

Moderator: Bill Finerfrock
October 21, 2009
1:00 pm CT

Operator: Good day everyone, and welcome to today's technical assistance national conference call on H1N1 flu. Today's call is being recorded.

At this time for opening remarks and introductions, I would like to turn the call over to Bill Finerfrock. Please go ahead, sir.

Bill Finerfrock: Thank you, operator and I want to welcome all of our callers, as well as our participants for today's presentation on the H1N1 flu availability of the vaccine and payment information for rural health clinics.

My name is Bill Finerfrock, and I'm the Executive Director of the National Association of Rural Health Clinics. And I will be the moderator for today's call.

Our presenters today are Dr. Suchita Lorick, who is a Medical Officer for the Centers for Disease Control and Prevention H1N1 vaccine implementation team. Megan Lindley, who is an Epidemiologist with the National Center for Immunization and Respiratory Diseases with the Centers for Disease Control and Prevention. And Captain Corinne Axelrod, who is a Health Insurance Specialist for the Centers for Medicare and Medicaid Services, and there will be some others from CMS who will be joining Captain Axelrod during her portion of the presentation.

We're here today to talk about the H1N1 vaccine, and various issues surrounding that. Our call is scheduled to last for approximately 1 hour, first 45 minutes will be devoted to the presenter's remarks, and the last 15 minutes or so will be reserved for questions and answers.

The call, as you all hopefully know, is sponsored by the Health Resources and Services Administration's, Office of Rural Health Policy, and they have also asked me to let you know that they have some H1N1 resources available on their Web site if you want to go to www.hrsa.gov/h1n1, and you can get some information that the Health Resources and Services Administration has made available for rural providers.

This call series is done in conjunction with the National Association of Rural Health Clinics, and the purpose is to provide RHC staff with valuable technical assistance on issues of interest to the RHC community.

Today's call is the 32nd in the series which began in 2004, and during that time, over 6,700 people have participated on the bimonthly RHC teleconferences. As you all know, there is no charge for this project, and we encourage you to refer others who might benefit from this series to sign up to receive announcements regarding call dates, topics and presentations.

Information can be obtained by going to www.ruralhealth.hrsa.gov/rhc. There will be questions and answer time at the end, and also an opportunity to have a little more dialog with our speakers.

You should have, or hopefully did receive copies of the slides that some of our speakers made available prior to the call, I encourage you to follow along on those slides with the speaker's remarks. In addition, a transcript and a recording of today's call will be made available after the call.

At this time, I'd like to turn the presentation over to Dr. Lorick, who's going to talk to us about some of the vaccine implementation issues as part of her responsibilities at CDC, and has some very important information for you. Dr. Lorick, the floor is yours.

Dr. Suchita Lorick: Great, thank you so much, Bill.

So like Bill said, I'll just give you a brief overview of the H1N1 vaccine implementation plans, and start with the second slide, which is the outline slide, I'm going to go over the ACIP recommendations for this vaccine. I'll briefly talk about clinical trials and licensure, talk about safety monitoring, vaccine logistics, and I have financing up there, but Megan Lindley will be covering that. So that won't be part of my talk.

OK, next slide. So the ACIP is the Advisory Committee on Immunization Practices, and they have recommended that when vaccine first becomes available, which was about 2 weeks ago now, we want to try to vaccinate as many people as possible in five initial target groups, which is about 159 million, which is about half the U.S. population. So these five initial target groups are pregnant women, household and caregiver contacts of children younger than 6 months of age, and this would include parents, siblings, daycare providers, health care and emergency medical services personnel, persons 6 months through 24 years of age, and persons 25 through 64 years of age who have medical conditions that put them at a higher risk for influenza complications.

And just so you have an idea for seasonal influenza vaccine coverage, or uptake, among these target groups, it's about 20 to 50% over the last few years.

And then in the case that vaccine was in a shorter supply than the demand, the ACIP also came up with a list of priority groups within the five initial target groups that I just discussed. So the next slide provides those five priority groups, so it includes pregnant women, which is the same as the target group. It includes household and caregiver contacts, which is also the same as the previous group, and then it includes a subset of health care and emergency medical services personnel, those with direct patient contact. And then it also includes a subset of kids 6 months through 4 years of age, so all kids in those age categories. And then children and adolescents that are 5 through 18 years who have medical conditions that put them at higher risk for complications. So this list of priority groups might be used by some states and locals when in the initial period as vaccine is coming out, and the supply doesn't keep up with the demand in the community.

So the next slide is also from the ACIP recommendations, and so they say that once the five initial target groups have been – once the demand is met in those target groups, we want to move on to persons 25 through 64 years of age, and then after those people have been offered vaccine, we want to move on to persons 65 and older. The order of these categories, the target groups, priority groups and these final groups are based on the epidemiology of what we're seeing with the illness, because as you folks might have heard about, younger people are getting more affected than older folks.

And then lastly, ACIP wanted to make sure that decisions about which groups should be vaccinated, for example, if providers should focus on the smaller priority groups, they should do that in consultation with their local public health authorities to make sure that vaccine is equitably being distributed.

And the next slide is just a graphical depiction of the groups and order ACIP is recommending.

OK and the next slide is a little bit more about the practical use of the vaccine. In the initial days, we were thinking that most people would need two doses, but based on information from the clinical trials that have been conducted by NIH and the manufacturers, we now know that children 6 months through 9 years of age should receive two doses of H1N1 vaccine separated by 4 weeks and persons 10 and older should get one dose, so that's the current recommendation.

And as far as administering H1N1 vaccine with other vaccines, inactivated, or the injectable H1N1 vaccine or shot can be given with the seasonal influenza vaccine, either the live one, which goes in the nose, or the shot, or any other (live or inactivated) vaccines. So if you're – if you have the inactivated shot for H1N1, you can give it at the same visit with any other vaccine, just make sure that the administration site is different if you're giving it with another injectable vaccine.

