

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**Hospital-Acquired Conditions (HAC) and Hospital Outpatient  
Healthcare-Associated Conditions (HOP-HAC)  
Listening Session**

**Conference Leader: Tom Valuck**

**December 18, 2008  
10:00 am ET**

Operator: Good morning. My name is (Mindy) and I will be your conference facilitator today. At this time I would like to welcome everyone to the Centers for Medicare and Medicaid Services Hospital Acquired Conditions and Hospital Outpatient Healthcare Associated Conditions listening session.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks there will be a comment session. If you have a comment during this time simply press star then the number 1 on your telephone keypad. If you would like to withdraw your comment press the pound key. Thank you. Mr. Herb Kuhn. You may begin your conference.

Herb Kuhn: Thank you very much operator. And good morning everyone. I am Herb Kuhn. I'm Deputy Administrator here at the Centers for Medicare and Medicaid Services. And I want to welcome everybody to our Second Annual Listening Session on Hospital Acquired Conditions and Outpatient Healthcare

Associated Conditions.

Joining us in this particular session as we did last year is the Centers for Disease Control and Prevention. And new this year and we're pleased to have them help us sponsor this event this year is the agency for healthcare research and quality. So welcome everybody.

We invited you here today to get your thoughts about the changes in the 2009 Medicare inpatient and outpatient payment rules aimed at reducing hospital acquired conditions and of course the so called never events and of course to lay the groundwork for rulemaking for 2010.

But this conference I think as most people know who participated in our conference last year is more than just about payment. For that matter, it's about more than hospital acquired conditions and never events.

It's really getting the most value out of healthcare that we can for Medicare and Medicaid beneficiaries but for everyone who acts - accesses the healthcare system across this country.

I think as people know for close to four decades now Medicare payments, Medicare reimbursement for that matter, has been based on resource consumption and volume. Basically the more the provider does the more the system continues to pay.

Our payment system for all intents and purposes has been on autopilot, paying for complications when things go wrong because there's been no connection between healthcare's value and what it costs. And our costs as people now have been skyrocketing.

You've heard these numbers before but they're worth repeating. I think everybody knows right now we spend more than \$2 trillion in this country on healthcare. A decade from now that's expected to double to over 4 trillion or almost 1 out of every \$5 in our economy will be devoted to healthcare.

But basically to put a little bit of a different spin on this let me give you some sense and size of the scale of healthcare particularly for the programs operated by CMS when you look at some of the current news items that are out there today.

And that has to do with some of the loan guarantees and some of the rescue packages that we're seeing.

Loan guarantees for JP Morgan's purchase of Bear Stearns was \$29 billion. That's about 2-1/2 weeks of spending for our combined programs here at CSM.

The loan package for AIG initially was \$85 billion. That's about six weeks worth of spending for our combined programs here at CMS.

The banking rescue package was several hundred billion dollars. That's about 2-1/2 weeks or one year two weeks of spending for CMS.

And then the one of course the one that's all in the news right now, the auto industry rescue package, about \$15 billion, about a week and a half of spending.

So what we do here today, what we do here in 2010 on this next regulation really does matter.

Now obviously in that regard our priority here at CMS is the well being of the 90 million elderly disabled and low income Americans who access our programs.

So the question before us is how do we reconcile escalating costs with making sure that each and every one of the beneficiaries of all these programs Medicare, Medicaid and SCHIP have highly reliable, high quality healthcare every time they access the system?

And obviously that brings us to the issue of value based purchasing. We've been working very hard here at CMS to integrate our payment systems and quality initiatives to maximize the value of the Medicare dollar.

We're establishing explicit payment incentives to grow better quality and avoid unnecessary healthcare cost.

And what you've been seeing us systematically do over the last several years is change the role of CMS from nothing more than just a passive payer to an active purchaser of high quality efficient care.

And paying for results is part of the issue of value based purchasing. So not paying for care that harms patients is part of this as well. And while payment is the means, it's not necessarily the end of what we're trying to do here. The effort is really about quality of healthcare and human lives as we go forward.

