

Centers for Medicare & Medicaid Services
Special Open Door Forum:
Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)
Wednesday, October 29, 2014
1:00 p.m. – 2:30 p.m. Eastern Time
Moderator: Natalie Highsmith

Operator: Good afternoon. My name is (Lisa) and I will be your conference operator today. At this time, I would like to welcome everyone to the CMS Special Open Door Forum Inpatient Rehabilitation Facility Quality Reporting Program Conference Call.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad.

If you would like to withdraw your question, press the pound key. Thank you. Natalie Highsmith, you may begin your conference.

Natalie Highsmith: Thank you and welcome everyone to today's special open door forum on the inpatient rehabilitation facility in Quality Reporting Program.

We are joined today by some representatives from the Centers for Disease Control, CDC. And on today's special open door forum is to provide data collection and submission information to providers for the quality measures 1716 and 1717.

Please continue to check the IRF training Web site. The PowerPoint presentation is not up yet but we should have it up shortly. So now, I will turn the call over to Charles Padgett who is the IRF Quality Reporting lead for the Centers for Medicare and Medicaid Services in our Office of Clinical Standards and Quality. Charles?

Charles Padgett: Hi. Thank you, Natalie. Welcome everybody to the special open door forum for the IRF Quality Reporting Program. As Natalie said today's special open door forum is going to cover the data submission, correction and submission of data for the methicillin resistant staphylococcus aureus measure and the C. difficile measure that are required for IRFs to begin reporting as of January 1st, 2015.

So, we're joined here in conference of the CDC and the CDC will be presenting on that and LabID Event Reporting. First though, I have a few just house-keeping items that I need to get out of the way. One is the slide deck or the PowerPoint presentation for this open door forum, we had some difficulty getting it up on our Web site.

We are hoping to get it up any moment now. So, I urge you to continue to check the cms.gov IRF Quality Reporting Program Training webpage. And that it should be posted under the Download section of that webpage. And I do have the webpage open and I will notify everybody if I see it go up as well.

Other than that, I do have one announcement. Last Friday, October 24th, CMS announced that we are extending the deadline for data submission for any CDC/NHSN data. So, for quarter one of 2014, so quarter one of 2014, CAUTI data was due to CMS originally on August 15th of 2014.

However, we decided to extend that deadline until November 15th of 2014 in order to allow IRFs to make sure that their data is in and correct that a reporting plan is in place and correct and that your event and summary data has been reported to the CDC. So, I urge you to go to the CDC/NHSN Web site. There are several reports that are available to you to run.

We also speak about some of those reports on our IRF Quality Reporting Program Web site. You can check there for directions on how to access those sorts of reports. You can also contact the CDC's help desk which is nhsn@cdc.gov . Again, that's nhsn@cdc.gov and the CDC can assist you in running a report to make certain that all of your data is in fact submitted and correct.

OK. So, we're going to move into the presentation here. I apologize that there's a delay in getting the slides up. Some of this material I will say is a bit complex. It does help to have a visual guidance in front of you. However, this call is being recorded and the recording transcript and materials will be available to you – the recording I expect will be available next week, so you can certainly listen to the recording and if you – the slide deck during that.

If in fact the slides don't come up during this call. So, I'm going to begin. The presentation just begins with a little bit of background. Of course, the – for the section 3004 of the Affordable Care Act requires that IRFs submit quality measure data in time and manner required by the secretary of Health and Human Services and any IRF that has not submit the required quality measure data to CMS by the established deadlines may receive a two percentage point reduction to their annual payment update or annual increase factor for IRFs for the applicable (current) year.

And it's October 1st – October 1st, 2014, IRFs began using a new version of the IRF-PAI. That's version 1.2 and in order to report quality data to CMS for specific measures, IRFs use the quality indicators section of the IRF-PAI. And this particular version contains revised pressure ulcer items as well as new patient influenza vaccination status items.

And IRF-PAI must be completed for all patients receiving inpatient services in the IRF under the following Medicare program which includes Medicare fee-for-service and also Medicare managed care. For additional information about the collection and submission of all IRF quality measure data using the IRF-PAI quality indicator items, I'd like you to visit our IRF Quality Reporting Program webpage.

We list the web address of that webpage and the IRF PPS webpage which have to do with payment items on the IRF-PAI on this. You can also find both of those by just googling IRF Quality Reporting Program. Our webpage will pop up as one of the first or second hits and if you type in IRF PPS webpage on Google, the same thing – the first or second hit will be the webpage that I'm referring to here.

I'm just going to review the quality measures that are required for the IRF Quality Reporting Program. These have all been finalized on or before August 6th, 2014. First one is percent of patients or residents with pressure ulcers that are new or worsened. It's the short-stay measure. NQF I.D. is 0678.

Data collection for this particular measure began on October 1st of 2012. There's percent of residents or patients who are assessed and appropriately given seasonal influenza vaccine -- the short-stay measure. NQF I.D. is 0680.

IRF-PAI data collection started on this measure on October 1st of 2014, just recently. There's an all-cause unplanned readmission measure for 30 days post-discharge from inpatient rehabilitation facilities. This is actually a claims-based measure and IRFs do not need to submit any additional data in order to have this measure calculated.

The fourth measure is NHSN catheter-associated urinary tract infection or CAUTI outcome measure, that's NQF I.D. 0138. Data collection for this measure began on October 1st of 2012. There's influenza vaccination coverage among health care personnel which is NQF 0431.

Data collection began on October 1st of 2014 for this measure as well. And there's two additional measures, one is NHSN facility-wide inpatient hospital onset, methicillin-resistant staphylococcus aureus or MRSA bacteremia outcome measure which is NQF I.D. 1716.

IRFs will be required to begin reporting this measure on January 1st of 2015 and this is one of the measures we're covering in the special open door forum today. And the second measure is NHSN facility-wide inpatient hospital onset, Clostridium difficile infection or CDI outcome measure, NQF 1717 and again, just as the MRSA measure, IRFs are required to begin reporting this measure on January 1st of 2015.

