a single dose of the new H1N1 vaccine "induce(d) a strong immune response in most healthy adults when administered in a single unadjuvanted 15-microgram dose" and that two doses would not be needed in most adults as previously anticipated. See the associated press release at www.hhs.gov/news/press/2009pres/09/20090911a.html. The results for the nasal mist form of the vaccine were not in as of 9/11/09 but a similar single dose responsiveness is anticipated The results for children under 9 were also not in yet but it is expected that 2 doses would be required for full immunity as is currently the case for seasonal influenza.

9. HRSA grantees should be aware of recommendations made by the CDC's Advisory Committee on Immunization Practices (ACIP) on July 29, 2009, that identify high-priority populations to target for vaccination, at least initially, when vaccine availability may be limited See www.cdc.gov/h1n1flu/vaccination/acip.htm .

10. These recommendations were formally adopted by the CDC on August 21, 2009 through their publication in the Morbidity and Mortality Weekly Report (MMWR). See www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm?s_cid=rr58e0821a1_e Please note the section in the MMWR entitled "Subset of Target Groups During Limited Vaccine Availability" as it contains important information for providers

11. Providers participating in Novel H1N1 vaccination will be expected to administer vaccine in accordance with national recommendations for use of the vaccine, especially early in the flu season when the availability of Novel H1N1 vaccine may be limited. Grantees may want to consider any necessary updates to the recordkeeping systems that would enable them to assess the uptake of Novel H1N1 vaccine among their patient population and record any adverse events detected that may be potentially attributable to the new vaccine www.cdc.gov/h1n1flu/vaccination/provider/preparing.htm .

12. HRSA grantees should plan to make available seasonal flu vaccination to its staff and patients as early as possible in order to reduce the incidence of seasonal influenza, free up resources for

Novel H1N1 vaccination when that vaccine becomes available, and make the monitoring and resolution between adverse events of seasonal influenza vaccine and Novel H1N1 vaccine easier. Additional information on this year's seasonable influenza vaccine can be found at: www.fda.gov/ForConsumers/ConsumerUpdates/ucm100139.htm. Some strategies for improving seasonal influenza vaccination rates in health care personnel can be found at www.jointcommission.org/PatientSafety/InfectionControl/flu_monograph.htm .

13. HRSA grantees should plan to make Novel H1N1 vaccination available to its workforce as soon as it is available since healthcare workers are at high risk of contracting Novel H1N1 influenza from infected patients and because infected healthcare workers can be a potential source of infection for vulnerable patients. Under current plans, health care workers and emergency medical responders will be among the first to receive the Novel H1N1 flu vaccine since they will most likely be among the first to encounter the Novel H1N1 virus. In addition, early vaccination of healthcare workers can reduce absenteeism in the health care worker population and help maintain healthcare system capacity www.cdc.gov/h1n1flu/vaccination/acip.htm. Nonetheless, since vaccination is voluntary, grantees may have to consider, and plan for, some level of absenteeism among its workforce should illness result from healthcare workers or their close contacts contracting the Novel H1N1 virus.

14. HRSA grantees should strongly encourage health care workers to receive the Novel H1N1 vaccination. Grantees should employ strategies to increase the rates of vaccination for their health care personnel such as waiving administration fees for health care personnel, providing educational materials (such as Vaccine Information Statements; see Item #16), sending reminder messages, holding informational staff meetings, monitoring employee participation in the vaccination initiative, and employing declination forms such as the one at www.immunize.org/catg.d/p4068.pdf . To the extent they are able, HRSA grantees are encouraged to become integrated into their local response plans and participate in local planning meetings and preparedness exercises. A comprehensive community mitigation plan that can be implemented while the Novel H1N1 vaccine is being developed can be found at www.pandemicflu.gov/plan/community/commitigation.html#app4

Collaborations – Working with Others

15. State Primary Care Associations (PCAs) should work with State authorities on behalf of health centers in their States, including State Health Departments, Primary Care Offices (PCOs) within State Health Departments, State Emergency Management Agencies (EMAs) and State SNS Coordinators to ensure that health centers and primary care grantees are integrated into State and local plans to the extent appropriate and that their capabilities and potential roles in community response are understood by the greater public health and healthcare community. Updated: Likewise, State Offices of Rural Health should work with the appropriate State authorities on behalf of Rural Health Clinics.