And as far as administering live 2009 H1N1 vaccine and seasonal live vaccine (LAIV), this is not recommended, because there's not enough studies and the thought is perhaps that if you're giving both

of them in the nose at the same time, you might not develop an adequate immunologic response to one or both of them, so that is not recommended, so that's one combination that should not be used.

And then as far as the licensure is concerned, manufacturers submitted a supplement to their seasonal influenza biologic license as a strain change. So each year in the U.S., for seasonal influenza vaccine, the manufacturers submit a strain change supplement, and the same method was used for 2009 H1N1 vaccine this year.

And the next slide, I'm going to cover briefly vaccine safety monitoring activities. So the primary objective of the safety monitoring response includes identifying clinically significant adverse events following receipt of vaccine in a timely manner, rapidly evaluating serious adverse events following receipt of vaccine, and determining their public health importance, evaluating if there is a risk for Guillan-Barre Syndrome associated with receipt of this vaccine and very importantly, communicate vaccine safety information in a clear and transparent manner to health care providers, public health officials and the public.

And next slide, safety monitoring will be done primarily through VAERS, which is the Vaccine Adverse Event Reporting System, and that's going to be the front line that we're going to use for monitoring the safety of this vaccine. And if you want more information, we have that available on the CDC Web site to learn about VAERS, or access VAERS to report a potential adverse event.

Next slide is – I think I'm going to skip this one. But it lists out five, and I know there's a couple of additional items that are not included here that have been added, but it goes into all the different methods that we're going to be using besides VAERS to actively monitor the safety of this vaccine. So if there are any questions later, I can try to address those, but I'll just skip this slide for now.

So the next slide is about the vaccine products. Vaccines have been developed for 2009 H1N1 by five manufacturers, that's CSL, GSK, MedImmune, Novartis and Sanofi. GSK is one manufacturer that is not

currently licensed, so currently there's four vaccines out for 2009 H1N1. GSK is in the process of getting their license.

There is inactivated and live intranasal vaccine available for 2009 H1N1. Although numerous epidemiologic studies have shown that thimerosal is not associated with adverse health effects. Because there is some preference out there for thimerosal-free vaccine, there is some available for groups like pregnant women and young children. Storage of this vaccine is identical to seasonal vaccine.

Along with the vaccine, federal government has purchased and is providing ancillary supplies, and these supplies include syringes, needles, sharps containers, alcohol swabs and vaccine record cards.

Next slide is titled purchase and allocation. So vaccine and ancillary supplies have been procured and purchased by the U.S. government, and they're being made available at no cost to states and providers. And they're allocated to states proportional to population. So each day and each week vaccine becomes available for ordering for states, and it's allocated based on that state's population.

Next slide is about influenza vaccine supply, I listed the link there, and the slide that follows it, slide 15, is just a screen shot of what we have up at the CDC Web site. So each week, the plan is that the CDC will report on its Web site and through our media brief the number of doses that have been allocated, which means the number of doses available for ordering for states, the number of doses that have been ordered by states, the number of doses that have been shipped to states and then a state by state listing of the number of doses that have been shipped.

So as you can see as of last week, about a little more than 11 million doses had been allocated, close to 8 million had been ordered, and close to 6 million had been shipped out.

The next slide, slide 16, is about vaccine distribution. Vaccine – both vaccine and ancillary supplies are being sent from the manufacturers to a central distributor, and the central distributor then ships it out to

state-designated locations. So this could include a local health department, a provider's office, a workplace, a school, or another site where the state will plan to redistribute the vaccine from if they have that need.

The next slide, slide 17 state and local public health have been planning large scale clinics, including school located clinics, and some have – we've heard that some have already started some of this. But because national availability of vaccine is just starting out, many of these large scale events haven't occurred yet, but we have heard that some are already starting.

And then state and locals have also been recruiting providers who are going to provide vaccine in a variety of settings.

The next slide, slide 18, as far as providers are concerned, like I said, state and local public health will be designating who can serve as a vaccine provider, and then each provider will enter into an agreement with the state and local public health department to receive this vaccine.

State and locals have developed registration systems to meet their needs, and for providers who are out there who are interested in learning about how to become a provider, at the CDC's 2009 H1N1 website, we have tried to consolidate this information, and at the link that's available at the bottom of slide 18, you can go and click on your state and figure out where you can look to find out if you can become a provider.

Next slide, slide 19 is just some of the links* that offer you a variety of resources, and if there are any specific questions, we can try to address those later. And slide 20 is just a footnote about what is the definition of health care personnel. By the length of it, you can see that it's very broad, so we want anybody who can potentially be exposed to infectious material or infectious persons to get vaccinated as soon as possible. And then the second footnote lists the chronic medical conditions that I mentioned in the target group population.

*Main CDC vaccination link: <http://www.cdc.gov/h1n1flu/vaccination/>

For healthcare providers and healthcare facilities interested in providing H1N1 vaccine:

<http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm>

<http://www.cdc.gov/H1N1flu/vaccination/decisiontree.htm>

<http://www.cdc.gov/H1N1flu/vaccination/pediatricpatients.htm>

For vaccine safety: http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety.htm

Clinical Q and As: http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm

And I think that's it. I'm going to turn it over now to Megan Lindley to go into the financing and billing.

Megan Lindley: Thanks, Suchita. So I am going to give a very brief overview of the financing and billing related to administration of H1N1 vaccine. I'm not going to go into the specifics about how RHCs are meant to bill or report those costs, because I know that Captain Axelrod and her colleagues are going to discuss that.