Data submission deadlines in the fiscal year of 2014 IRF PPS final rules, we established quarterly data submission deadline for the quality indicator items. Each quarterly data submission deadline actually occurs approximately 135

days after the end of each quarter. IRFs must submit quality data for each quarter by this established quarterly deadline.

Data submitted after the quarterly data submission deadline will not be accepted for purposes of IRF's Quality Reporting Program compliance determinations. Missing one or more of these deadlines may lead to a finding of noncompliance. So, the quality indicator items for the IRF-PAI, as I said, have established quarterly deadlines, so, which are four and a half months beyond the end of the quarter.

So, for quarter one of 2014 which – or I should say this, actually beginning on October 1st of 2014, Quality Reporting Program for IRFs began looking at this data or collecting this data or rather having IRF submit this data on a fiscal year basis.

So, the first quarter will be October 1st, 2014 to December 31st, 2014. And then, on October 1st to December 31st of each year, they're asked or – and the data submission deadline for quarter one would then be May 15th of 2015 or May 15th of – or May 15th each year thereafter.

Quarter two would be January 1st, 2015 through March 31st, 2015. Then, January through March of each year following and the data submission deadline for quarter two data would be August 15th of 2015 or August 15th of each year thereafter. Quarter three would be April 1st, 2015 through June 30th, 2015 then April 1st to June 30th for each year following and the deadline for quarter three would be November 15th of 2015 or November 15th each year thereafter.

And finally, quarter four would be July 1st of 2015 through September 30th, 2015 and July 1st to September 30th each year and the quarterly deadline for quarter four would be February 15th of 2015 and then February 15th of each year thereafter.

I just wanted to again remind you for quarter one of 2014, actually I'll go into that on the next slide. So, for data that IRFs report via the CDC/NHSN, that data is submitted on a calendar year basis. So, quarter one for that would

begin on January 1st, go through March 31st and the data submission deadline would be August 15th of each year.

This year, that deadline was – yes, August 15th, I'm sorry. For quarter one, as I said, we have decided to extend that deadline which was originally August 15th to November 15th, 2014. So, we're giving you a little extra time to go in and make sure that your data with NHSN is correct and that you have appropriately completed your reporting plan as well as your summary and event data, all three which are required in order for that data to be transmitted to CMS.

And then the quarters for NHSN data are calendar year quarters. Quarter two is April 1st to June 30th with a deadline of November 15th. Quarter three is July 1st to September 30th with a deadline of February 15th and quarter four is October 1st to December 31st with a deadline of May 15th of the following year.

As I stated earlier, when I was talking about the measures, data collection and submission for the patient influenza measure just began on October 1st of 2014. This is following of course the fiscal year reporting. So, quarter one would be October 1st to December 30th with a deadline of May 15th. Quarter two would be January 1st to March 31st of 2015 and with a deadline of August 15th, 2015.

And for the patient influenza item, we originally stated there was just going to be one deadline for this measure. In our last rule, we did change it and state that because this was reported using the quality indicator section of the IRF-PAI which was due quarterly, there were two deadlines, one for each quarter.

Now, these items – the patient influenza items on the quality indicator section of the IRF-PAI, IRFs are not required to report them outside the influenza vaccination season. So, you must report them from October 1st through March 31st of the following year.

However, from April 1st through September 30th, you are not required to report them. However, if you decide not to answer one of these items, you

must use a default response in place of an actual response. And all these information is covered in our IRF Quality Reporting Program manual which is available on our Web site.

The last measure I want to just quickly touch on is the health care personnel influenza measure. This is NQF I.D 0431. This measure; is reported to CMS via the CDC/NHSN and include health care personnel that have worked one or more days during the influenza vaccination season.

So, any health care worker that is – worked one or more days between the days of October 1st and March 31st of the following year is going to be included in this measure. And, you're only required to submit summary data to the CDC once at the end of the influenza vaccination season.

So, and the deadline for the submission of that data will be May 15th. So, you can go into NHSN and report this on a monthly basis. However, if you do that, you will be required to update your totals every month manually so that you have a comprehensive number there. This information is also covered thoroughly on the CDC/NHSN Web site if you want more information surrounding this measure and its reporting.

OK. As I said earlier, we are lucky enough to have our CDC colleagues join us in collaboration for this training. We are going – so they're going to be presenting on as I said the multi-drug resistant organisms, Clostridium difficile and the methicillin-resistant staphylococcus aureus or MRSA. They're going to talk about the data collection and submission of the data for these measures.

And, they're also going to be covering a general kind of overview of LabID Event Reporting. So, I'm going to turn the call over now to Angela Anttila who is the nurse epidemiologist with the CDC and she will take it from here. Angela?

Angela Anttila: Charles, can you hear me OK?

Charles Padgett: I sure can.

Angela Anttila: OK, perfect. OK. So, I'm going to get started. I just want to let everyone know that there is a very comprehensive slide deck available or once it's available on the CMS Web site, it's going to give you a wealth of information due to time constraints today and boredom on your part.

I don't want to bore you. I'm going to really just hit the high-level points that I think that are going to be most important for you to know today. But I do encourage you to get those slides as soon as possible. So, for today, we're going to briefly talk about line surveillance for MRSA bacteremia and C. difficile infections are important.

Going to understand the requirements for IRF facilities for reporting. I'm going to go over how to set up your monthly reporting plan so that you are including MRSA bacteremia and C. difficile LabID Event. I'm going to discuss the definitions from MRSA bacteremia and C. difficile LabID Event Reporting.

I'm going to describe how to correctly enter this data into the NHSN application as well as how to enter your denominator data. So, just to begin with very briefly with an overview, we all know why MRSA bacteremia is important. We know that staph bacteria including MRSA is one of the most causes of health care-associated infection.

We know from a report that came out in 2013 on antibiotic resistance that despite a slight decrease in the percentage of staph aureus resistant to ampicillin that MRSA continues to dominate among the pathogens, especially in health care. Moving on to C. difficile, between 2000 and 2007, there was an approximate 400 percent increase in C. difficile infection with most of them be and among the elderly at 90 percent.