16. To the extent that they have the capacity and as appropriate, HRSA grantees should explore partnerships with local hospitals that would allow them to contribute to local surge capacity by either a) agreeing to see overflow patients, b) making staff available to augment mass vaccination efforts, or c) agreeing to serve as a Point of Distribution (POD). For additional information please see www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm . Examples of promising practices are available at: www.cidrappractices.org/practices/article.do?page=home and

www.cidrappractices.org/files/343/343_toolkit.pdf .

17. Updated: HRSA grantees providing vaccination should be sure to provide a Novel H1N1 Vaccination Information Statement (VIS) to patients. Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that can be found at: www.cdc.gov/vaccines/pubs/vis/default.htm . VISs explain both the benefits and risks of a vaccine to vaccine recipients, their parents, or their legal representatives. Federal law requires that VISs be provided before each dose whenever certain vaccinations are given. VISs also contain information on vaccine injury compensation for those few individuals who may have a serious reaction to a vaccine. VISs are also available in a variety of languages from www.immunize.org/vis . Vaccine administration should not be delayed if VISs are not yet available www.cdc.gov/vaccines/pubs/vis/vis-misconception.htm. The VIS for Novel H1N1 vaccine is not yet available but is expected to be released prior to or in conjunction with the release of Novel H1N1 vaccine. The Novel H1N1 VIS will not be included in vaccine kits distributed by the national distributor at the direction of State health departments. Grantees will be expected to download Novel H1N1 VISs from one of the websites above and make them available to Novel H1N1 vaccine recipients before each dose is administered.

    Updated:
    NOTE: **Correction to 2009-10 seasonal flu VISs.** Both of the seasonal influenza **T**rivalent **I**nactivated Vaccine (TIV) and **L**ive, **A**ttenuated **I**nfluenza **V**accine (LAIV) VISs initially posted on the CDC website on 8/11/2009 contained an error. Seasonal influenza vaccination is recommended for caregivers and household contacts of adults 50 years old and older. The initially posted VISs mistakenly listed this age as 65. It was corrected on the CDC web site on 8/13/09. See www.cdc.gov/vaccines/pubs/vis/vis-news.htm#flu. Please see sure to use the correct 8/13/09 version of the seasonal influenza VISs which can be found at www.cdc.gov/vaccines/pubs/vis/default.htm.

18. HRSA encourages grantees with mobile populations, such as migrant farm workers and the homeless, to utilize the Health Network program www.migrantclinician.org/clinical_topics/h1n1-fluswine-flu.html to assist with bridge case management and patient navigation. Updated: Relevant "Guidance for Homeless and Emergency Shelters on the Novel Influenza A (H1N1) Virus" is available from the CDC at www.cdc.gov/h1n1flu/guidance/homeless.htm. Additional resources to help in caring for homeless individuals during the pandemic are collected at the National Health Care for the Homeless Council's web page at www.nhchc.org/CommunicableDiseases.html
    The National Health Care for the Homeless Council is also developing a practical guide for shelter providers which is expected to be available in October 2009.

19. Since Novel H1N1 vaccine will not be available before the start of the school year, HRSA grantees operating school-based health centers are encouraged to advocate within their schools for early student and parent/caregiver education regarding the Novel H1N1 virus (see www.flu.gov/plan/school/toolkit.html), community mitigation strategies, good hygiene and cough etiquette, and when to stay home in accordance with CDC guidance www.flu.gov/plan/school/schoolguidance.html . In addition, HRSA grantees without school-based sites should consider outreach and coordination with local schools, pre-schools, and headstart programs in their community to potentially offer vaccinations, especially to uninsured and underserved children.

20. HRSA encourages clinical service delivery grantees working with populations in nursing homes and other residential care facilities to address their unique service delivery issues. Patients in residential care facilities may have a higher risk for complications. Grantee staff and facility staff should follow the CDC-developed interim infection control guidance for healthcare facilities found at www.cdc.gov/h1n1flu/guidelines_infection_control.htm (note: there is an underscore between words "guidelines", "infection" and "control" in the web address, as in "guidelines_infection_control" that may not be apparent on screen due to the underlining of the URL).