And to give you some numbers to get a sense of some of the scale of the things that we'll be talking about today, you know, as you look at the 21st Century healthcare in this country, if you're being treated for one serious health issue, getting treatment shouldn't put you at risk of going home with a new unrelated issue.

And that's equally as serious as the condition that first brought you to the hospital, the out patient center as you went forward.

And so again, let me give you a sense of the extent of the problem that we all see across this country.

CDC will tell you they've estimated the number of hospital associated infections at approximately 1.7 million -- more than four hospital associated infections for every 100 inpatient admissions.

(Arch) will tell you that preventable errors are behind the death of one of every ten patients who died within 90 days of surgery.

According to the Journal of American Medical Association, JAMA, 92,000 or 42% of drug resistant MRSA infections were hospital acquired in 2005. Approximately 19,000 people died as a result.

And the Leapfrog Group found that close to 90% of over 1000 hospitals they surveyed did not consistently follow recommendations to prevent many of the most common hospital acquired infections.

In fact only 36% of the hospitals for example, had procedures to ensure that staff actually washed their hands.

Now there is enormous appetite for the policy changes we've been moving on so far and for the ones we're going to talk about today.

People want and deserve reliable high quality efficient care that's out there. And we're just extraordinarily grateful and pleased with the leadership that

the healthcare community has provided in this area as well.

And to give you an example of that, nearly 2300 people let us know that they wanted to participate in this program today. Most of them are by phone but we have many in the auditorium here in Baltimore today.

And this broad based consensus that's been bringing us along has really made a lot of difference and a lot of progress over the last couple of years.

If you look at the most recent inpatient perspective payment rule, the final rule, you notice that we added three additional hospital acquired conditions to the eight that were already on the list.

We also this past year asked state Medicaid directors to look at the IPPS rule and begin to incorporate those kinds of changes in those 11 conditions in their Medicaid programs. And over 20 states now are beginning to move in that direction or have already acted in that way.

We've begun the process to use our national coverage determination policy to look at so called never events. And people know right now that we have open in CDs. The comment period will close in about ten days on looking at surgery on the wrong body part, surgery on the wrong patient and wrong surgery performed on a patient.

And if you're wondering whether this continued effort, this issue of really trying to drive the reliability of care through hospital acquired condition payer policy and other issues dealing with value-based purchasing, if all this will end at the end of this administration, I just really ask people to look at the two reports that were issued on Tuesday of this week by the Department of Health and Human Services Office of Inspector General.

And the work I think was CMS, CDCR, many of the stakeholders in this room have really sparked a serious nonpartisan look at this issue by the OIG.

In fact these reports are the first in a series of six that will I think inform and provide the backdrop for the new administration when they move on - when they come in next year and begin looking at these policies - as they begin looking at these policies.

But in that regard today, what we really are trying to do is continue to move forward. CMS in particular hopes to set the stage for reforms which will be part again of the 2010 rulemaking cycle.

And obviously we'd also like to get your thoughts today in terms of expanding this policy into the outpatient setting as people know that read the final outpatient rule that would put out on November 1, we did talk about this issue and the importance of not only taking this policy from the inpatient side to the outpatient side.

So I think those that have looked at the agenda know that we have a full day planned. Again, I'm delighted that we're joined by some of our colleagues from CDC, (Ann Haddox), Chesley Richards and (Donna Pickett). And then from (Arch) we have (Irene Frazier) and (Ann Lichshouser) will be with us as well as well as many experts within CMS that you'll be talking to and interacting with today.

This morning as you look at the agenda it's focused on the inpatient side. And of course this afternoon is where we'll break into new ground to talk about the issues in the outpatient setting.

So in conclusion what we're all about here today is a real good collaboration I think with public health officials from CDC, (Arch), the folks from CMS and with the provider community, to see while we continue to work together to drive quality, reliability of care as we go forward to continue to help CMS in this major transformation that we're going through that is the change from being in a passive player to an active purchaser of high quality efficient care.

So with that I'm pleased now to turn this program over to (Ann Haddox). And I think (Ann) is with us - available by phone. So (Ann)?