There was an estimate at 14,000 deaths per year related to C. difficile infection and the hospital stays for C. difficile infections tripled in the last decade. We also know that although there are number of risk factors for C. difficile infection, the main modifiable risk factors are antimicrobial exposure and acquisition of C. difficile.

And so, that just reinforces the importance of prevention efforts to focus on reducing these risk factors. So, next time, I'm going to go in to an overview of the CMS requirements for inpatient rehabilitation facilities. And before I do that, I just want to let you know if you don't already know that we have a wealth of resources on the NHSN Web site and you will be able to get that Web site from the slides when you're able to download them.

We are in the process of updating guidance document for our reporting, so stay tuned for that. Also, you will find the protocols, training opportunities, helpful tips and analyses on the Web site as well. So, for 2015 for inpatient rehabilitation facilities or IRF, you're going to be required to – if you're participating in the CMS Inpatient Quality Reporting Program, you're going to be required to report facility-wide inpatient, also referred to as FacWideIN MRSA bacteremia and *C. difficile* laboratory identified or LabID Event from inpatient rehabilitation facilities.

That will begin on January 1st, 2015 and it will include freestanding IRFs as well as IRF units located within a hospital setting and that includes acute care hospital as well as critical access. So, beginning with the specific requirements for MRSA bacteremia LabID Event, the organism is methicillin-resistant staphylococcus aureus or MRSA.

They're going to use the NHSN, MDRO and CDI module protocol under LabID Event. The required location will be FacWideIN which includes CMS licensed IRF units within an enrolled acute care or critical access hospital and CMS licensed freestanding IRFs.

And I'm going to explain more about what I mean by FacWideIN for each individual on facility type. The required data will be MRSA blood specimen and you will report this community onset as well as health care facility onset LabID Event.

Similarly for *C. difficile*, the organism will be clustered in *difficile*. You will hear this referred to as *C. diff* or CDI for *C. difficile* infection. The data collection again will occur to the MDRO and CDI module protocol within the

NHSN manual. The locations are the same as those that I just mentioned for MRSA bacteremia.

The required data will be *C. difficile* toxin-positive results tested on unformed stool specimens. And again, it will include your community onset as well as health care facility onset LabID Event. I have a nice table in the slides that you're going to want to look at and it is – they are to differentiate between a freestanding and hospital IRF unit reporting requirements.

I'm not going to spend a lot of time on this table during this call but please look at the table when you get your slides and hopefully these maps out and makes it a little bit easier for you.

I believe that most of you are already familiar with using NHSN for CAUTI reporting, but just quickly to let you know, we do have four modules within the patient safety component. We have device associated which is what you're using for your CAUTI.

We have procedure associated for surgical site infection reporting. We have antimicrobial use and resistance and then we have the MDRO and CDI module. So, specifically inside the MDRO and CDI module, there are two reporting methods that active participants can choose from. There will be infection surveillance and LabID Event Reporting.

I want to emphasize for the CMS reporting requirements. You will be following the LabID Event Reporting Protocol. Within that protocol, you will see the definition for MRSA and *C. difficile*. *C. difficile* again is identified as a *C. difficile* toxin-positive and then for MRSA, it's staph aureus testing oxacillin, cefoxitin or methicillin resistance.

Many of your labs will just report this out as MRSA. To give you a little bit of a background on LabID Event Reporting and what it means, LabID Event Reporting allow laboratory testing of data to be used without clinical evaluation of a patient. It allows a much less labor intensive method to track *C. difficile* and MDRO such as MRSA.

It provides proxy infection measures of health care acquisition, exposure burden and infection burden, again, based primarily on laboratory and limited admission data. I do want to let you know that the metrics in the MDRO and CDI module do align with the recommendations from published literature. And just really quickly, some of the advantages of LabID of that reporting, it does allow objective laboratory-based metrics.

Without the extents of chart review, it allows facilities to identify your vulnerable patient population. And again, estimate your infection burden and exposure. It allows you to assess need for an effectiveness of your interventions and your infection prevention program. And, because it uses standardized case definition, it does increase comparability between clinical settings.

OK. So now, I'm going to get into reporting and the first thing that I'm going to review is location options and mapping the inpatient IRF locations and NHSN. And again, like I said, you're already most likely doing this or have done this for your CAUTI reporting. So, then it go through this fairly quickly.

But if you're located inside a hospital, OK? You will select your CMS licensed IRF units within that hospital, just like you're doing now for CAUTI and you're going to report LabID events separately for each specific IRF unit that you're monitoring within your hospital.

For your denominator data, you're going to report the patient days and admissions for that IRF unit. Now, if you are a freestanding IRF, it's going to be a little bit different for you because you're going to actually be reporting overall facility-wide inpatient or FacWideIN. Now, you will – so that what means is you're going to be reporting all inpatient IRF locations within that rehab facility, but just like the IRFs located in a hospital, you will report the LabID Event from each IRF unit separately, OK?

So, that's the same for both. Another key difference is that for freestanding IRFs, you're going to report your facility-wide denominator summed across all IRF location within that facility, OK? And depending if your freestanding IRFs share space with any other type of facilities such as an (LTAC) or skilled

nursing facility, you may have to subtract out counts from locations that have different CCN numbers.

I don't imagine that there are many of you that are going to be in that situation. However, if you are, we will be providing you with additional information. So, please let us know as questions arrive and just stay tuned for more information that's going to be posted to our Web site.

I had on my slides to go over how to set up a location. But, it's my understanding that you guys have already done this. So, I'm not going to spend a lot of time, just in case we have some new people on the phone that haven't done this, I'm going to go through it very quickly.

But again, my slides are detailed. So, when you're able to get a copy of them, I think this will help you. But to – if you have not already set up your locations or if you just want to see what locations you've set up, you're going to go into the application. And on the left hand side of the screen, you'll go to Facility and you'll click Location.

And then from there, you can click Find, if you want to find – excuse me, find what locations you have set up in your facility or you can simply add additional locations as needed within the facility.