So the first slide in my presentation, which is actually slide 2, has some general financing principles. As Suchita just pointed out, the vaccine and the supplies that accompany it have been purchased and provided free of charge by the federal government, so there is no financing for those, because providers are not permitted to charge for them since they've been provided for free.

And I did want to mention in a sub-note, for those of you who are used to administering pediatric vaccines, the H1N1 vaccine is not part of the Vaccines for Children program, it's been purchased by a separate authority. So the more stringent rules that you may be familiar with that apply to Vaccines for Children do not necessarily apply to H1N1 vaccine.

And although providers are not permitted to charge for the vaccine itself, and payers are not paying for the vaccine itself, a provider can charge a vaccine administration fee either to the patient who receives the vaccine, or can bill an insurance plan or another third party payer for that vaccine administration.

And the general goal of the vaccination financing efforts related to H1N1 vaccine is really to balance the need to give vaccine providers a reasonable payment for providing this service while making the vaccine affordable to any individual that wants to receive it.

The next slide, slide 3, just has a brief description of which payers are covering the H1N1 vaccine administration, and it's pretty much anyone you can think of. Medicare is covering it for their beneficiaries; the Medicaid and (CHIP) programs cover it for all eligible children in the programs, and for adults in the Medicaid mandatory coverage settings, which does include RHCs.

TRICARE and CHAMPVA programs cover the vaccine for military dependents and retirees. The Indian Health Service, Veteran's Affairs and Department of Defense are covering their populations in certain settings. And a large number of small and large private health insurance plans are also covering the vaccine, so there's good coverage out there among health care payers.

So if you go to slide 4, what happens if you don't have health insurance? So this would be for people who are under insured for this particular vaccine, or completely uninsured. So if a person without insurance coverage for H1N1 vaccine is seen in the private sector, those providers are being encouraged to vaccinate people, even if they cannot afford to pay a vaccine administration fee. If the provider's not able to do that, we're asking them to refer those patients to a public health clinic or another affiliated public health provider where they can be vaccinated free of charge.

Providers are permitted to collect an out of pocket charge up to the regional Medicare reimbursement rate for seasonal influenza vaccine administration, and that again is an effort to allow the provider to be given

a reasonable payment for the vaccine, but to cap that collection amount to make it affordable even to people who don't have health insurance.

Slide 5, the other option obviously for a person without health insurance coverage would be to be seen in the public sector. And phase three Public Health Emergency Response funding, which is called PHER funding, has been provided to CDC grantees, and the use of these funds is to support implementation of mass H1N1 vaccination campaigns, and those grantees are the 50 states, some large cities and U.S. territories. And one of the potential uses for those funds is to cover the cost of vaccine administration in public health clinics.

As a condition of receiving those funds, the PHER grantees and people who vaccinate on behalf of public health agencies are prohibited from turning away persons due to an inability to pay. So as usual, they're serving as the safety net for people who might not otherwise be able to afford to get the vaccine.

Moving on to slide 6, a very brief overview of billing for vaccine administration. There's a lot more detail about this available on the CDC Web site, and for CMS available on the CMS Web site. But there's so many nuances that it would take a long time to go into, so I'm not going to.

But generally, many of the public and private health insurance plans that are offering coverage for the H1N1 vaccine are also waiving cost sharing, that's not necessarily true, but it is true for many plans. So that's another way to reduce barriers to getting the vaccine.

There are new (CPT) and HCPCS codes that are specific to H1N1 vaccine and H1N1 vaccine administration. And these have been developed and disseminated pretty widely to facilitate billing for the vaccine administration. All providers are permitted to bill health insurance plans or other third party payers, and by all providers, I mean private providers, public health providers, whoever is giving the vaccine. However, public health departments or providers who are vaccinating on behalf of public health

are not permitted to collect any out of pocket charges, and that does include co-pays, even if the patient's health insurance plan allows for a co-pay.

And I think there'll probably be a lot of questions about am I a private provider or am I vaccinating on behalf of public health? And I would say in general, if you have not received funding from the public health departments specifically for H1N1 vaccination, then you do not need to follow the rules for public health departments. And we have told the public health departments that sharing that funding with other kinds of clinics and health centers is an option, but not a requirement, so that may be something that's happening for you, or it may not.

The final slide is links to financing information, the first one is on CDCs Web site, and it goes to a Q&A about vaccine financing, which includes more detail about which payers are covering the vaccine, and what levels of cost sharing are being required. The second link is to the billing Q&A, which has a lot of information about how providers can bill if they've also received those PHER funds, that vaccine implementation money that I mentioned earlier.

The third link is the HHS site that I think Suchita also provided, flu.gov. And then the fourth link is the main page of CMS' H1N1 site that has a lot of good information with more detail about the Medicare and Medicaid coverage and billing for the H1N1 vaccine.

So that is a very high level overview, and I'll go ahead and turn this over to Captain Corinne Axelrod to ((inaudible)) the ((inaudible)).

Captain Corinne Axelrod: Hi, this is Corinne and thank you, Bill, for organizing this call on this really timely and important topic. And thank you for inviting CMS to participate on this call.

Bill Finerfrock: Corinne, could you just hold on for one second?

Captain Corinne Axelrod: Yes.

Bill Finerfrock: I had a question, Megan, on your slide, your last one, the link on the second one there, the ((inaudible)) H1N1 vaccination state local, is that correct, V-A-C-C-I-N-G, or is that a typo?

Megan Lindley: Let me see, no doubt it's a typo, unless we've learned to spell ...

Bill Finerfrock: ... to me that it should be an E for vaccine underscore billing QA, but it just ...

Megan Lindley: Yes.

Bill Finerfrock: ... as I was looking at it, as you were going down, it struck me that that might be a typo.