Man: Operator, is (Ann Haddox) is available on the line to address the group?

Herb Kuhn: Operator, did you hear that? Is (Ann Haddox) available?

Operator: One moment. Let me see if she's on the line.  
Thank you.

Herb Kuhn: Thank you.

Operator: I don't see her on the line.

Herb Kuhn: Okay. Then we'll see if we can get (Ann) in a little bit to continue. But meanwhile I'm going to turn this over to Dr. (Tom Valuk) who will take us forward from here. (Tom)?

(Tom Valuk): Thank you Herb. I'm (Tom Valuk). I'm the Medical Officer and Senior Adviser in the Center for Medicare Management. And I'd just like to begin by thanking Herb Kuhn, our Deputy Administrator who's provided such strong leadership on this and the other value based purchasing topics and Dr. (Jeff Rich) who's here who's the director of the Center for Medicare Management



where I work and who's going to be addressing you later on the hospital acquired conditions that have been selected particularly mediastinitis which is in his specialty area more likely to be addressed in his specialty area.

And if (Ann Haddox) joins us at some point in the conversation, then we will go to her and take welcoming comments from the Centers for Disease Prevention and Control.

So we'll see if maybe after the end of my opening remarks here if (Ann) still available. So welcome to all of you. As Herb said, we have about 2300 people signed up to participate today, about 150 or so in the room, and the rest on the phone. And we really appreciate your engagement.

We're working off of the slide presentation that's been posted on the CMS Web site. It's on the hospital acquired conditions page.

So if you'll use your search engine to look for CMS and hospital acquired conditions you should find the hospital acquired conditions and present on admission indicator Web site. And in the resources section, educational resources section you should find the presentation for today.

I'm beginning on Slide 4. And we'll move along through an overview of how our value based purchasing sets the stage for the particular value based purchasing initiative that we're going to be addressing today. That's the hospital acquired conditions provision for inpatient services and healthcare associated conditions for outpatient services.

This is a presentation overview. We'll begin by talking about our principles for value based purchasing, what we're trying to accomplish here and then our demonstrations and pilots to study the most effective way to apply the

concepts and then some background on the actual provision at hand, the hospital acquired conditions provision.

And then turn it over to some of our quality experts here at CMS and experts from CDC who are going to be talking about the specific conditions that have been selected.

This is the vision from our quality improvement roadmap, the right care for every person every time with attention to the six key dimensions of quality that you see listed here.

And this information is consistent with the direction that the Institute of Medicine has provided for quality of American healthcare in the Crossing the Quality Chasm Report and subsequent work on quality.

Under the vision then we have the strategies that we're pursuing. You see that one of the five key strategies is value based purchasing, improving quality and avoiding unnecessary costs through the use of our financial incentives.

But we also have other principles to pay attention to for as we go about implementation. Working through partnerships, collaborative work like that we're engaging in today to get your input into our policymaking, measuring quality and reporting comparative results, so both the measurement and transparency aspect.

Using our incentives to encourage the adoption of effective health information technology and then using that technology to gather quality measurement data and give feedback to providers of healthcare and to promote innovation by using the information that we're receiving through measurement to construct an evidence base for the effective use of technology.

So we have the vision and the strategies. But why are we moving in this direction? Well I think as many of you, our quality experts, you'll understand the opportunity for quality improvement -- that's been well documented -- and also the opportunity to avoid unnecessary costs in our system.

The thing that I always mentioned as a takeaway from this slide is that CMS recognizes that our payment systems are a big part of the problem, that there are incentives inherent in our current payment systems that need to be changed in order to better align with the goals that we have in the vision and the strategies that we have just reviewed.

So we're working to transform the Medicare program from simply being a passive payer to being a more active purchaser of higher quality more efficient healthcare. And we're using the tools that are a part of our statutory authority in order to pursue that goal.

Those tools include measurements, payment incentives, public reporting. Herb Kuhn mentioned conditions or mentioned coverage policy. Conditions of participation are like structure standards. We have the QIO program for direct provider support.