For your freestanding IRFs, you can select the rehabilitation ward or rehabilitation pediatric ward as your CDC location code when mapping if you haven't already done that. OK. We're going to move on to the monthly reporting plans. I think this will be some new information for you. The monthly reporting plan is really important as it informs the CDC which modules and facility is participating during any given month.

We referred to this as in-plan data. The plan also informs CDC which data can be used for aggregate analysis. And this includes sharing applicable data with CMS. A facility must enter a plan for every month of the year, so just like you're doing that for CAUTI and this is a reminder and it just then will submit data to CMS only for those completed month at which you have

reported in the plans following MRSA bacteremia and C. difficile LabID Event.

So, in this slide, you're going to notice I did some screenshot for you to show you exactly how to set up your monthly reporting plans. But again, to do this, if you already have reporting plans set up, you can edit those and add or if you need to add new reporting plan, you can do that on the left side of the screen. You're going to click under Reporting Plan, you'll click "Add" or "Find" if you already have reporting plans set up and then you can edit.

And then you're going to want to scroll down to the multi-drug resistant organism module section. So, at the beginning of each month, you're going to want to add MRSA bacteremia and C. difficile LabID events to your monthly reporting plan. For IRF units within a hospital, you're going to do this using your CMS IRF location.

OK? So, when you go to your plan, it's really important that each month, your plan contains the two rows that you're going to see and my screenshot on the slide. So that would be – if you have one IRF unit within your hospital, you'll have two rows. One row is going to be selecting MRSA as your organism type, OK?

And the next row will be selecting C. difficile as your organism type. For MRSA, you will select LabID Events, blood specimens only. If you're planning to only track blood specimens and then for C. difficile, you will select LabID Events of specimens and even though it says all specimens, it's referring to all loose stool specimens.

To let you know, if your facility chooses to report LabID Events for all specimen sources, only MRSA LabID Events from blood specimens will be – data will be sent to CMS. OK. So, if you're a freestanding IRF at the beginning of each month, you're going to add facility-wide reporting for MRSA bacteremia and C. difficile LabID Events to your monthly reporting plan.

And for the location, you're going to select FacWideIN location, OK? So, this is different than what you're doing now for CAUTI but you'll select FacWideIN for location and then for your specific organism type, you'll do MRSA. And then, under that, you're going to select LabID Event blood specimen only. And then for your second row, you're going to again select FacWideIN as your location.

This time, you're going to select C. difficile as your specific organism type. And again, you're going to check the boxes as LabID Event of specimens. If you need to add additional rows, you'll notice some additional options at the bottom of the screen that will allow you to edit and add and clear.

OK. So that is the review of monthly reporting plans. The next thing I'm going to discuss is to how you're going to identify and enter all MRSA bacteremia and C. difficile LabID Events into NHSN. Again, remember, I location and you're going to use the NHSN/MDRO CDI LabID Event protocol.

OK? So, the definition of our MRSA-positive blood isolate is any MRSA blood specimen obtained for clinical decision making purposes, which to my knowledge, that's the only reason why they would be doing a MRSA blood specimen. And that for those facilities that are reporting MRSA all specimens, just keep in mind that LabID Event Reporting for MRSA, all specimens does exclude any type of screening cultures, but that's not going to be an issue for blood specimens.

OK? So, a MRSA bacteremia LabID Event is defined as MRSA-positive blood specimen for a patient and a location with no prior positive blood specimen result collected within 14 days for that patient in that location. And that does include across calendar months if you're collecting blood specimens only.

So, 14 days per patient per location. You may hear of this referred to as non-duplicate MRSA bacteremia LabID Event. In the handouts, I have a great algorithm for you to follow. This algorithm is also available in the protocol and I have heard from other users that it really just makes it a lot easier to

follow the protocol using the algorithm, especially for those of you who are visual learners.

OK. So, once you identify a LabID Event, the next use in the protocol, the next thing that you have to do is enter that event. And again, this is similar to what you're doing now with CAUTI data. You go to Event and click Add and then from there, you're going to enter that LabID Event into any just – and to NHSN using the specific CMS IRF inpatient location, where that patient was assigned at the time of specimen collection.

That's really important. And then, you will not be able to use FacWideIN location when reporting individual LabID Event. So, I think the key method here is that LabID Events when you're reporting event level information, you're going to report at the location level and the specimen collection date is going to be the date that you enter as your LabID Event date.

We do get some questions about the date admitted to facility. And I do want to let you know that if you are a freestanding IRF, the date admitted to the facility will be the calendar date that the patient is admitted as an inpatient to your IRF freestanding facility. If you are an IRF unit within an acute care facility or a clinical access hospital, the date admitted will be the date admitted to that actual hospital.

And then, you'll enter the – also enter the date admitted to that location. For 2015, we have added additional questions to the event reporting for LabID Events and there's some very specific information about these additional questions in this slide, but just to give you an overview, the first question asked the last physical night – the last physical overnight location of a patient immediately prior to arrival into the facility and you're going to have several options to select from.

And then the next question is asking, have the patient been discharged from another facility in the past four weeks? And if yes, you'll also have options to choose from. For 2015, these two questions are optional questions. But we do believe that they're important as it's going to allow our facilities to improve tracking through the continuum up here for the patients.

OK? We're going to talk a little bit about how NHSN will categorize your MRSA blood specimen LabID Events. We categorize based on the date the patient is admitted to the facility or the location. If you're inside a facility and the date of specimen collection.

For MRSA bacteremia, you have your community onset cases and these are LabID Event specimens collected in an outpatient location or an inpatient location equal to or less than three days after admission to the facility, so that's day one, day two, or day three.

That's community onset and you have a health care facility onset which is a LabID Event specimen collected more than three days after admission to the facility and that's on day four or after. And again, these are based on admission date and specimen collection date. A common question that we receive from facilities is what data will be reported to CMS.