Megan Lindley: It is very much a typo, yes, please we did try to spell vaccine correctly on the Web site, even though I didn't. So yes ...

Bill Finerfrock: All right, I just happened to notice. And before we get too far away, and people were wondering. So I'm sorry, Corinne, go ahead.

Captain Corinne Axelrod: Oh no, no problem, that's the advantage of not having any slides - I don't have any typos! But anyway, thank you for inviting us to be on this call.

As already mentioned, there is no reimbursement for the vaccine, because it is provided to you at no charge, and no encounter is billed in a rural health clinic if the only purpose of the visit is to get the vaccine. This is the flu, and like the seasonal flu, it's addressed through the cost report. So I have here with me Steve Raitzyk, who is also in the Center for Medicare Management, and works on the cost reports. Gertrude Saunders and I think Maria Durham are also on the call, and we're all available here for any questions afterwards.

But what I'd like to do now is turn this over to Steve, who's going to talk about how to address this on the cost report.

Steve Raitzyk: Basically we're still in the process of developing instructions and the actual cost reporting forms. The MACs (Medicare Administrative Contractors) and the regional offices and our cost reporting vendors have already been notified of how we're going to handle this on the cost report. The cost report is how the providers – it's how the providers get reimbursed for these shots.

I don't know how many people are familiar with the actual cost reporting form, this is CMS222-92. And on supplemental worksheet B-1, a current cost report shows a – that worksheet is for the computation of pneumococcal and influenza vaccine costs. And basically right now the cost report has the column for pneumococcal and a column for influenza, and we developed a cost of those shots plus the administrative costs of providing those shots, and we reimbursed the providers based on that data.

Because of the H1N1, we had to subdivide those – the influenza column into two additional columns, one is going to be just the H1N1 for just people that come in for that shot only. Since there's no cost to administer that shot, since there's no cost for the shot, the actual staff time and the administrative costs that go with that shot has to be accounted for and paid for to the providers. So we have a separate column to do that.

And there's also a separate column for people that come in and get both shots, the influenza and the H1N1 at the same time. And since the H1N1, there is no cost for that shot, we had to – and there is a cost for the influenza shot, we had to have a separate sub column for that as well.

Bill Finerfrock: I'm sorry, you're talking about the fact that there's no cost for the purchase of the vaccine as opposed to the fact that there is a cost for the administration of the vaccine?

Steve Raitzyk: Correct. And that's what we're in the process of developing these cost reporting instructions to do. Many of you know how government works, this isn't something that can be done overnight, it's got to go through a whole bunch of clearance processes. And the rules are out there to the MACs and to the regional offices, then to the vendors. The forms and the instructions have not been finalized yet. So everybody that needs to know is aware of it, the providers just need to be aware that they need to keep the cost of the influenza and H1N1 separate – the cost of administering it.

Bill Finerfrock: But we have a lot of clinics that would be on a calendar year basis, and so they're going to be coming up in the next couple of months completing their cost report for 2009. And what are they supposed to be doing with regard to the H1N1? Sounds like nothing ...

Steve Raitzyk: Nothing right now, until the instructions get out there. Right now, we're going to – because the H1N1 shots were effective I guess October 1, our instructions are going to be for cost reporting periods ending on or after 10/1/09.

Bill Finerfrock: Right, but people are getting ready to – they're going to be ending those within the next month, I mean different people, as you know are on different fiscal years for their RHC. How soon will guidance – can we expect some guidance?

Steve Raitzyk: I can't give you an exact date, I know it's in the process, hopefully sooner than later. The cost reports are not due to the – to the max until 5 months after the end of the cost reporting period. So there will be plenty of time for providers to compile this data, and actually most of them are working with cost reporting vendors, and as I previously said, the vendors are already aware of all the instructions.

Bill Finerfrock: OK.

Steve Raitzyk: And at this point, I don't think I have anymore to tell you. I – we are working on it, it's not something that's being put off. It's just not something that can be done overnight, it's going through a lot

of clearances, and – but the rules are out there, and once the cost reporting forms are approved, they'll be out there immediately after that.

Bill Finerfrock: When you say that the rules are out there, are those available to like the National Association of Rural Health Clinics?

Steve Raitzyk: I don't think so, I'll have to check on that. We disseminated it to the – to the MACs, to the ROs and to the cost reporting vendors at this point.

Captain Corinne Axelrod: Generally information is not available to the public until it's completed the clearance process, so it may not actually be available to you yet, Bill.

Bill Finerfrock: Right, and that was – I understood that. The fact, however, that you've given it to the vendors who would be a subset or a part of the public, the fact that you had given it to the vendors, that you perhaps could give it to others.

Steve Raitzyk: Well the vendors have to know, because they have to get this thing implemented, so when they do start getting the cost reports, they're all set up to provide for that.

Captain Corinne Axelrod: Why don't we follow up on that and see if it can become available to you, and as soon as it does, we'll make sure to get that out.

Steve Raitzyk: OK, thank you.

Bill Finerfrock: Go ahead, sorry, I didn't mean to interrupt; I just thought I'd get some clarification while you were still there.

Steve Raitzyk: Yes, and that's pretty much all I have at this point. There is – there – I will say that there is another – one of the things that may be holding these instructions up just a little bit is there is another change, as a lot of you know happening with the RHCs, FQHCs cost reports due to the phase-out of the outpatient mental health treatment limitations. So we're trying to do that at the same time as well, so.

Bill Finerfrock: OK. Is there anybody else from CMS that wanted to make any comments?

Captain Corinne Axelrod: No, I think we're just here and available for any questions.

Bill Finerfrock: All right, at this point, operator, why don't we go ahead and open up the phone lines, if you would give the instructions for anyone who wants to ask a question, we'll go ahead and open up the phone lines for anyone who wants to ask a question of Dr. Lorick or Megan Lindley or any of the folks from CMS.