So we currently have for hospitals, physicians and home health agencies pay for reporting programs. And we're moving to pay for performance programs. And in fact the hospital acquired conditions provision is a pay for performance program.

We also have a plan for hospital value based purchasing or pay for performance that's been submitted to Congress just over a year ago. And we're now working on a plan for physician value based purchasing.

We also through our demonstration programs are looking at other mechanisms to tie performance to payment such as gain sharing, competitive bidding, bundled payment, coverage. And I mentioned coverage decisions and direct provider support.

So why the attention here? Why the urgency? Well Herb Kuhn mentioned the financial situation of our Part A trust fund that we are now projected to potentially be depleted by 2016.

So even though this is a fairly new slide in the slide show it's already out of date given our financial situation and the continuing growth in health spending.

And the impact is particularly severe on our beneficiaries. You see that nearly 1/3 of Medicare - nearly 1/3 of Social Security checks for our beneficiaries are consumed by or will soon be consumed by Medicare premiums, deductibles and cost sharing.

So this picture has led to broad and deep support for value based purchasing for Medicare's payment system.

It's obviously been a priority of this administration. But what we see in the product of the President-elect advisers and the Blueprint for Health Reform, what we see in Senator Baucus' whitepaper are signs that value based purchasing will continue to be a priority both for the new administration and for the new Congress.

That would reinforce the congressional interest over the last decade and the strong support for this approach from MedPAC and from the Institute of

Medicine that we've seen in reports that have come out regularly or periodically from those organizations.

And we also have learned from the private sector there are a number of initiatives that are being sponsored by private health plans or employer groups that we're learning from. And then they say that we open the door for them to pursue value based purchasing in the private sector such as through the hospital acquired conditions provision.

So we're pursuing the learning about the implementation of these concepts through our demonstrations and pilots. On this slide you see the demonstrations that are within the various payment systems, the hospital payment system, the premier demo, physician payment systems, the physician group practice and Medicare care management performance demonstration and then other payment systems, nursing homes and home health.

But we also have demonstrations that cross the various payment systems, our Medicare health support pilots, the various care coordination and disease management demonstrations, gain sharing which I already mentioned, the acute care episode demonstration which is about bundled payments, our data aggregation pilots and electronic health record demonstrations as well as the concept of the medical home.

All of these tie some aspects of payments to performance that are giving us good information to inform our implementation of these various initiatives.

And then the initiatives are listed here as the VBP programs. You see that hospital acquired conditions is one of them along with hospital paper reporting program that we have for inpatient and outpatient services and the value based purchasing plan which I previously mentioned.

On the physician side to provide a broader context we have the paper reporting quality reporting initiative. And we're working on physician cost of care measurement and reporting in our physician resource use initiative.

We've also begun the physician value based purchasing plan that will be issued in a report to Congress by May 1 of 2010 as required by the most recent Medicare legislation.

And we have pay for reporting for home health and authority for pay for performance for end stage renal disease. And three sets of the Medicaid programs have some aspect of value based purchasing in their state led payment system.

So this is very broad and deep now. And I wanted to use this slide to give a perspective of where the hospital acquired conditions provision has been.

So why the focus on hospital acquired conditions and patient safety? Well I don't need to spend much time on these next three slides because I think the lay media has reported on this extensively. And for those of us who work in healthcare, we're acutely aware of the problem.

The Institute of Medicine had their milestone report in 1999, 2000, that showed the burden and really drove the point home. And that's been revisited by studies both within the public sector as well as the private sector just confirming the extent of the problem in terms of both morbidity and mortality and cost of care.

And more recently in the Leapfrog Group survey of about 1250 hospitals, the hospitals themselves reported that they did not consistently follow

recommendations for the prevention of some of the most common hospital acquired conditions -- 87% of the hospitals.

So the policymakers see this type of information about the burden of the patient safety problem and have given us authority to use our statutory tools to combat these conditions.

And this is our statutory authority. Beginning October 1 more than a year ago now, hospitals were required to submit a new data field on their claims for payment, the present on admission indicator to differentiate the conditions that were acquired during hospitalization from those that were present at admission.