All in-plan health care facility onset MRSA bacteremia LabID Event data from participating IRFs, so what this means is for freestanding IRF facility-wide inpatient MRSA bacteremia, health care facility onset, incidence rate, which is defined again as unique blood source LabID Event identified greater than three days after admission to the IRF facility.

So, for our IRF units within a hospital, all MRSA bacteremia, health care facility onset, incidence rate or all CMS-certified IRF units combined, defined again as unique blood source LabID Events collected in CMS-certified IRF units and identified greater than three days after admission to that location.

I will tell you, if you can please make a note. I am seeing a typo in my slides. So, under IRF unit for hospital, if you could just change that to make sure that it says the last sentence identified greater than three days after admission.

Charles Padgett: Angela, can you give me the slide number?

Angela Anttila: Let's see here. It is slide 58. Do you see it, Charles? It's the last sentence under IRF unit inside the hospital.

Charles Padgett: OK. And what did you need to change in that sentence?

Angela Anttila: I have on here identified greater than three days after admission to the facility and it should actually be to the unit, to that MRSA unit.

Charles Padgett: OK. Great, I'll get that changed on the slides. Thank you.

Angela Anttila: To remind you because we also get this question quite often, if we're only reporting health care facility onset, why do facilities have to also report community onset LabID Event? And I just want to reemphasize that it's very, very important that you report both your community onset LabID Events as well as your health care facility onset LabID Event because we do use this data for prevalence, admission prevalence in the facility.

So very important that you do report both of those. I put a couple of common questions within the slide. But I think that I'm going to skip over some of these just for the sake of time, but just to let you know again that there are some examples within the slides as common questions that we get from users, from our acute care facilities that I thought would also be questions that you may have.

So, for one, an example is one of the patient comes into my facility and we suspect that they have a bloodstream infection when they come in. But we don't collect the blood culture until they've affordable discount against my facility. And the answer is yes, because again, remember LabID Events are categorized as health care facility onset or community onset, they strictly on that admission date and specimen collection date, OK?

So, we – there are no exceptions made for signs and symptoms that the patient may have had on admission but testing not done until later. And just remember that this does allow us to institute a more effective standardization across all of our facilities that some of the processes do differ across facilities.

OK. So, before I move on to *C. difficile*, I just want to review some really important points for MRSA bacteremia LabID Event Reporting. So first, MRSA bacteremia LabID Events must be reported at the facility-wide

inpatient level for our freestanding IRFs, OK? And that includes reporting MRSA blood LabID Event from each map unit inside that freestanding IRF, OK?

Also, for our freestanding IRF, you must report facility-wide denominators, summed across all inpatient IRF locations, so that would be your total facility patient days and admission. With facility-wide inpatient selected as your location and that's for denominator reporting, depending on your facility and if you share space with other non-IRF facilities, you may have to subtract counts from other facilities on the same – in the same space that have a different CCN but again, I don't want to confuse you with all of that.

Please just let us know if that pertains to your facility. I'm not thinking it's going to pertain to many of you. Also, all MRSA blood LabID Events must be entered regardless if they're community onset or health care facility onset. And a blood specimen qualified as a LabID Event if there has not been a previous positive blood culture for that patient and location and the previous 14 days.

OK? Just some review points for IRFs located inside a hospital, you're going to do location specific reporting which means that your numerator and denominator counts are reported separately for each CMS-certified IRF unit inside the hospital. And the other point that I have on here are exactly the same as far as the 14 days and entering community onset and health care facility onset.

I also in the slides have some examples of line list and is they're considered a LabID Event or not and again, for the sake of time, I'm going to skip over these today but just know that they are available for you and that's even included the answers.

OK. We're going to move on to C. difficile LabID Event Reporting. Again, the specimen source is loose stools only, OK? You're going to be using the MDRO and CDI module protocol within the NHSN patient safety manual. The required locations include fac-wide for our freestanding IRFs and IRF units within an enrolled acute care or critical access hospital.

The setting will include adult or pediatric inpatient or outpatient location. Again, I don't think this applies to any of you but I do want to mention it for CDI – reporting for C. difficile LabID Event Reporting. It does exclude any locations that predominantly have babies. I'm not sure that that's going to apply to any of your facilities but I just want to make a note of that just in case.

So, if it does apply to you, again, please reach out to us and I will be happy to provide you with additional information. So, the definition of a C. difficile-positive laboratory assay is a positive laboratory test result for C. difficile toxin A and/or toxin B, OK, but it does include molecular assays or PCR testing that you may be familiar with.

The definition also includes toxin produces C. difficile organism detected by a culture or other laboratory means, performed on a loose stool specimen. Again, remember, you're only going to want to test on unformed stool specimens that are going to conform to the shape of the container. And our guidance to our acute care facilities is that they institute a lab policy that the lab will only test C. difficile on unformed stool specimens and that puts babies some chart review time because then you know every toxins that is positive has only been tested on loose stool specimens.

I also have a slide deck for you, just some common diagnostic test and if it represents a toxin test or if it does not. I put this in here because I do get some questions especially from the newer I.P.s that aren't as familiar with LabID or excuse me, with C. difficile. So, this is in here if you need it.

And the definition of a C. difficile LabID Event, this is very similar to MRSA LabID Event and that the 14-day rule applies. So, it's a toxin-positive C. difficile stool specimen for a patient and a location with no prior C. difficile specimen result reported within 14 days for that patient and location, OK?

This is also referred to as non-duplicate LabID Event. I just want to mention something about the 14 days. Again, it's per location, meaning that if the patient has a stool specimen or MRSA blood – or excuse me, has a C. diff or MRSA blood collected from unit A on 1115 and then they transfer to unit B

on 1215 and have another positive, you would report both of those because the positive occurred on two different units, that 14 day starts over every time the patient transfers to a new unit, OK?

And just like for MRSA bacteremia, I have some algorithms available for you in this slide that I think will be helpful. So, the next thing I'm going to talk about is how to enter a LabID Event for *C. difficile* is very similar. Again, you're going to go to your event, you're going to click Add. You're going to for your event type is going to be LabID or laboratory identified MDRO and CDI event type.

