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**Oregon Novel H1N1 Vaccination Planning Q&A
October 28, 2009**

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This document is available online at:

<http://www.oregon.gov/DHS/ph/acd/flu/h1n1flu-subcommittee.shtml>

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VACCINE PURCHASE

- 1. How will novel H1N1 vaccine be purchased?**
Planners should assume novel H1N1 vaccine will be procured and purchased by the federal government and made available for vaccinators at no cost.

VACCINE DISTRIBUTION

- 2. (REVISED October 26, 2009)**

How long will it take for vaccine orders to be processed?

Oregon H1N1 Vaccine and Ancillary Supply - from Order to Arrival Timeline				
Order submitted prior to 11:00am to OIP	Order submitted to CDC	Order Received by McKesson	Vaccine/Supplies Shipped out	Vaccine/Supplies arrive
Saturday, Sunday, Monday	Monday	Tuesday	Tuesday	Wednesday
Tuesday	Tuesday	Wednesday	Wednesday	Thursday
Wednesday	Wednesday	Thursday	Thursday	Friday
Thursday	Thursday	Friday	Sunday	Monday
Friday	Friday	Monday	Monday	Tuesday

- 3. How many manufacturers are producing vaccine?**
Five manufacturers are producing vaccine for the U.S.: Sanofi Pasteur, Novartis, GSK, Medimmune, and CSL.
- 4. (REVISED Sept. 10, 2009)**
In what dose increments will H1N1 vaccine be shipped?
Vaccine shipments will be in increments of 100 doses per formulation.
- 5. (REVISED Sept. 10, 2009)**
What is the minimum H1N1 vaccine shipment size?
H1N1 vaccine shipments will be a minimum of 100 doses per formulation.
- 6. (ADDED August 10, 2009)**
How will vaccine be shipped to projects areas?
H1N1 vaccine will be distributed using a centralized distribution model. The vaccine will be shipped through McKesson Specialty, the federal contractor for regular publicly-funded vaccine distribution.
- 7. Where will vaccine be shipped?**
Vaccine will be shipped to locations designated by local health departments, tribes and state agencies.
- 8. Will project areas be able to limit the amount of vaccine they receive?**
Yes, states will be able to state what proportion of their initial and weekly allocations they wish to receive.
- 9. (REVISED Sept. 25, 2009)**
Can the number of ship-to sites currently designated by project areas in their pandemic plans be changed?
Yes, but only if it does not exceed the maximum number of ship-to sites for Oregon as determined by the CDC.
- 10. (REVISED Oct. 20, 2009)**
Will vaccine be in multi-dose vials?

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The majority of vaccine will be in multi-dose vials, the remainder in single dose vials or nasal sprayers.

11. **Will LHDs need to work with local retail pharmacies individually to administer H1N1 vaccine, or can this be done at the corporate or regional level?**
OIP contacted the larger pharmacy chains' regional offices to request which of their locations (by county) could be available to administer H1N1 vaccine. This information was shared with affected LHDs.
12. **(REVISED Oct. 20, 2009)**
Can partner providers select the type of vaccine they prefer?
This determination will be made by each agency (Tribal, LHD, State Agency).
13. **(REVISED Oct. 20, 2009)**
Will LHDs need to partner with hospitals in order to supply them with H1N1 vaccine for their staff?
Partnering with the hospital (see Option 2 in Oregon Immunization Program – H1N1 Vaccine Distribution Options) will be an excellent opportunity to ensure that healthcare workers are vaccinated, but ultimately this determination will be made by the LHD.
14. **(REVISED Sept. 25, 2009)**
Can the OIP estimate the amount of H1N1 vaccine each LHD will initially receive?
Revised estimates for target populations by tribes, LHDs, and state agencies were distributed on Sept. 24, 2009