And then we were also required to select conditions that we would no longer pay the higher DRG for when they were acquired during the hospitalization.

So the statute further delineated our selection criteria for these conditions. They must be high cost high volume or both. They must trigger the higher paying DRG when present as a secondary diagnosis. And they must be considered reasonably preventable through the application of evidence based guidelines.

We'll be talking about the implication of these through the day today.

On the process side then we've worked with our colleagues from the Centers for Disease Control and Prevention and had a cross departmental workgroup as well as representation from across CMS internally to select candidates to propose through rulemaking.

And then we have had three rounds now of rulemaking with public comment

from many of those who I see here in this room.

And we also had a listening session similar to this about - just about a year ago on December 17, 2007. We've gotten a lot of input from you and the various stakeholders. And we've built that into our rulemaking. And that's the purpose of today's meeting as well.

And we're very much looking forward to the day and accomplishing that goal of receiving further input from the stakeholders regarding our inpatient and in consideration of a potential outpatient policy for healthcare associated conditions.

Before we go to the next agenda item I wanted to quickly review the agenda for today and to talk a little bit about how the day is planned to precede.

So the morning session is going to be dedicated to the inpatient hospital acquired conditions. After we check and see if (Ann Haddox) has joined us to provide welcoming comments from CDC then we would go on to our next agenda item which will be CMS and CDC experts talking about the inpatient selected and candidate conditions.

Then we have CMS and CDC experts talking about the present on admission indicator reporting followed by our first public comment session.

We'll be taking comments for a couple of minutes to give everybody who wants to weigh in a chance. We'll start with the folks here in Baltimore. And then after we've taken several comments from Baltimore we will move to the phones.

We'll break at about 12:45 for lunch for just a little bit over an hour. And then



when we come back we will have a presentation from our colleagues at (Arch) on the patient safety indicators and the relationship to present on admission indicator data and spend the rest of the afternoon talking about the outpatient healthcare associated conditions with a review of the rulemaking, then discussion of some candidate conditions and close with another public comment session.

Initially in the afternoon we'll want that public comment session to be focused on the outpatient setting. But as the discussion progresses we'd like to just revert back to general comments, anything that anyone wants to say, especially if they didn't get a chance to say it in the morning session about the inpatient condition.

And then we would plan to close at about 4:30. We will definitely end by 5 o'clock. So that's the order of the day.

A couple of other housekeeping remarks. We are going to be have any formal breaks besides lunch. So for those of you in the room or on the phone, if you need to take a break you should do that at your own discretion.

And for those of you who are on the phone please stay on the line during the lunch hour. And we'll just pick up where we have left off when we return to the room at 2 o'clock.

We're not only taking verbal comments today, informal verbal comments to inform our next round of rulemaking, but we're also accepting written comments. And I'm going to be saying this a couple of times today.

So even those of you who provide verbal comments, we'll be taking notes fast and furious as you'll notice. But even those of you who provide verbal

comments, if you will submit written comments by the end of the month, December 31st to our HAC POA mailbox.

And let me give you the address now and then I'll be repeating this during each of the comment periods.

The comments should be sent to [hacpoa@cms.hhs.gov](mailto:hacpoa@cms.hhs.gov) by December 31.

So with that I would just ask (Mindy Harmon), our operator, if you would check one more time and see if (Ann Haddox) from the CDC has joined us.

Operator: Okay, just one moment.

And at this time I don't show her online.

Herb Kuhn: Okay, thank you very much Ms. (Harmon). And so we will precede along the agenda. At this point Dr. (Jeff Rich), Dr. (Chesley Richards), Dr. Joe Kelly and (Lisa Graber) will be talking about the inpatient selected and candidate healthcare hospital associated conditions.

Joe is going to go first.

Joe Kelly: Welcome everybody. I'm Joe Kelly. I'm a Medical Officer in the Hospital and Ambulatory Policy Group at CMM. And welcome to Baltimore and happy holidays to everyone.