You're going to include the date that a specimen was collected and when you go to location, make sure the location that you'll enter is the location of the patient at the patient that specimen was collected. Your organism type will be *C. difficile*. The specific body site is going to be digestive system and all of that is going to pre-populate for you once you select *C. difficile*.

Stool specimen is going to be your specimen source. And again, the same admission to facility rule applies. If you are a freestanding IRF, the date admitted to the facility will be the calendar that the patient is admitted as an inpatient to your freestanding IRF. If you are an IRF within a hospital, the date admitted to the facility is actually referred to the date admitted to that hospital.

OK? You're going to have the same additional questions when entering a *C. difficile* LabID Event. The categorization for *C. difficile* are the same but we had expanded categorization. So, we still have health care facility onset which is a LabID Event specimen collected greater than three days after admission into the facility.

And so that's on or after day four facility or location. And then, community onset is exactly the same as MRSA bacteremia, that's a LabID Event specimen collected in an outpatient location or in an inpatient location in three days or less after admission to the facility or units, so remember day one, day two or day three counts as community onset.

But then for *C. difficile*, we have additional categorization. So, for your community onset categorizations, you also will have community onset healthcare facility-associated or CO-HCFA as we call it.

And what that is, is that's a – that's a community onset LabID Event, those collected from a patient, who was discharged from your facility in four weeks, equal to or less than four weeks prior to the date at that current stool specimen. So, what this additional – your facilities are not penalized when it comes to CO-HCFA but it just allows you to track your prevention efforts outside of your facility if you want to.

And then, NHSN will further categorize *C. difficile* LabID Event based on the specimen collection date and prior specimen collection date of a previous *C. difficile* LabID Event for the same facility. And this pertains to previous *C. difficile* LabID Events entered in the NHSN for that patient in that facility.

So, those two categorizations are incident CDI assay and that's any *C. difficile* LabID Event from a specimen obtained greater than eight weeks after the most recent *C. difficile* LabID Event for that patient. A recurrent CDI assay is any CDI LabID Event from a specimen obtained greater than two weeks but less than eight weeks after the most recent CDI LabID Event for that patient.

I know that this is a lot to take in especially with you not having the slides in front of you. So, if you guys have any questions at all, please do not hesitate to send me some questions of NHSN mailbox. And I promise you will eventually get it.

OK. So, what CDI data are reported to CMS, again, this is very similar as what I've already mentioned for MRSA bacteremia, all in-plan health care facility onset CDI LabID Event data from participating IRF. So, for our freestanding IRF is going to be your facility-wide inpatient. CDI health care facility onset incidence rate, again, which is defined as a non-duplicate *C. difficile* LabID Event identified greater than three days after admission to that freestanding IRF.

And then for IRF unit located inside of a hospital, acute care facility or a critical access hospital, the CDI health care facility onset incidence rate for all CMS-certified IRF units combined. And Charles, there's another typo in this slide on slide 79.

Charles Padgett: OK. Where is that on 79?

Angela Anttila: At the bottom, the last sentence where it says (inaudible) three days after admission to the facility...

Charles Padgett: To be units.

Angela Anttila: It should be units.

Charles Padgett: OK, thank you.

Angela Anttila: OK, thank you. OK. And just another reminder, same as for MRSA bacteremia, you are going to want to report your community onset LabID Events as well as your health care facility onset LabID Events, OK?

That's a must so that the analysis can be done correctly for your facility. OK. In your slides, I put some common questions and answers that I received from acute care facilities that I think may be helpful for you. Just to kind of to summarize some of these questions. Just remember signs and symptoms are not applicable to LabID Event reporting, so even if a patient presents to your facility with diarrhea on admission but your facility too does not test that patient for five days, your facility will still be penalized for that.

And as it will be categorized as a health care facility onset *C. difficile* case, OK? So, remember, what's important is the admission date and the specimen collection date. OK. I'm going to review now some of the important bullets for *C. difficile*. OK. So, for our freestanding IRF, remember that *C. difficile* LabID Events must be reported at the facility-wide inpatient level, FacWideIN which includes reporting LabID Events from each mapped non-baby unit within unit inside that IRF facility.

Your denominators will be facility-wide denominators, summed across all inpatient IRF locations within that freestanding facility which is will be your total facility patient days and total facility admissions. And again, you will for your denominator reporting, we'll select FacWideIN as the denominator location.

OK? Remember the only loose stool should be tested for C. difficile and we do recommend that you speak with your laboratories about instituting a policy for testing loose stools only. And then, the 14-day rule applies to both C. difficile and MRSA bacteremia. Remember, it's no previous positive laboratory result for that patient in that location within the previous 14 days.

For our IRFs located inside of a hospital, I just want to reemphasize that location specific reporting is required which means numerator and denominator counts are reported separately for each CMS IRFs unit inside the hospital. OK? Let's see here.

OK. So now, I'm going to move on to denominator reporting. Let's see. So, for denominator reporting, this is going to be different than what you're used to with your CAUTI reporting. You're going to click on Summary Data on the left hand side of the screen and then you're going to click Add. So first, I'm going to start with IRF units within a hospital.

So, if you're an IRF unit within a hospital on the summary data entry screen, you must select CMS IRF unit as the location for which you're entering the summary data. And you can do this by clicking on that dropdown menu located next to Location Code. After you do that, you will select the appropriate month and year and then, you're going to have some summary data fields populate for you and these are required and that is where you're going to enter your specific patient date and facility admission.

And I want to let you know that we're working on additional guidance for IRFs and so stay tuned for that and you will get some very specific guidance how to enter this denominator data and what data goes in, into each individual field. And there's a denominator data for freestanding IRFs is very similar,

except for the location code, instead of selecting that individual IRF location, you're going to select FacWideIN as your location code, OK?

So, just to repeat, for freestanding IRFs on your denominator, for MDRO and CDI prevention process and outcome measure screen, you will select FacWideIN as your location code, OK? Then you will select your months and then your year and then you're also going to have several different boxes pop up for you to enter a denominator data.