VACCINE ALLOCATION

15. **How will vaccine be allocated among states?**
Vaccine will be allocated to each state in proportion to its population (pro rata). Estimated allocations under the different planning scenarios have been sent to each project area.
16. **(REVISED Oct. 20, 2009)**
Will there be a separate allocation for active duty Department of Defense (DoD)?
Yes, there will be a separate allocation at the national level for active duty DoD. It is not included in the project area allocations. Civilian employees and active duty dependents will receive their vaccine through public and private providers.
17. **Will there be a separate allocation for DoD dependants, retirees, and civilian employees?**
There is no separate allocation for these groups. Military facilities may be willing to vaccinate these groups, but will need to be allocated vaccine for these populations by the project areas.
18. **(REVISED July 31, 2009)**
Will there be a separate vaccine allocation for Indian Health Service (IHS)-served populations and other tribal communities?
There will be no separate allocation at the *national* level. Oregon will provide separate allocations for tribal provider sites.
19. **(ADDED August 5, 2009)**
How will tribal sites receive their vaccine allocations, directly or through the LHD?
Tribal provider sites will have their own vaccine allocations. OIP urges tribal sites to work closely with their LHDs to coordinate vaccination efforts.
20. **(Revised Sept. 10, 2009)**
There are a number of complicated issues regarding tribal members who live off-reservation and non-tribal people living on reservation and how they should be accounted for in target group prioritization. How will this be addressed?
Tribal clinic priority group estimates have been calculated by the Northwest Portland Area Indian Health Board (NWPaiHB). We urge LHDs and tribal sites to work closely to coordinate regarding these issues.
21. **(ADDED August 5, 2009)**

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What is the distinction between partnering and subcontracting?

In a contract scenario (ex.: mass vaccinators) the LHD pays the contractor to conduct vaccination services. With a partner scenario the LHD shares its vaccine allocation and authorizes the partner agency receive vaccine and administer it directly, but no payment is exchanged between an LHD and partner.

22. (REVISED Oct. 20, 2009)

What is the process for LHDs gathering information on provider sites in their jurisdictions and providers' registration?

LHDs placed the contact and locating information for each site that will provide H1N1 vaccine in their jurisdiction in an Excel spreadsheet and sent it to the OIP. Once OIP had this information, the selected providers could register online. Agencies can add new providers throughout the season.

23. (REVISED Oct. 20, 2009)

How should LHDs work with multi-county chain pharmacy and health system sites that can provide H1N1 vaccine in their jurisdictions?

The OIP gathered a list of the sites from the corporate office for each company and health system from a primary H1N1 contact at each company. Site and corporate primary contact information was sent to the appropriate LHDs. The LHDs determined which sites would administer vaccine and communicated this to the corporate primary contact. Once this was done and the LHD has submitted their provider spreadsheet, each site registered online.

24. (REVISED Oct. 20, 2009)

Under Option 2 of the Oregon H1N1 Vaccine Distribution Plan, if LHD projections for vaccine allocation between participating clinics prove incorrect, can LHDs redistribute vaccine between participating clinics?

LHDs may redistribute vaccine without prior OIP approval in their jurisdiction. Each LHD could choose whether to give OIP a maximum dose percentage per provider, or each LHD could grant pre-approval of each provider order.

25. (ADDED August 5, 2009)

If individuals seek medications out-of-county, will the LHD then relinquish vaccine back to the state to give another county with increased demand? Will the OIP serve as vaccine broker?

There is no residency requirement to receive H1N1 vaccine, as with other vaccines. The OIP will broker vaccine should the need arise.

ANCILLARY SUPPLIES

26. (REVISED Sept. 23, 2009)

Will syringes and needles be provided with vaccine?

HHS will provide needles, syringes, sharps containers and alcohol swabs. All syringes will have safety needles. Please see the appendix for more information.

27. (REVISED August 26, 2009)

How will ancillary supplies be distributed?

Ancillary supplies will be distributed to the same sites to which vaccine is shipped. Supplies will be shipped separately from vaccine.

VACCINE ADMINISTRATION

28. (REVISED Sept. 25, 2009)

Will two doses of vaccine be required?

For children aged 9 years and under, yes. Those 10 and over will receive one dose.