And before I go any further I'd like to thank (Tom Valuk) and especially (Lisa Graber) for all the work they've done in putting this listening session together. It's been quite a project.

The first list of conditions will be the selected hospital acquired conditions that will - or that were implemented October 1 of 2008. And the first eight conditions were selected in the previous rulemaking cycle.

And then the most recent rulemaking cycle we added three more. And I'm that sure most of you are quite familiar with these conditions so I'm just going to read them all.

The first one is foreign object retained after surgery. The second is air embolism. The third is blood incompatibility. The fourth is pressure ulcers, specifically stages three and four. The fifth is falls. And since we had coding issues with falls really we listed a variety of consequences of falls as well as some other conditions which we felt were not appropriate to occur in the hospital setting.

The next set of conditions where manifestations of poor glycemic controls, specifically hypoglycemic coma, diabetic, ketoacidosis, nonketotic hyperosmotic coma, secondary diabetes with ketoacidosis and secondary diabetes with hyperosmolarity.

The seventh is catheter associated urinary tract infections. The eighth is vascular catheter associated infections. The ninth is DVT and pulmonary embolism following specifically total knee replacement and hip replacement.

The next section is selected HACs for implementation. And this is where we'd really like to get your comments and thoughts. And - oh excuse me, haven't finished.

The next set of conditions that will be implemented and were implemented in October of 2008, surgical site infections, specifically mediastinitis after

coronary bypass artery bypass graft, surgical site infections following certain elected orthopedic procedures of the spine, the neck, the shoulder and the elbow and surgical site infections following bariatric surgery for obesity, specifically laparoscopic gastric bypass, gastroenteropathy and laparoscopic gastric restrictive surgery.

Now for the candidate HACs. And again, these are the ones that we really would like to get your thoughts and comments about.

And I should mention that these are all conditions that were suggested by commenters between the MPRM and the final rule of last year and the Web page that's - that (Lisa) has shown are the pages within the final rule where these are discussed.

And these are not as specific. And I think that the reasons for that will become clear.

The first was surgical site infections following device procedures. Specifically it was suggested that we consider surgical site infections following cardiovascular device insertion procedures such as pacemakers and defibrillators but also other device procedures.

The second is failure to rescue which is quite vague but we think is certain preventable surgical complications.

The third is death or disability associated with drugs, devices or biologics which encompasses a wide variety of conditions.

The fourth is dehydration. The fifth is malnutrition. The sixth is water borne pathogens, specifically Legionella, pseudomonas and others.

The seventh is surgical site infections following other procedures, orthopedic as well as non-orthopedic. The eight is ventilator associated pneumonia which has been considered in the past. And the ninth is clostridium difficile associated disease which has also been considered in the past.

But we welcome your thoughts and comments on that during the panel discussion.

Chelsey Richards: Good morning. My name is Chelsey Richards. I'm the Deputy Director CDC's Division of Healthcare Quality Promotion. It's great to be with you. And again, happy holidays to all of you.

Next slide. CDC strongly supports CMS's efforts to align payment and value. We think that this is a critically important policy effort to promote prevention of health - hospital acquired conditions.

We think prevention of these conditions which we've been involved in in a number of areas for a number of years has really been pushed forward in a positive way by CMS's action on hospital acquired conditions.

And we would like to see payment evolve to increasingly reward the application of evidence based prevention strategies to reward transparency of outcomes from hospital reporting and through other mechanisms and to disincentivize most importantly the payment for preventable conditions.

So ideally we are working with CMS to make sure that these payment policies reward prevention and support prevention in hospitals. Next slide.

CDC has a number of efforts related to patient safety ranging from the

National Center of Health Statistic efforts in providing statistics on patient safety related activities to prevention. But I want to highlight the prevention activities because they're focused in four specific areas.

One, we have a large program focused on healthcare associated infections and have been working actively with CMS on that piece of the hospital acquired conditions policy.

We also have programs that work with FDA on adverse drug events and on transfusion and transplant safety. And we have a large program on antimicrobial resistance.