So that's going to include total facility patient days, total facility admissions and so forth. Again, we're going to be providing you with additional guidance. It's a little bit challenging to explain this screen to you – with you all not having the screenshot in front of you but I promise we will make sure that this is crystal clear to all of you before reporting starts.

OK. So, the last thing on my checklist that I want to do is walk you through how to resolve alert if that should happen to you. Because as many of our acute care – if any of you work – also work on acute care, you could probably relate to this alert because I know that they frustrate some of our users, especially if you're not quite sure what to do with them.

So, once you had identified and reported your MRSA bacteremia and your C. difficile LabID Events during the month, you are finished with this particular step. Now, if you did not identified any LabID Events for MRSA bacteremia or C. difficile at the end of the month then you must indicate this on your summary data record. And this is very, very important because if you skip this, then your data will not be shared with CMS.

And on the slides, you're going to see I put a screenshot on here that's going to help you. So, on the summary form, you will actually go into this and you're going to check the boxes as Report No Events. And you will check this for any C. difficile or MRSA LabID Events section if you did not report any LabID Events for that organism for the month, OK?

If you – let's say, you decide to if the 25th of the month and you did not have any LabID Events for the month and you go into this form and you click on

Report No Events for C. difficile, Report No Events on MRSA bacteremia and you're just feeling really good about your facility. And then, all of a sudden on the 28th, you get a LabID Event.

You don't have to go back in and uncheck your selections. The application will automatically do that for you, OK? So, no worries about that. Once you check Report No Events, if you do enter events after that date, the application will automatically remove the checkboxes for you to save you some time.

For the freestanding IRFs, you will be selecting a Clostridium difficile test type quarterly. So, it's going to be the last month of each calendar year quarter, so it's March, June, September and December. Again, you don't have to memorize that. It's in the slides for you. So, just be aware of that.

I just want to let you know that the CDI test type is very important as it's going to allow for future risk adjustment of your data. I want to caution you too very friendly, use the other box. If you can find a more appropriate response available on the form because if you select "Other" then you may have your data incorrectly risk adjusted. So, just caution you against that.

Only use "Other" if you know for sure there is not another specific laboratory name for the C. difficile test that your facility performed. Most likely and in most cases, your specific facility test will be located on that form. And if you have questions about that, if you're not sure, just shoot us over an e-mail in the NHSN box, we'll be happy to look that up for you.

I want to let you know that there is a LabID Event calculator available for use in the application and it is available on our Web site under the MDRO and CDI page. It is an external calculator, meaning none of the data goes into NHSN. It's just kind of like a calculator that's there for your convenience.

And it really aids in decision making around the 14-day rule. What I have found is that this calculator is most useful to new I.P.s or I.P.s that are just beginning to learn LabID Event Reporting. I.P.s that have been using LabID Event Reporting have more experience with it. The calculator is less helpful for those groups of folks.

I have screenshot on the slides for you. I think it's going to be pretty complicated for me to try to walk you through this calculator without you see in the picture, but the slides are very detailed and give you exact details and walks you through each step of using this calculator.

And again, once you start using this, if you have questions, please send an e-mail to the NHSN box and we will be happy to help you and guide you through this process. But I think that if you have not entered LabID Event reports previously, this calculator will be very helpful to you.

OK. And so that is it for my slides. So, Charles, do you have some wrap-up that you need to discuss before we open it...

Charles Padgett: Yes, yes, thank you very much. Quickly, I'm just going to let people know so that we have a few minutes for some questions, the last few pages of the slide deck has some resources, e-mail and Web site resources that are available for everybody that have our IRF Web site listed, our e-mail – IRF's e-mail, if you have questions following this open door forum for MRSA CDI specific questions about the protocol, how to report, that sort of thing, we're going to ask that you e-mail the cdc@nhsn@cdc.gov.

If you have questions surrounding the requirements, the deadlines, the quarterly deadlines, so questions such as those, please by all means feel free to reach out to our IRF's help desk at irf.questions@cms.hhs.gov and then there's also a link listed on here. We even to go sign up for LISTSERV's notification and some other important information for you. So, I have checked the Web site. I apologize. The slides not come out during this open door forum.

They said it would be up this afternoon at the very latest. And as I said, the audio of this open door forum will be available to you next week. And of course, you'll then have the slide deck and OK, so now, we're going to move on to some questions from the participants and I will hand it over to the operator I believe.

Operator: At this time, I would like to remind everyone, in order to ask a question, press star then the number one on your telephone keypad. Please limit yourself to one question and one follow-up. We'll pause for just a moment to compile the Q&A roster.

And our first question comes from Chet Bhasin, your line is open.

Chet Bhasin: Thank you. In going back to – we're a hospital-based unit and that's where I'm coming from. In the 14-day look back, when you're factoring in the day of admission when the patient at the hospital and then they have the inpatient rehab admission. What do you do in situations when you have a patient that's come from an external hospital, not your host and then they're admitting to your rehab units?

Angela Anttila: And so, that's a great question. So, the categorizations do not cost between facilities for the date that that patient is transferred into your facility will be the admission date. And if they're transferring directly into your IRF units, then that will be the admission date for your facility as well as for that IRF unit.

Chet Bhasin: So, we should for – So, just for clarity, any patient that is coming from outside of our host hospital, we should more or less think of ourselves as a freestanding for those patients?

Angela Anttila: Yes. So, it's really the – So, you're saying if they're transferring indirectly into your IRF unit, right?

Chet Bhasin: Right. Like we're a hospital-based unit and let's just say, you know, and it's known as Texas Health Dallas and let's just say the hospital ABCD down the street is – sends a patient over which happens and I'd like to know, do I consider the admission day that the hospital ABCD to be the initial admission date or do I consider the admission date into my IRF to be the admission date for the 14-day...

Angela Anttila: So, the admission date will be that calendar date that that patient is admitted either into the facility or that IRF unit whichever comes first.

Chet Bhasin: OK.

Angela Anttila: That makes sense?