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29. **(REVISED Oct. 20, 2009)**
What will be the recommended interval between the first and second dose?
Approximately 28 days, but providers should consult the vaccine package insert.
30. **(REVISED August 13, 2009)**
Will it be necessary for the first and second dose to be the same product?
Ideally, first and second doses would be from the same product. However, practical considerations make this difficult to implement. Planners should assume they will be interchangeable.
31. **(ADDED August 13, 2009)**
How much Thimerosal-free vaccine will be available?
It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women.
32. **(ADDED August 13, 2009)**
Will there be federal requirements to recall persons for their second dose, if a second dose is needed?
There will be no federal requirement to send out recall notices. Providing information on second dose at the time of the first dose, as well as using the media to disseminate this message will be the primary means of educating persons about who needs a second dose administered.
33. **(REVISED October 20, 2009)**
Will vaccine be adjuvanted?
No. However, adjuvant needles/syringe mixing units were included in the ancillary supply kits **as a precaution** when the kit planning occurred (10 units per kit of 100 needles / syringes). Steps are being taken to no longer include adjuvant needles/syringe mixing units in future packaged ancillary supply kits however; providers are receiving, and will continue to receive these units in the kits until the initial inventory is depleted. These items were included as a precaution, and their use is not anticipated.
34. **(REVISED Sept. 25, 2009)**
Will the vaccine be administered under EUA (Emergency Use Authorization), and if so, what are the implications?
Now that the H1N1 vaccines are FDA-approved, EUA will not apply.
35. **(REVISED Oct. 20, 2009)**
Will vaccination cards be designed and distributed at the state and local level or will they come from CDC?
Cards go out with ancillary supply shipments.
36. **(REVISED Oct. 20, 2009)**
How will providers get H1N1 Vaccine Information Statements (VIS)?
For public clinics, the OIP will provide them. For private providers, the provider kit at <http://www.oregon.gov/DHS/ph/acd/flu/h1n1/flu-subcommittee.shtml> contains a camera-ready electronic version. Translated versions are available at the following websites:
'Inactivated' 2009 H1N1 Influenza Vaccine VIS: http://www.immunize.org/vis/vis_h1n1inactive.asp
'LAIV' 2009 H1N1 Influenza Vaccine VIS: http://www.immunize.org/vis/vis_h1n1live.asp
37. **(REVISED October 26, 2009)**
What are the CPT codes for H1N1?
Diagnosis code: 488.1 (Diagnosis of H1N1)
V code: v04.81 good for seasonal or other flu vaccine.
CPT:
 - 90663 H1N1 vaccine (all types)
 - 90470 H1N1 administration (IM, intranasal), including counseling when performed. (Use for Medicaid)
 - G9142 Influenza A (H1N1) immunization administration (includes physician counseling the patient/family) ("G" codes are used for Medicare)

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- G9141 Influenza A (H1N1) vaccine, any route of administration (code for vaccine itself)--would be \$0 billed, since this is federally supplied
- G9142 for Medicare/Medicaid dual eligibles when billing Oregon Health Plan.

CVX codes, by vaccine type:

125	Novel Influenza-H1N1-09, nasal	Novel Influenza-H1N1-09, live virus for nasal administration
126	Novel influenza-H1N1-09, preservative-free	Novel influenza-H1N1-09, preservative-free, injectible
127	Novel influenza-H1N1-09	Novel influenza-H1N1-09, injectible
128 ⁹	Novel influenza-H1N1-09, all formulations	Novel influenza-H1N1-09, all formulations

⁹This code is used whenever the actual formulation is not determined or when aggregating all Novel H1N1 Influenza-09 immunizations for reporting to CRA. It should not be used for seasonal influenza vaccine that is not otherwise specified.

38. (ADDED September 8, 2009)

Will we be able to administer both the seasonal and H1N1 influenza vaccines at the same visit?

You can in most cases. See the points below:

- You can administer both the inactivated seasonal and the inactivated H1N1 influenza vaccines at the same visit (using separate syringes and sites) or at any time before or after each other.
- You can administer the inactivated seasonal and live H1N1 influenza vaccines together or at any time before or after each other.
- You can administer the live seasonal and inactivated H1N1 influenza vaccines together or at any time before or after each other.
- Administering both the live attenuated seasonal and the live attenuated H1N1 influenza vaccines at the same visit is NOT recommended because of concerns about competition between the two vaccine viruses. If you have only live vaccines for both seasonal and H1N1 influenza available, you should separate the doses of the two live vaccines by at least 4 weeks.

This graphic may provide a more simple guide:

Administering live attenuated seasonal and live attenuated H1N1 influenza vaccines together		
	Inactivated H1N1	Live H1N1
Inactivated Seasonal	Yes	Yes
Live Seasonal	Yes	NO

39. (ADDED September 8, 2009)

In anticipation of H1N1 monovalent vaccine arriving later this fall, CDC recommends that we begin vaccinating with seasonal influenza vaccine now. Does protection from seasonal influenza vaccine decline or wane within 3 or 4 months of vaccination? Should I wait until October or November to vaccinate my elderly or medically frail patients?