21. HRSA grantees without their own home health care capability should consider engaging with the home health care community to manage appropriate cases at home, if that is prudent, rather than in the outpatient setting.

Workforce Considerations

22. HRSA grantees should encourage their personnel to adopt family preparedness plans that can protect family members, reduce absenteeism, and ensure greater availability of workforce during a pandemic. Discussing the upcoming flu season at home can help encourage communication, reduce anxiety, foster the importance of good hygiene and cough etiquette, and promote early vaccination for both seasonal and Novel H1N1 influenza. The following resources may be helpful: www.pandemicflu.gov/plan/pdf/guide.pdf
www.cdc.gov/h1n1flu/guidance_homecare.htm
www.pandemicflu.gov/plan/pdf/individuals.pdf
www.ready.gov/america/makeaplan/index.html

23. HRSA grantees should develop a pandemic influenza plan and exercise their plan at least annually, preferably before the coming flu season. See www.pandemicflu.gov/plan/medical.html and www.cdc.gov/h1n1flu/10steps.htm

24. An important component of a grantee's pandemic influenza plan is workplace planning. Information on workplace planning can be found at www.pandemicflu.gov/plan/business/ and www.pandemictoolkit.com/downloads/Guideln_OSHA3327pandemic.pdf .

25. National organizations representing HRSA grantees, if not already COCA partners, should consider signing up for the CDC's Clinician Outreach Communications Activity (COCA) and sharing information with their members. Updated: Interested parties can sign up for COCA opportunities through emergency.cdc.gov/coca/index.asp.

26. HRSA grantees should have their Medical Director and clinical staff monitor the CDC guidance on pandemic influenza at www.cdc.gov/h1n1flu/guidance . Although dentists do not routinely administer vaccines, HRSA grantees that provide oral health services should be sure that their dental providers are familiar with the information provided in the CDC Division of Oral Health's "Prevention of Swine Influenza A (H1N1) in the Dental Healthcare Setting" www.cdc.gov/oralHealth/InfectionControl/pdf/swineflu.doc. Grantees should have their Medical Director and clinical staff participate in COCA outreach opportunities to stay up to date with evolving guidance. Questions on H1N1-related clinical issues may be sent to coca@cdc.gov. The CDC has established a specific web page listing resources for clinicians at www.cdc.gov/h1n1flu/clinicians/?s_cid=ccu083109_NovelH1N12_e.

27. HRSA grantees should ensure that their clinical staff members are familiar with CDC's latest case definitions, infection control practices in the healthcare setting, and antiviral recommendations. These documents are available at www.cdc.gov/h1n1flu/guidance/.
Updated: On 9/8/09 CDC updated its antiviral guidance entitled "Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season" which can be found at www.cdc.gov/h1n1flu/recommendations.htm

28. During the 1st phase of the H1N1 pandemic, rapid test kits were used to differentiate between Novel H1N1 influenza and seasonal influenza. As the clinical affects of the Novel H1N1 virus became more apparent, the need for rapid test kits in the outpatient setting diminished. HRSA grantees should consider the possibility, that if the 2nd phase of the Novel H1N1 pandemic is more sever that what has been experienced thus far, the need for rapid test kits to differentiate between Novel H1N1 influenza and seasonal influenza could return. Grantees should monitor CDC guidance regarding the need for rapid test kits in the outpatient setting and may want to identify a private or public supply chain for rapid test kits in case should they become necessary. For more information see www.cdc.gov/h1n1flu/guidance/rapid_testing.htm (note: The URL has an underscore between words "rapid" and "testing" in the web address, as in "rapid_testing" that may not be apparent on screen due to the underlining of the URL).