And again, we do a lot of activities at CDC ranging from outbreak investigations, surveillance, funding some research. But prevention is what we're really focused on. And this policy we think is critical in the future for prevention.

Now in terms of the policy itself, it required that the conditions selected be reasonably preventable. And we've all heard the discussions and participated in the discussions of how difficult that is to translate.

But one of the ways to translate is that there are available evidence based prevention guidelines. There are a number of organizations that have these guidelines including CDC.

But one of the key guideline bodies at CDC that supports HHS is the Healthcare Infection Control Practices Advisory Committee. So I just want to spend a couple of minutes talking about that.

The guidelines are developed by professional organizations, task force,

government agencies and academic institutions. And their recommendations increasingly are based on the scientific evidence. And they're developed by scientists and clinicians.

But they're also developed increasingly with an eye towards policy and certainly towards consumers. Next slide.

Now the Healthcare Infection Control Practices Advisory Committee is set up to advise HHS and CDC on the practice of infection control in hospitals. Next slide.

And the HICPAC members are constituted from experts in the field of infectious disease specifically around healthcare associated infections and other related healthcare associated conditions, public health and related fields.

And there are a number of representatives on HICPAC from all the federal agencies including (Arch), FDA, CMS, HRSA and NIH. Next slide.

And then a number of non-voting liaison organizations that include organizations focused on infection control and hospital epidemiology, infectious diseases, surgery and a variety of other professional fields. Next slide.

HICPAC's had a number of guidelines over the last decade or so. You can see here listed the various types of guidelines that have come from HICPAC. Again, these are evidence based guidelines published in the Federal register available from the CDC Web site.

And they form the foundation of infection control in hospitals. These are the guidelines that are used by joint commission's and by other organizations in

terms of certification and accreditation. Next slide.

The guideline process is one that's difficult. So we can't - we try to revise guidelines and put out new guidelines as timely as possible. But in order to have the time to really go through the evidence they do take a while.

We are working to try to shorten that process to be as timely as possible. But it's a tough process to make sure that evidence is completely reviewed and synthesized in a way to provide a guideline that's helpful to hospitals.

These are the future guidelines that are currently being planned and are at various stages of release. UTI - the new UTI guideline is pretty close to release as is the norovirus in healthcare settings, some of the other guidelines that were further away. Next slide.

Many of you may be aware that the GAO - Congress asked the GAO to look into HHS' efforts around healthcare associated infections. There was a GAO report and were two big conclusions.

One, that there were a lot of data bases within the government that needed to do a better job of working together at CMS, at (Arch), at FDA, at CDC.

The other conclusion was that the HICPAC guidelines, there are 13 guidelines with 1200 recommendations. And we needed to do a better job of getting those guidelines into a form that could be more usable for hospitals and even for consumers. And so that's a process that we've undertaken at CDC in collaboration with our various partners. Next slide.

We're moving toward - in some of our guidelines it's been more of a guidance. We're moving toward more of a formal guideline process. And



again, the UTI and norovirus virus guidelines are the ones that will be a little bit different than previous guidelines and are closest to release.

Our objectives are to have more rapid production and updating, easier application and greater transparency and reproducibility.

If you've seen some of these guidelines like for example our environmental guideline for hospitals, it's 300 or 400 pages and a couple thousand references.

And to try to do that every - completely every two years is tough. But we know that only parts of that guideline really change. So we're trying to focus on the parts of the guidelines that are dynamic and change those more frequently. Next slide.

We've engaged the - just the next slide. Next slide.

We've engaged the University of Pennsylvania's Center for Evidence-based Medicine in helping us grade guidelines. So we've moved to the grade system instead of the old HICPAC evidence-based grading system. And the new guidelines will incorporate that system.

And again, the new guidelines will be formed around questions. It will have questioned driven outlines. The three questions focused on a UTI guideline are who should receive urinary catheters making that very explicit based on evidence, what are the factors that decrease risk of infection and what are the best methods to manage urinary catheter associated complications. Next slide.

And this just gives you a flavor of what the new guidelines, how they'll be organized and put out. This is the HICPAC Web site if you want to look in

terms of any HICPAC recommendations.