CDC recommends that seasonal influenza vaccine be administered to all age groups as soon as it becomes available. Antibody to seasonal inactivated influenza vaccine declines in the months following vaccination. However, antibody level at a point several months after vaccination does not necessarily correlate with clinical vaccine effectiveness. There are no studies that compare vaccine effectiveness according to the month when the vaccination was given. The authors of a recent review on antibody declines among the elderly after vaccination reported, "In conclusion, we found no compelling evidence for more rapid decline of the influenza vaccine-induced antibody response in the elderly, compared with young adults, or evidence that seroprotection is lost at 4 months if it has been initially achieved after immunization." (see Skowronski et al., Rapid Decline of Influenza Vaccine-Induced Antibody in the Elderly: Is It Real, or Is It Relevant? Journal of Infectious Diseases 2008; 197:490-502). In addition, there is a lack of evidence for late season outbreaks

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among vaccinated persons that can be attributed to waning immunity.

VACCINE STORAGE AND HANDLING

40. (ADDED August 6, 2009)

What are the storage and handling requirements for H1N1 vaccine?

From Oregon's H1N1 Vaccine Provider Agreement:

- Store and handle the vaccine in accordance with the package insert provided with the vaccine. Refrigerators used for H1N1 vaccine must be stored as follows:
 - Units must not be used for anything except pharmaceuticals,
 - Units must be equipped with a commercial grade thermometer.
 - Units must not be dormitory style refrigerators.
 - Temperatures must be read and logged at least once daily for each refrigerator unit.

PRIORITY GROUPS

41. (REVISED Oct. 20, 2009)

When will a decision be made about priority groups for H1N1 vaccine?

The Advisory Committee on Immunization Practices (ACIP) July 29 recommendations for groups to receive H1N1 vaccine are:

- **Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated;
- **Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants less than 6 months old might help protect infants by “cocooning” them from the virus;
- **Healthcare and emergency medical services personnel** because infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;
 - **Expanded information from ACIP's recommendations published on August 21:** “Health-care personnel (HCP) include all paid and unpaid persons working in health-care settings who have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, maintenance, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP. The recommendations in this report apply to HCP in acute-care hospitals, nursing homes, skilled nursing facilities, physicians' offices, urgent care centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Emergency medical services personnel might include persons in an occupation (e.g., emergency medical technicians and fire fighters) who provide emergency medical care as part of their normal job duties.”
 - **Further description:**

All paid and unpaid persons working in health care settings which have the potential for exposure to patients with influenza, infectious materials, including body substances, contaminated medical supplies and equipment, or contaminated environmental surfaces. Including caregivers in foster homes with medically fragile children and caregivers in residential treatment facilities such as adult foster homes, in home personal care providers and outpatient treatment facilities. Settings include acute-care hospitals, nursing homes,

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skilled nursing facilities, physician's offices, urgent care centers, home health care and outpatient clinics. Does not include Child Welfare residential facilities or foster homes for non-medically fragile children.

- **All people from 6 months through 24 years of age**
 - **Children from 6 months through 18 years of age** because we have seen many cases of novel H1N1 influenza in children and they are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and
 - **Young adults 19 through 24 years of age** because we have seen many cases of novel H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and,
 - **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza**
 - **Expanded information from ACIP's recommendations published on August 21** – “Chronic medical conditions that confer a higher risk for influenza-related complications include chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic disorders (including diabetes mellitus) or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)”

Specific to Oregon

- National Guard, front-line law enforcement and corrections officers- State and local law enforcement with reoccurring contact with public and the Oregon State Public Health Laboratory.

42. (REVISED Oct. 20, 2009)

Will there be requirements regarding documentation of priority group membership?

There are no requirements for documenting priority group membership. OIP has drafted an optional self-declaration form.

43. (REVISED August 10, 2009)

How do providers address the possibility of individuals wanting vaccine and fraudulently representing themselves as having a high-risk condition?

Self-declaration of a high-risk condition is acceptable. LHDs and other providers have the option of having people sign self-declaration forms. The OIP has developed a draft form for provider use.