Communications Strategies

29. As HRSA grantees plan ahead and implement prudent preparedness measures they should remain vigilant in ensuring civil rights compliance by sharing important information regarding the Novel H1N1 pandemic in prevailing languages other than English, by ensuring that no harassment or discrimination is directed toward those who may have contracted the virus or come from areas where the Novel H1N1 virus is more prevalent, and by providing access to information and health services to people with disabilities. The following websites may help in these efforts:
www.hhs.gov/ocr
www.lep.gov
www.hrsa.gov/healthliteracy/training.htm

30. HRSA grantees should consider a communications strategy aimed at their patient population and staff including messaging, signage, handouts, and public service announcements (PSAs) to educate about pandemic influenza symptoms and precautions, and encourage reporting of appropriate symptoms to clinic staff, frequent hand washing, and good hygiene. See www.pandemicflu.gov/news/rcommunication.html . Signage in multiple languages is available at: www.cdc.gov/flu/protect/covercough.htm .
Patient education materials are also available:

    a. in English at: www.cdc.gov/h1n1flu/qa.htm and Updated: www.cdc.gov/flu/freeresources/print.htm

    b. in Spanish at: www.cdc.gov/swineflu/espanol/influenza_porcina_usted.htm (note: there are underscores between words "influenza" and "porcina" and "usted" in the web address, as in "influenza_porcina_usted" that may not be apparent on screen due to the underlining of the URL). Additional H1N1 Influenza Resources in Other Languages are available at:

www.omhrc.gov/templates/content.aspx?lvl=2&lvlid=192&ID=7809 .

31. HRSA grantees should consider adoption of waiting room policies to minimize the chance of Novel H1N1 or other respiratory virus transmission between virus-infected patients and non-infected patients, particularly since people with chronic conditions, pregnant women, and children, many of whom are seen by health centers, are particularly vulnerable to complications of the H1N1 virus. These policies may also apply to other grantee areas such as classrooms, reception areas, and meeting spaces. See www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm and www.cdc.gov/h1n1flu/masks.htm .

32. HRSA grantees should consider implementing or expanding any telephone triage capability they may have to reduce the number of patients reporting to their service sites unnecessarily and thus reduce the potential for transmission of active H1N1 infection. Information from the CDC on managing calls and calls centers can be found at www.cdc.gov/h1n1flu/callcenters.htm . Information from the Agency for Healthcare Research and Quality (AHRQ), can be found at www.ahrq.gov/prep/callcenters . An example of a telephone triage protocol can be found at: www.aafp.org/online/en/home/publications/journals/afp/preprint/influenza-telephone-triage.html . To the extent possible, HRSA grantees utilizing telephone triage capability may want to follow up with patients with whom they only had telephone contact in order to inquire about signs of worsening which may require in-person evaluation. On-going experience has demonstrated that there are observed benefits to early recognition and treatment of patients and that a follow-up regime can help identify patients whose condition may be rapidly deteriorating.

33. Poison control centers should prepare for an influx of H1N1 questions and work with public health authorities in the areas they serve to prepare information sheets that may allow them to appropriately field H1N1 questions. Scripts for call centers are under development by Federal authorities to help triage patients and reduce surge as a result of suspected H1N1 infection at emergency departments. Poison control centers should be on the look-out for these scripts once they are developed.

34. HRSA grantees should maintain vigilance since the second phase of a pandemic can often be more severe, yet strive to reduce unwarranted concern through education and preparation.

Reporting

35. HRSA grantees with lab capability should continue to report required information to local and State authorities through established reporting channels. As with the initial Novel 2009 H1N1 outbreak, the required frequency and detail of reporting may change over time as the severity and epidemiology of the second phase (and subsequent phases) of the pandemic become apparent. Updated: Individual case counts were kept early during the 2009 H1N1 outbreak when the 2009 H1N1 virus first emerged. As the outbreak expanded and became more widespread, individual case counts became increasingly impractical and not representative of the true extent of the outbreak. This was because only a small proportion of persons with respiratory illness were actually tested and confirmed for influenza (including 2009 H1N1) so the true benefit of keeping track of these numbers was questionable. In addition, the extensive spread of 2009 H1N1 flu within the United States made it extremely resource-intensive for states to count individual cases. On July 24, 2009, CDC discontinued reporting of individual

cases of 2009 H1N1, but continued to track hospitalizations and deaths. See http://www.cdc.gov/h1n1flu/reportingqa.htm. CDC issue updated guidance on 9/8/09 entitled "Interim Guidance for State and Local Health Departments for Reporting Influenza-Associated Hospitalizations and Deaths for the 2009-2010 Season" available at http://www.cdc.gov/H1N1flu/hospitalreporting.htm

Grantees may wish to contact their local health department to confirm testing protocols and reporting procedures provided at www.cdc.gov/h1n1flu/specimencollection.htm