Operator: Thank you. If you would like to ask a question at this time, please press star 1 on your telephone keypad. A voice prompt on your phone line will indicate when your line is open to ask a question. Please state your name before posing your question. Once again, that is star 1 if you have a question. We'll pause for just a moment to assemble our queue.

Bill Finerfrock: And if – when you come live, if you could also let us know where you're from, what state you're calling from just so we get a sense of the geographic or the regional distribution of where some of the questions are coming from, we would appreciate it. While the queue is – we'll go ahead and let that and then open it up. And if – I have a couple of questions that were e-mailed, if we don't cover them, I'll make sure that they get asked.

Megan Lindley: Bill, this is Megan, while we're waiting for the queue, can I just say one thing very briefly?

Bill Finerfrock: Absolutely.

Megan Lindley: I have to apologize, I misled you, I was testing the link, and actually the incorrect spelling of vaccine is correct in that ...

Bill Finerfrock: Yes.

Megan Lindley: ... if you spell it correctly, you will not get to the billing Q&A, so it should be V-A-C-C-I-N-G.

Bill Finerfrock: That makes perfect sense.

Megan Lindley: I know, doesn't it? I guess we didn't get that quite right on our Web site.

Bill Finerfrock: OK, very good. It just kind of caught my eye, and I thought, let me get this cleared up, because – all right, thank you. Operator, do we have any questions lined up?

Operator: We do. We'll take our first question.

Bill Finerfrock: Go ahead, caller, if you would identify yourself by name and where you're calling from.

(Ginger): Yes, this is (Ginger) from New Tazewell, Tennessee.

Bill Finerfrock: Go ahead, (Ginger).

(Ginger): The question we have is if someone has tested positive for the H1N1 and been treated, what is the recommendation on providing that vaccine? Yes or no?

Dr. Suchita Lorick: Hi, this is Suchita Lorick. So it's a very good question, and it's going to come up a lot as the season rolls on. The current recommendation is that unless that person was tested by using the (RTPCR) method, which is the only way to definitively diagnose H1N1, then they should go ahead and get vaccinated, because perhaps they could have had another infection, or it could have been seasonal, and we can't be sure. So the current recommendation from CDC is that they would go ahead and get the H1N1 vaccine unless they were tested by (RTPCR).

(Ginger): OK, thank you very much.

Dr. Suchita Lorick: Sure.

Bill Finerfrock: Great question. Next question, operator?

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller.

(MaryAnn Jackson): Can you hear me?

Bill Finerfrock: Yes, we can.

(MaryAnn Jackson): OK, this is (MaryAnn Jackson) at – in Port Lavaca, Texas. You mentioned that if a patient comes in for just the shot, we can put in our cost report. What if they come in for a visit, do we not put that shot – come in for a visit for something else and get the shot?

(Georgine): Hi, this is (Georgine) from CMS. As far as billing, you can follow your normal billing procedures for that office visit, it qualifies as a billable visit, you're going to bill for that, but you're still going to report the information that's associated with the H1N1 administration on the cost report.

(MaryAnn Jackson): OK ...

(Georgine): Because that is reimbursed at 100%.

Bill Finerfrock: So they're going to want to keep a log, presumably the new information – right now they're keeping a log on flu and pneumococcal, and the new log will do flu, pneumococcal, H1 only, H1 plus flu combined, and they'll want to create a – their log will reflect which of those, so for purposes they'll capture the administration appropriately. But as you said, the visit itself would still be an RHC visit, but you still want to create a log that's going to capture that information for H1N1, correct?

(Georgine): Yes.

(MaryAnn Jackson): Thank you.

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller.

(Jennifer): Hi, my name is (Jennifer), and I'm calling from (Chewito), Washington.

Bill Finerfrock: Go ahead.

(Jennifer): And I didn't have the slideshow that you were showing, I was just listening to what you were – had been talking about. And I'm trying to find out where I go to find the correct ICD9 billing code for private insurances when we do bill the administration fee.

Bill Finerfrock: Anyone know what the correct code is for the administration of H1N1 vaccine?

Megan Lindley: This is Megan. The ICD9 codes and the CPT I think and HCPCS codes I believe are on the AMAs Web site. What I can do is look up the exact URL and then perhaps send it to Bill or somebody who could forward it on to you. But I know that AMA and I think AAP also have coding guides up with their H1N1 materials.

(Jennifer): OK.

Bill Finerfrock: If you want to send that to me, I will put it out on the listserv, if you're on the listserv, we'll get that information out to you, in which case if you're not on the listserv, some of you may get information from a secondary or a tertiary source about these calls. Feel free to e-mail me directly at info, I-N-F-O, @narhc.org, and I'll be happy to send you the coding links that we're going to get from Megan.

(Jennifer): OK, thank you.

Operator: We'll take our next question.

Bill Finerfrock: OK, caller?

(Pat): This is (Pat) at Dr. (Dwight's) office in Bamberg, South Carolina. I was calling, I understand the reimbursement for the administration would be billed through our cost report, how about for South Carolina Medicaid?

Bill Finerfrock: I don't know that we have any Medicaid specific folks, my guess is that each state is going to handle that a little differently. How does South Carolina handle flu vaccinations that are not H1N1?

(Pat): The regular immunizations we receive through (BVAC) and we are not allowed to charge for administration.

Bill Finerfrock: And that may be the same then for in this instance. I would contact your state Medicaid or your state office of rural health down there in South Carolina, you have a very good office of rural health there that may be able to help you get an answer to that question.

(Pat): OK, thank you.

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller.

(Craig Brower): This is (Craig Brower) from Sidney, Nebraska. And my question is on the public events, is there any way to estimate how many people may be at those events, either by experience or any kind of factor that we can take against our population?