44. (ADDED August 5, 2009)

How should LHDs address changes in focus on different priority groups as the H1N1 vaccination campaign continues?

Each LHD will be responsible for working with local partners to plan H1N1 vaccine distribution and administration. The Oregon Immunization Program (OIP) developed two distribution options (*Oregon Immunization Program – H1N1 Vaccine Distribution Options*) which are available to LHDs to use as guidance.

45. (ADDED August 5, 2009)

Will LHDs need another set of assumptions/priorities for immunization during increased disease/demand in the community?

We will follow the Advisory Committee for Immunization Practices (ACIP) recommendations regarding target populations. Should the recommendations change, we will share that information as soon as possible.

46. (REVISED Oct. 20, 2009)

Can you give an H1N1 shot to someone ill with the disease or would it be better to give a shot 21-28 days later (following initial illness)?

Please consult the vaccine package insert.

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47. (ADDED August 5, 2009)

How do we protect students with chronic medical conditions prior to the availability of H1N1 vaccine?

These children's families and schools should also practice non-medical countermeasures such as hand-washing, covering coughs, and staying home when ill. These children will need to receive seasonal influenza vaccine as soon as it's available.

48. (REVISED Sept. 25, 2009)

Besides health care workers, are there other key resource/critical infrastructure personnel that should receive H1N1 vaccine?

National guard, front-line law enforcement and corrections officers should receive H1N1 vaccine

49. (REVISED Sept. 25, 2009)

How will LHDs determine how to expand a priority group?

Oregon providers are expected to follow ACIP recommendations and Oregon Division of Public Health regarding priority groups

DOSES ADMINISTERED MONITORING

50. (REVISED Sept. 25, 2009)

For school vaccination clinics, will parents or guardians be asked to complete and sign the same vaccine record form as used for regularly recommended vaccines for children < 15 years of age?

OIP recommends following regular procedure regarding vaccine administration record (VAR) use. OIP has made an H1N1 VAR available to providers.

PNEUMOCOCCAL VACCINATION

51. Are there any changes in recommendations for pneumococcal vaccines?

The ACIP recommends that persons recommended for pneumococcal vaccine receive it in light of the potential for increased risk of pneumococcal disease associated with influenza. There are at present no recommendations to give pneumococcal vaccine to groups for whom it is not currently recommended. ACIP will revisit this question over the summer as epidemiologic data from the Southern hemisphere influenza season and from the U.S. become available.

PRIVATE SECTOR ADMINISTRATION

52. (REVISED Oct. 20, 2009)

Will insurance plans reimburse private providers for administration?

Please see the Oregon Medical Association's website for information on the larger health plans at <http://www.theoma.org/Page.asp?NavID=791>

INFECTION CONTROL

53. (ADDED October 19, 2009)

What is the guidance for preventing transmission of 2009 H1N1 influenza in healthcare facilities?

CDC's updated interim guidance that applies uniquely to the special circumstances of the current 2009 H1N1 pandemic and will be updated as necessary as new information becomes available throughout the course of this influenza season. It is posted at: http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm.

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VACCINE SAFETY/ADVERSE EVENTS

54. (ADDED October 19, 2009)

How safe is the vaccine?

The 2009 H1N1 influenza vaccines have not been associated with any unexpected adverse. In addition, the 2009-2010 seasonal influenza vaccines also have not been associated with any unexpected adverse events (or possible side effects).

55. (ADDED October 19, 2009)

How should adverse events be reported?

Public providers may report through the OIP to the Vaccine Adverse Event Reporting System (VAERS), as they have done previously with other vaccine adverse events. For H1N1 *only*, public clinics have the option of reporting directly to VAERS. Private providers may report directly to VAERS. CDC jointly operates VAERS with the Food and Drug Administration (FDA). A reporting form is available for download at <http://www.oregon.gov/DHS/ph/imm/docs/vaersformImmiaddress.pdf>

56. (ADDED October 20, 2009)

Who can report to VAERS?

Providers, manufacturers, people who were vaccinated or their caregivers. (Please note: VAERS cannot determine cause-and-effect. The report of an adverse event to VAERS does not confirm that a vaccine caused the event. It only confirms that the event occurred sometime after vaccine receipt. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report.)

VACCINE BILLING

57. (ADDED October 20, 2009)

What is the definition of a "public health clinic"?