In addition, tracking the total number of vaccine doses administered will be important during the early phase of the novel H1N1 vaccination program to assess early uptake. If the vaccine supply is limited, tracking also provides a means for determining whether vaccine is being administered according to ACIP age-group recommendations as adopted in the CDC's August 21, 2009 Morbidity and Mortality Weekly Report (MMWR), particularly in the section entitled "Subset of Target Groups During Limited Vaccine Availability".. See www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm?s_cid=rr58e0821a1_e
CDC Project Areas (50 States, 8 territories, and 4 metropolitan areas) will be expected to track doses administered and to collect minimum data elements (specified in the link below) to monitor their program and to fulfill federal reporting requirements. The number of vaccine doses administered will be reported to CDC on a weekly basis, along with minimum data elements, in aggregate form. See www.cdc.gov/H1N1flu/vaccination/statelocal/pdf/H1N1_DosesAdministered.pdf
Private-not-for-profit (PNP) grantees should be aware that in addition to public sector vaccine administration, many areas are planning to engage private provider offices and other private sector settings in vaccine administration. It is critical that doses-administered tracking occur in those settings, as well as in public sector settings, during the initial period, defined as administration of up to the initial 40 million doses of vaccine. Private providers who participate in vaccination during this period must be willing to track and report doses administered on a weekly basis. Vaccine kits provided at the direction of State health department are expected to contain vaccine record cards.

36. HRSA grantees should report any adverse events following immunization (AEFI) with H1N1 by filing a Vaccine Adverse Event Reporting System (VAERS) form through the VAERS web site at www.vaers.hhs.gov or by calling 1-800-822-7967. CDC is working with State Vaccine Safety Coordinators in the 62 CDC Project Areas for the Pandemic (H1N1) 2009 Influenza adverse event monitoring following immunization (AEFI). CDC has posted a document entitled "Influenza A (H1N1) 2009 Monovalent Vaccine Safety Monitoring: CDC Planning for State, Local, Tribal, and Territorial Health Officials" at www.cdc.gov/h1n1flu/vaccination/safety_planning.htm that may be helpful to HRSA grantees.

37. HRSA grantees should be aware of the Public Readiness and Emergency Preparedness (PREP) Act which provides important liability protections for both the manufacture and the administration of covered countermeasures, such as the Novel H1N1 vaccine currently under development. Liability protections were put in place to ensure that an adequate supply of countermeasures was produced and made available in the US by vaccine manufacturers. The PREP Act also provides a mechanism to compensate eligible individuals for covered injuries from a covered countermeasure. For an overview of these protections, see www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html

    a. The PREP Act authorizes the Secretary of the Department of Health and Human Services ("Secretary") to issue PREP Act declarations that provide immunity from tort

liability (except in cases of willful misconduct) for the development, manufacture, testing, distribution, administration, and use of such countermeasures to certain diseases, threats and conditions. The Secretarial PREP Act declaration specifies the categories of health threats or conditions for which the specific countermeasures are recommended, the period during which liability protections are in effect, the population(s) of individuals protected, and the geographic areas for which the protections are in effect.

b. A PREP Act declaration covering pandemic countermeasures was originally issued by the Secretary on October 10, 2008 (when avian influenza was the greatest concern) and subsequently amended on April 26, 2009, in order to clarify that the Original Declaration also applies to Novel H1N1 influenza (as ell as other influenza strains which originate from animals and which have pandemic potential). See www.hhs.gov/disasters/discussion/planners/prepact/index.html .

c. The PREP Act also authorizes creation of a Countermeasures Injury Compensation Fund from which to compensate eligible individuals for covered injuries from a covered countermeasure. These provisions were put in place to encourage broad use of countermeasures by the population at large during a pandemic. The authority to operate the Countermeasures Injury Compensation Program (CICP) was delegated by the Secretary of HHS to the Administrator of HRSA. Information regarding the Countermeasures Injury Compensation Program (CICP) can be accessed directly via www.hrsa.gov/countermeasurescomp . Vaccine Information Statements (VIS) distributed to recipients at the time of vaccination provide information on applicable vaccine injury compensation programs www.hrsa.gov/vaccinecompensation and on how to report adverse events www.cdc.gov/vaccines/pubs/vis/default.htm .