Bill Finerfrock: Are you asking when you do it how many people like – if you live in a town of 1000, you should expect that 15%, so anticipate 150 people, is that what you're asking?

(Craig Brower): Exactly.

Bill Finerfrock: Has anybody done any kind of metrics or analysis of that as far as planning purposes are concerned?

Dr. Suchita Lorick: This is Suchita, I was just going to say that you know as you might guess, it'll probably depend on a variety of factors, including how widely it was advertised. If vaccine was available in other venues before you know if there's any publicized things going on in your state driving people to seek a vaccine that week. So unfortunately, I don't know of any formula that you might be able to use to estimate some of that. You could potentially once you plan a clinic do a quick sample amongst your

target audience you know pick up the phone and just cold call some people if you want to see if they've heard of it, they're coming as an estimate. But I don't know if, Megan, you had some thoughts on that.

Megan Lindley: No, unfortunately I don't.

Bill Finerfrock: What about – let's suppose that you over estimate, you assume there's going to be 150 people, you order – or you have vaccine on hand for 150 people, and only 100 show up. Is there a process for – should you just keep the vaccine, should you return it so that other areas that may have not gotten enough may use it? What would be the advice in those instances?

Dr. Suchita Lorick: I think – this is Suchita again, I think that'll depend on who's running the clinic, so – and you know how you're handling the vaccine storage and cold chain for the vaccines. In most instances I would guess that people take that vaccine back to their refrigerators for the next round, or if they're completely done with all their events, they would contact their local or state health department to see if others have a need, and they can get it to those places.

Bill Finerfrock: OK. You made reference – I'll just – I'll ask a question here. We had some that were e-mailed in, and I think they've been addressed, but just to be clear. In terms of the commercial insurers, Megan, I think you made reference to this. Do you know are they doing any kind of special billing? Obviously we – there's the opportunity; there's thousands of insurance companies to be able to say for sure. But any kind of general advice, or any experience, or what you're seeing with regard to commercial insurers as far as billing for the administration from a commercial insurance perspective.

Megan Lindley: Unfortunately it's a really mixed bag. Some insurers have put out, for example, press releases saying that they're not only covering the vaccine for beneficiaries that have vaccine benefits, they're actually covering it for everyone. Some are not covering it; some are covering it only for people with preventive services coverage. And as far as the billing, that also is something that is being done unfortunately on an insurer by insurer basis. When we spoke to America's Health Insurance Plans, which

is a – the group that represents many major insurers, their feeling was that providers should probably bill as they normally would in absence of receiving guidance from the insurer.

But it is a little complex, because I know that some of them, for example, want the providers just to submit a vaccine administration code, because that's the only part of the claim that will be paid. And others are going to request that you submit the code for the vaccine, but with a zero dollar charge, because it can't be reimbursed. So unfortunately I think the best piece of advice is to try and contact the major insurers that you work with, and see what they want to do.

Bill Finerfrock: OK. All right, operator, do we have anymore calls in the queue?

Operator: We do, we'll take our next question.

Bill Finerfrock: Go ahead, caller.

Operator: Your line is open, please go ahead.

We'll move on to our next question.

Bill Finerfrock: Go ahead, caller.

(Brandy): Yes, my name is (Brandy), I'm calling from (Larosal), Louisiana. We were wondering with the H1N1 vaccine, is it going to be along the same lines as the seasonal flu vaccine in reference to giving it only in certain seasons? Because H1N1 originally was exposed to everyone in the springtime. So will it be available year round, or just seasonal?

Dr. Suchita Lorick: So right now the – this is Suchita again – so right now the H1N1 vaccine will be available I think all the way through summer, like seasonal vaccine is. We do know that most people stop

vaccinating for seasonal flu around December, and we've been encouraging folks to try to keep vaccinating past December, because as many of you might know, seasonal flu sometimes doesn't peak until February or so. And we expect that potentially for the H1N1 virus, it might come back in waves, so we would encourage folks out there to continue vaccinating throughout the season. As far as what happens with it next year, it's still up in the air whether this new H1N1 2009 virus strain would be included in next year's seasonal vaccine.

I hope that addresses your question.

(Brandy): Yes, thank you.

Dr. Suchita Lorick: Sure.

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller.

Operator: Please go ahead.

Bill Finerfrock: Caller, your line's open.

Operator: We'll move on to our next question.

Bill Finerfrock: We may be getting people whose questions are being answered by earlier questions too.

So is there another caller there?

OK.

(Jeff): Hello?

Bill Finerfrock: Hello, go ahead.

(Jeff): Yes, I'm (Jeff) in South Carolina. Regarding your billing presentation when you discussed being able to charge uninsured or under insured the regional Medicare reimbursement rate. Our department of health where we get our vaccine from in our memorandum of agreement that we signed actually – excuse me – it looks like they extended that and said we can only charge that amount for people with private health insurance as well, which confused us. Is that familiar to you at all or sound right?

Megan Lindley: Oh, yes, that's a great catch. That issue that you're discussing was accidentally introduced by the wording in the provider agreement, which I think was the basis of the (MOU) that you're talking about.

(Jeff): Yes.

Megan Lindley: That – the limit of the Medicare regional rate is only meant to apply to out of pocket charges, and we've actually – the billing Q&A that I referenced in my presentation does include a question and answer about that. But CDC doesn't have either the authority or the desire to regulate the relationship between insurers – private insurers and providers, so ...

(Jeff): So.

Megan Lindley: ... you should feel free to bill a private insurer at whatever rate it is that they allow you to, and accept whatever reimbursement they provide.

(Jeff): OK, so that applies only to the uninsured or under insured then?

Megan Lindley: Yes.

(Jeff): OK, thank you.