For the purpose of this document, a "public health clinic" is a clinic that is conducted by, or on behalf of, a state or local health jurisdiction and that receives Public Health Emergency Response (PHER) implementation funds to administer H1N1 influenza vaccine. This may include a commercial community vaccinator (CCV) or other private provider that has a service contract or similar agreement with the public health entity. Vaccine administration could occur in a variety of settings such as hospitals, provider offices, schools, clinics, and any other setting where vaccine can be appropriately given.

The provider agreement that each H1N1 vaccine provider must sign in order to receive an allocation of H1N1 vaccine does not constitute an agreement for the provider to administer H1N1 vaccine on behalf of the public health department. Providers must enter into separate agreements with state or local jurisdictions in order to provide vaccine on behalf of those jurisdictions. "Public health clinics" are only those clinics in which such agreements have been entered into and for which providers are paid, in whole or in part, with PHER funds.

58. (ADDED October 20, 2009)

Can Medicare cover the administration of the H1N1 vaccine given to Medicare beneficiaries, when non-Medicare patients who demonstrate no ability to pay receive the vaccine free of charge?

Yes. Although Medicare payment is generally prohibited when a service is paid for by another governmental entity, in light of the H1N1 influenza pandemic it has been determined that these administration services meet one of the exceptions to the payment exclusion concerning governmental entities. All other Medicare rules will still apply to any claim submitted for vaccine administration.

59. (ADDED October 20, 2009)

May providers bill private third-party payers or insurers for H1N1 vaccine administration if the level of reimbursement provided by the private insurer is greater than the regional Medicare vaccine administration rate?

Yes. The H1N1 provider agreement states that the provider "may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare vaccine administration fee." This means that the provider may not request out-of-pocket payment from a patient that is greater than the amount that Medicare reimburses for influenza

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vaccine administration in that jurisdiction. "Charge" refers to collecting an out-of-pocket payment from the patient.

However, the provider agreement does not dictate the level of reimbursement for vaccine administration that is provided by an insurance plan or payer. Providers should bill payers and insurance plans at their regular agreed-upon rates, and may accept whatever level of reimbursement is provided by a plan or payer for H1N1 vaccine administration.

60. Will Medicaid pay the administration fee for their covered clients?

Yes, in both clinics and pharmacies. A provider memo with billing and coding instructions has been distributed.

61. (REVISED October 26, 2009)

Medicaid's long-standing policy requires that legally liable third parties be billed for the services for which Medicaid is to be billed. For H1N1 vaccine administration, how will the free care policy be applied?

Providers without systems capabilities to bill legally liable third party private insurers may bill Medicaid for services provided to Medicaid eligible individuals.

This is specific to H1N1 vaccinations and only applies to providers that vaccinate Medicaid-eligible patients. This does not alleviate providers' responsibilities for collecting TPL during the normal course of business.

(Agencies should be aware that if a future audit revealed the clinic had capacity to bill private insurance, did not bill private insurance, but did bill Medicaid-- the clinic would be in violation of the Centers for Medicaid/Medicare Services' free services provision.)

62. (ADDED October 20, 2009)

May providers charge patients a co-pay or other out-of-pocket charge in public health clinics or mass vaccination sites/clinics conducted on behalf of a public health entity?

Public health clinics and mass vaccination sites/clinics conducted on behalf of a public health entity should not charge patients a co-pay or other out-of-pocket charge, even if the patient's health plan includes a co-pay for vaccine administration. Many public and private health plans will not require co-pays or other cost sharing for H1N1 vaccine administration.

63. (ADDED October 20, 2009)

May providers bill third party payers or insurers in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of, a public health jurisdiction?

Providers may bill third party payers or insurers in public health clinics or mass vaccination sites/clinics conducted by, or on behalf of, a public health entity. Public health jurisdictions that do not currently have a billing system in place should not use PHER funds to develop billing systems.

64. (ADDED October 20, 2009)

If a provider receives PHER funds to conduct a public health clinic, can that provider charge any patients for administration of H1N1 vaccine at any time?