Chet Bhasin: Yes.

Angela Anttila: OK.

Chet Bhasin: Thank you.

Angela Anttila: And it could be the same day, if it's a direct admission into the IRF and that's OK.

Operator: And our next question comes from the line of Stephanie Borngesser, your line is open.

Stephanie Borngesser: Hello. We are a hospital-based unit as well. And my questions comes from the – or current state of reporting FacWideIN MRSA bacteremia and CDI LabID Event for again in FacWideIN. And now that we have to carve out the rehab population, do we need to remove that from our FacWideIN data as well?

Angela Anttila: Yes. Great question. So, you don't want to do it now but for 2015, you're going to see quite a bit of changes coming including some changes to your acute care side as well. But yes, you're going to want to remove the IRF unit, the CMS IRF unit from your FacWideIN data for your hospital and you're going to report that IRF as a location-based reporting.

Stephanie Borngesser: Thank you.

Angela Anttila: You're welcome.

Operator: And our next questions comes from the line of Kimberly McHatton, your line is open.

Kimberly McHatton: Hello, yes. I was just hoping to get the web address again to be able to download the PowerPoint presentation for today.

Angela Anttila: OK. So, Charles?

Charles Padgett: Yes, sure. So, the PowerPoint presentation is located and it's not up yet. I'm telling – I've just checked, so but it should be up this afternoon. But it will be located on the IRF Quality Reporting Training webpage. And in order to get to that, the easiest way – I mean it's a very long web address to give over the phone.

So, the easiest way for you to get to it is to just Google IRF Quality Reporting Program. And the main IRF Quality Reporting webpage will be the first hit when you Google that and it's the cms.gov Web site. Just click on that. That will take you to the main webpage and then, you can get to the training webpage. It will be a link that's available to you in the upper left hand corner of that main webpage, you'll see a link that says Training and you just click on that.

And the PowerPoint will be available to you on the Download section of that training webpage.

Natalie Highsmith: And also, this is Natalie. The web link is included in the call announcement that was sent out on the LISTSERV but it should be in that paragraph right before the dial-in information is listed.

Kimberly McHatton: OK. Thank you.

Angela Anttila: Charles, this is Angela. Is there any way that you can postpone posting those slides for an hour or two just so we've got a couple of minor changes that we would like to tell you about before the users get the slides, just to avoid any confusion.

Charles Padgett: Yes, OK. Let's talk after this.

Angela Anttila: OK.

Kimberly McHatton: OK, I didn't...

Charles Padgett: Do we have another...

Operator: Ms. McHatton, your line is back open.

Kimberly McHatton: OK. We are a freestanding rehab facility but we do have a skilled unit within the IRF. So, the reporting data will not include those patients, correct?

Angela Anttila: Correct. And we are working on some guidance document because what you'll need to do is also exclude the denominator count, you know, the admissions and the patient day for that skilled nursing unit as well.

Kimberly McHatton: OK. All right.

Angela Anttila: And so those you – you will not find a lot in my slides about that and our guidance documents aren't quite ready yet. So, if you have any questions, if they'll become ready, just send me an e-mail at the NHSN mailbox and I'll help you with that. But we will be having some specific guidance coming up soon.

Kimberly McHatton: Thank you.

Operator: And our next questions comes from the line of Debby Bedford, your line is open.

Debby Bedford: Thank you. My question was already answered. I was trying to get the information about how to get to the slides. Thank you.

Angela Anttila: You're welcome.

Operator: And again, if you'd like to ask a question, that's star one on your telephone keypad. And our next questions comes from Valerie Kohn, your line is open.

Valerie Kohn: Yes, hi. I'm wondering if you can please review the fetus test types what's acceptable just so we can confirm that the lab is using the right method.

Angela Anttila: Yes. So, what you're going to want to make sure is that you're just looking for your test types that are looking for on toxin. The main difference I think is

when you're comparing difference between antigens and toxins. So, for C. diff, it has to be toxin-positive.

And then, there are a variety of test types. Let me just get back on the slide what page I have that on here. And you know what? Our protocol in our Web site, I have it on our Web site as well. Let me just pull that. Let me find this.

You know, of the top of your head what test types you guys are using and I may be able to just tell you.

Valerie Kohn: Sure.

Charles Padgett: I think it's on page 71, Angela.

Angela Anttila: Thanks. I found it. Yes, so what's in – and there may be more than what's on this slide. These are just the most common ones that I found. So, for example, the GDH test alone detects antigen so you're going to want to make sure your lab is doing the toxin EIA or PCR testing. They may also be doing culture, maybe not – we don't see that as much.

And then, you know, also less frequency would be the cell cytotoxicity neutralization assay which is CCNA. But what you're going to want to look for your – in your lab is probably EIA or NAAT or PCR.

Valerie Kohn: So, it has to be toxin-positive, not antigen-positive?

Angela Anttila: And they can test for antigen but then they have to also test for toxin as well.

Valerie Kohn: Thank you.

Angela Anttila: You're welcome. A lot of the facilities will do a two-step and we see that quite often.

Operator: And we have no further questions in queue, I'll turn the call back to the presenters.

Charles Padgett: OK. All right, I just would like to thank everybody for attending today's special open door forum. I hope it's informative. Again, I just want to extend my apology about the slides, not the posted prior to this event. As I said, I do expect them to be up this afternoon and no later than that and we will also be posting information about the – how to get to the transcript and the audio recording of this open door forum on our Web site.

And there is a link to those areas on the announcement if you did receive that but we will also be posting this on our Web site and so that all of that information is available to you. Again, if you have questions about MRSA or C. difficile and specifically related to the protocol or the lab testing, that sort of thing, we're going to ask that you contact the CDC directly.

You can contact the NHSN help desk at nhsn@cdc.gov and for other questions surrounding deadlines, timelines, requirements for the IRF QRT Program; you can e-mail our help desk at irf.questions@cms.hhs.gov . Again, thank you for your time and we hope to talk to you soon.

Operator: This concludes today's conference call. You many now disconnect.

END