Operator: We'll move on to our next question.

Bill Finerfrock: OK, next question.

(Rita): Yes, this is (Rita) from Benkelman, Nebraska, and I have a question for Dr. Lorick.

Dr. Suchita Lorick: Sure.

(Rita): In our allotment of vaccine, we're seeing that our neighboring county has significant outbreak, and some of our allotment is going to that county. Is that the prudent thing to do as far as vaccination since vaccination is preventative to like basically shift it to the counties that are having outbreaks?

Dr. Suchita Lorick : So if I understand correctly, you're saying that in your state, you're seeing that vaccine is being sent preferentially to counties where there's currently outbreaks instead of a county where there isn't? Is that right?

(Rita): Yes, that's correct.

Dr. Suchita Lorick : Yes you know each state is trying to sort of use their best judgment to try and target the folks that are at the highest risk. And as you know different states are doing a variety of different things. For example, some states are trying to – like what I'm hearing you mention in Nebraska, are trying to focus in on schools, because that's where the young kids are, and that's where they're seeing a lot of activity. Others are totally doing something else where they're feeling like they need to get their health care workers protected first since they're the front line in taking care of kids.

So I think at a state and local level, a variety of things are happening, and people are using – and also that depends on the availability of the type of vaccine at the national level. For example, the (LAIV) versus the inactivated shot, because some groups are eligible to get one or the other, and some groups prefer to get one or the other. So I think states are using a lot of different factors to determine where a vaccine is going.

But you know I would definitely take it up and address it with your folks – with your state contacts if you think that there's something happening that you don't agree with. But I think you know they may be trying to sort of – I don't know if this is accurate, but they may be potentially trying to stop an outbreak, or trying to get an outbreak under control in that area potentially, I'm not sure, not knowing all the details there.

Hopefully that helps.

Bill Finerfrock: OK, thank you, caller. Next question.

Operator: We'll take our next question.

(Linda): Can you please go back over the log and ...

Bill Finerfrock: Who you are and where you're calling from, please?

(Linda): Oh, I'm sorry, I'm (Linda); I'm from – calling from Laurens Family Practice in Laurens, South Carolina.

Bill Finerfrock: OK.

(Linda): Can you please go back over the difference between the patient coming in for an H1N1 shot at – and a seasonal flu shot at the same time or just the one at a time as far as the charging and the log?

Bill Finerfrock: This is with regard to the Medicare?

(Linda): Yes.

Bill Finerfrock: One of the folks from CMS.

Steve Raitzyk: You talking about the cost reporting?

Bill Finerfrock: You had referenced the fact that under the new instructions, they would be keeping a count of flu only – seasonal flu only, pneumococcal, and then flu with H1N1, and then H1N1 only. You want to, I think, go over that again?

Steve Raitzyk: Yes, basically we've always kept – on this supplemental worksheet B-1, we always kept track of the influenza shots separately, and of course that includes the cost of the vaccine and the staff time involved in doing the vaccine. The H1N1 has a separate column because there will not be a cost for the vaccine, but there still will be staff time and administrative costs associated with it that providers are going to want to be paid for.

So we do that separately. And then in there – in a case where they have the influenza and the H1N1 done at the same time, because the flu shot has the cost involved, and the H1N1 does not, we count for that separately as well.

(Linda): OK.

Steve Raitzyk: Does that help? Does that answer your question?

(Linda): Yes, thank you.

Steve Raitzyk: OK.

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller, lines are open.

(Helen): Hi, this is (Helen) from (Parkside) Family Clinic in Cuero, Texas.

Bill Finerfrock: OK.

(Helen): And I really don't have a question, but someone had asked a question about the diagnosis used. And in looking at some e-mails that I received from Blue Cross and Blue Shield and our (Cigna), the diagnosis code is – that they're requesting is V04.81. And also for the administration, there's two separate codes, the G9141 for administration and G9142 for the vaccine. Along with the regular CPT HCPCS codes, I'm sorry.

Bill Finerfrock: OK.

(Helen): And if you – Blue Cross and Blue Shield ...

Bill Finerfrock: OK.

(Helen): ... click on the provider link, and it's the first thing that says what's new, special coverage for H1N1 vaccine information, and also you can go to the Cigna Web site.

Bill Finerfrock: Great, thank you very much, (Helen), that's very helpful.

(Helen): Thank you.

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller, your line's open.

Operator: We'll move on to our next question.

(Lisa): Hi, this is (Lisa) with Emmett Medical Center in Emmett, Idaho. And I need to know if there is a shortage for the H1N1 vaccine, as well as for seasonal flu vaccine as I am unable to get any.

Dr. Suchita Lorick: Hi, this is Suchita Lorick. So right now, as you've probably heard, there is some lower than expected supply on the H1N1 vaccine side, and that's why you may be still waiting to receive some vaccine that you may have ordered with your health department. And as far as the seasonal side goes, I am trying to find the numbers, but I don't have them in front of me. If I recall correctly, the projected estimate that the manufacturers had put out about a few months ago has only dropped by about 3 or 4 million. So I think they are going to have vaccine available, just maybe 3 or 4 million less than what had – what they had projected.

What we do know is happening is potentially there's more demand for seasonal vaccine going on right now, as well as although vaccines came out early, the rest of it seems to be coming out a little slower than expected on the seasonal side. So you're butting increased demand up against some of that delay in the vaccine. And unfortunately from what I understand, manufacturers can't go back to making anymore seasonal vaccine, because they're currently making H1N1 vaccine. So you know the best I could advise is that potentially you contact your local or state health department to see if they have any

knowledge of folks who might have some seasonal flu vaccine supplies that they're not using that you could get your hands on.