Providers should not charge any patient who visits a clinic conducted on behalf of public health that is paid for entirely, or in part, by PHER funds. If the PHER funds are only for one clinic on a single day, the provider may charge on any other day, or for patients that are not seen at the PHER-funded clinic. For example, if there is a clinic at the provider site that is paid for with PHER funds, but patients are also being seen one-on-one at that site, the provider may charge for the one-on-one visits as long as those visits are not being paid for with PHER monies, but may not charge anyone seen in the public health clinic.

65. (ADDED October 20, 2009)

If PHER funds are used to pay the salary of a health department employee, may that employee assist with vaccination clinics in which patients are charged for administration of vaccine?

Yes. Employees hired with PHER dollars may assist with H1N1 vaccination in any setting.

66. (ADDED October 20, 2009)

If a provider receives PHER funds to conduct a public health clinic, can patients with insurance

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Yes. PHER funds are intended to cover administration costs of vaccination regardless of insurance status. Providers may bill third-party payers or insurance plans in clinics conducted on behalf of public health if desired. Providers who receive PHER funds and who also bill insurance should ensure that duplicate payments are not received for the same service provided to the same patient.

67. (ADDED October 20, 2009)

May providers bill health insurance plans that require a charge of \$0.01 for the vaccine in order to process claims, even though it is not permissible to charge for H1N1 vaccine?

Yes. It is understood that billing software is complex and may require submission of a nominal fee for the vaccine in order to process claims. Providers may bill a charge of \$.01 with the vaccine code. However, providers may not bill patients any fee for the vaccine, and should inform patients about the \$.01 fee and that it may appear in their insurance statement.

68. (ADDED October 20, 2009)

Are federally qualified health centers (FQHCs) or rural health clinics (RHCs) permitted to bill third party payers or insurers for administration of H1N1 vaccine?

Yes. FQHCs and RHCs should follow the same rules as other providers. If the FQHC or RHC has received PHER funds from a state or local health jurisdiction, that clinic may bill third-party payers or insurers for H1N1 vaccine administration, but may not collect copayments or out of pocket charges from patients, even on a sliding fee scale. If the FQHC or RHC has not received PHER funds to support H1N1 vaccine administration, it may bill or charge patients for vaccine administration costs (but not for the vaccine itself) as it usually does, when permitted by the insurer or third party payer. Like other public and private providers, FQHCs and RHCs providing H1N1 flu vaccine must abide by the terms of the H1N1 provider agreement.

69. (REVISED October 26, 2009)

May voluntary donations be collected from patients in public health clinics or mass vaccination sites/clinics conducted on behalf of a public health entity?

Agencies may solicit fee donations from clients if the following guidelines are followed:

- Client may not be solicited or informed until after immunization services are rendered.
- Advertisement and publicity may not include solicitations for donations.
- Solicitation is to be by provision of a pre-addressed envelope for clients to mail check or money order directly to the agency.
- Under no circumstance will agency or Contractor receive donations directly from clients, only donations mailed to agency may be accepted.
- Solicitation must clearly state that it is an optional donation. Fee, Administration Fee, Charge, or similar verbiage are not to be used.
- A mass vaccination contracting with an agency to hold a public health vaccination clinic will not accept or solicit donations from clients, but may provide the pre-printed envelopes for the agency whose service area contains the clinic.

ADDITIONAL QUESTIONS

70. (ADDED August 5, 2009)

How should schools address absenteeism of students with chronic health conditions (due to parental concerns) prior to the availability of H1N1 vaccine?

Community mitigation is key at state and local levels.

71. If LHDs activate their volunteer management systems for PODS or clinics, will volunteers be covered when there is no declaration of emergency? Or will LHDs has to assume liability?

Under current law, emergency volunteers would not have liability coverage unless there was a Governor declared emergency. A Governor's declaration is not required if a volunteer is a retired physician and meets the requirements in ORS 30.302, or a volunteer is a health care provider working without compensation and meets the requirements in ORS 677.340.

However, there is a current PREP Act declaration, issued by the HHS Secretary on June 15, 2009, that provides immunity from tort liability, as long as someone is acting in accordance with the declaration. The

This version supersedes previous versions. Please discard previous versions.

text of the amendment can be found at: <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>

The declaration covers program planners and qualified persons. A qualified person is "a licensed individual who is authorized to prescribe, administer, or dispense the countermeasure under the law of the State in which such Covered Countermeasure was prescribed, administered or dispensed."

Please note that Tribes, LHDs, and state agencies should seek their own legal advice in this matter.