(Lisa): Yes, and as far as I know, there's no one around that has any seasonal flu, and I didn't get the amount that I pre-booked from January, and in talking to the state folks about the H1N1, they're getting as much as they can, and apparently it's filtering down, and we're not getting that either.

Dr. Suchita Lorick: Yes, and you know as I mentioned with the call – the person who called from Nebraska, each state is sort of using a different strategy as to where they're allocating some of their first doses of vaccine that come out. And I can't recall if you said if you're at a local health department, or a family clinic. But you know in your state, the strategy might be to try to get vaccine to schools first, or to health care providers at hospitals first. So you might be feeling the impact of some of that.

So it is true that nationally the supply is a little less than we had hoped for. And that's related to some of the strains not growing as well, among other things. So I think we do recognize that that's going on out there, and we ...

(Lisa): Is there an expectation that we really will get it though at sometime?

Dr. Suchita Lorick: Oh yes, so the total amount of projected vaccine has not changed, we expect that we're going to get all that vaccine out, it's just been delayed. So that's what's going on.

(Lisa): OK, thank you.

Dr. Suchita Lorick: Sure.

Bill Finerfrock: We have time for one or two other questions, if there are still some folks in the queue.

Operator: We'll take our next question.

Bill Finerfrock: Go ahead, caller.

(Craig): This is (Craig) from Sidney Medical Associates, Sidney, Nebraska again. One question my providers have is specific to OB, and they actually have lots of questions in that area. Is there a contact or someplace that they can go to to get those specific questions answered? And I'm looking for a contact.

Dr. Suchita Lorick: So can you expand maybe a little bit on what type of questions they have, or the OBs might have?

(Craig): Safety for OB is most – if I can categorize their questions, it's safety for their OB patients.

Dr. Suchita Lorick: OK, so the vaccine safety. I'm not sure if you're – if you've been going to the CDC Web site, but there is a whole section on safety that has a lot of important questions and answers, and many of them targeted just for pregnant women. So that might be a good place to start, but if that's not meeting their needs, you can have them send their questions to CDCinfo, i-n-f-o @CDC.gov.

(Craig): OK.

Dr. Suchita Lorick: And that will trickle down to our folks on the maternal child health team who also have OBs on there.

Bill Finerfrock: (Craig), have you been to the CDC section and looked at those questions, or ...

(Craig): Yes, we have, and it isn't satisfying their curiosities ...

Bill Finerfrock: OK.

(Craig): ... or their questions.

Bill Finerfrock: OK, thank you, that was very helpful. I think that's good for CDC to know too, particularly if they get a lot of questions in a particular area, that's what helps to incentivize them to put it up under their FAQs that obviously that these are questions that more than one person has. So I would encourage you to submit it to that CDC info address that you were given.

(Craig): And that's CDCinfo@CDC.gov?

Dr. Suchita Lorick: Yes, I'm trying to see if I can get my hands on something so I can verify that. I don't know, Megan, if you're online, if you could just ...

Megan Lindley: Yes, let me just check, and then I'll announce it.

Dr. Suchita Lorick: OK. And then alternately if you have them at your fingertips, if you – I don't know if Bill is – if you guys have a common e-mail address that they could be filtered through and sent to us, that would be OK as well. If folks send it through the CDC main, it sort of gets to the right place, but I'm OK with either way, if Bill, you want it to go that route.

Bill Finerfrock: We're happy to facilitate it. But I think – I would encourage folks to as much as possible go there directly, one I think to familiarize themselves with that process, and two, that there's sufficient volume there to perhaps justify doing it as a separate FAQ as opposed to ten people contacting me and my generating one question on behalf of ten people, that you know that there were ten people who asked the question.

Dr. Suchita Lorick: No, I think that's an excellent point, because that gives us a queue to make sure we're addressing those concerns ...

Bill Finerfrock: Right.

Dr. Suchita Lorick: ... systematically.

Megan Lindley: And this is Megan, just to confirm that e-mail address is CDCinfo@CDC.gov, just like Suchita said.

Bill Finerfrock: Right. This will be the last question, we have one more question, then we're going to have to close it out for today.

Operator: We'll take our last question.

(Nancy): Hello?

Bill Finerfrock: Hello, go ahead, you get the last word, caller.

(Nancy): OK, this is (Nancy) and I'm calling from South Louisiana. Where do we get the slides?

Bill Finerfrock: Those are – they were distributed through the listserv, they will also be posted on the Office of Rural Health Policy's Web site, which should be hopefully by later today, those will be up and available. That Web site is www.ruralhealth.hrsa.gov/rhc, and you'll see a link, and then the slides once they're available. That's also where we put up the transcript, and where you can get the recording when it is available as well.

(Nancy): OK, can you say that Web site one more time a little slower?

Bill Finerfrock: [www.ruralhealth](http://www.ruralhealth.gov), one word, R-U-R-A-L-H-E-A-L-T-H dot H-R-S-A dot G-O-V, forward slash R-H-C.

(Nancy): OK, thank you.

Bill Finerfrock: You're welcome.

(Nancy): Appreciate it.

Bill Finerfrock: Well thank you to our folks from CDC and CMS, I think this was extremely helpful, I know I learned a lot. I'm pretty sure a lot of the folks – the listeners learned a lot, and in the end of the day, this is all for the benefit of the patients, and I think as a consequence of folks having more information both on the vaccine, some of the clinical issues, the payment issues, we will help to insure that more people have it available than might otherwise have been the case.

So I want to thank our speakers, I want to thank our listeners, and appreciate everyone's participation.

Our next call will be in 2 months, and we'll get information out on that as we get closer to the date on the topic and the specific times. But thank you all for participating in the Rural Health Clinic technical assistance conference call series.

Operator: Thank you, everyone, that does conclude today's conference, we thank you for your participation.

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