I just want to end by saying again the CDC, we really strongly support the CMS effort on hospital acquired conditions. We've seen this to be in areas of infection control and hospital epidemiology, really a revolutionary sort of ground shaking time.

And we are seeing hospitals do a lot better and put a lot more effort into prevention of hospital acquired infections. And we hope to have continued success with this policy as we move forward. Thank you.

(Lisa Graber): Thank you Chelsey. I'm (Lisa Graber). And I work in CMS' Division of Acute Care. And I'll be talking today about how we are considering expanding the hospital acquired conditions payment provision and many future considerations that we're taking note of today.

We discussed many of these issues in the Federal register for the last cycle of IPPS rulemaking. And I'm hoping today that we can continue the conversation on how to expand this particular payment provision.

We discussed five different topic areas for the future of this payment provision in the Federal register. The first was on the topic of risk adjustment.

From a payment perspective when we talk about risk adjustment we're really talking about possible payment adjustments to reflect various sources and degrees of individual patients or patient population.

Such examples of the kind of adjustments we could consider are medical history of the patients, current health status and severity of illness. Rather than not paying any additional amount when a HAC occurs, payment reductions

could be related to the expected occurrence of an HAC.

An example could be if the complication is less likely, the payment reduction could be greater than if you were to expect that type of complication.

Also we may be looking at proportional payments to reduce unintended consequences. We're very cognizant of the issue of unintended consequences.

Also support for individual level adjustments. For current technology and resources limits our capacity to do individual risk adjustments but they may be easier to do for us at a sub population level.

Some examples of sub population adjustments can be for patients that have burns, trauma, are immuno-suppressed or (propellative) care. So these are higher levels at which patients may be at higher risk for HACs. And that's one of the things that we're taking into consideration.

The second thing that we discussed in the Federal register related to future considerations for the payment provision is rates of hospital acquired conditions that may possibly be used within a hospital value based purchasing program.

These rates could be included in a measurement domain within a hospital VBP program. They may be more meaningful, actionable and fair on the part of providers and they can change as rates of an HAC versus an individual adjustment on a discharge.

We could determine expected rates of HACs and use them as a benchmark for comparison and reward those who stay at or below the benchmark while decreasing the payment to those who exceed the benchmark.

Some of us elected HACs that we already have in place may lend themselves to being better candidates for (rates) of HACs. And I would appreciate your thoughts today in this regard.

We also discussed uses of present on admission indicator information. We discussed the possibility of combining Medicare POA data with other payer services.

We also discussed how important it is to health services researchers for targeted prevention strategies and best practices.

We mentioned possibly publicly reporting a present on admission indicator data, for example on a resource like hospital compare to better inform decision-making on the parts of beneficiaries, providers, other healthcare consumers, purchasers and caregivers.

We also talked about the use for timely feedback to hospitals for peer comparison on where they are with their POA indicator data.

The fourth topic we discussed in the Federal register was adoption of ITD 10 to more accurately identify hospital acquired conditions.

At this point the ICD time regulation has been cleared to the executive branch but it is pending publication on a Federal register at this point.

The final thing that we discussed in the Federal register was expansion of the principles behind the HAC payment provision to other settings of care. This afternoon we will be concentrating on a robust discussion of expansion to the outpatient setting.

We noted in the Federal register that implementation of principles would be different for each payment setting. However, one of the goals of value based purchasing is to align incentives across all settings of care.

We also discussed expansion beyond just the outpatient setting to several other payment settings and put discussion pieces in each of the following Federal regulations.

We also discussed this in the inpatient rehab facility regulations, the long-term care hospital regulation, the skilled nursing facility and physician fee schedule regulations.

I also just wanted to inform you of how you can be a part of the process for the things that we're considering for the future of the payment provision.

We frequently post updates to the Hospital Acquired Conditions and Present on Admission Indicator Web site. And you will be able to engage in the process of future considerations in both the fiscal year 2010 and calendar year 2010 payment regulations that CMS will be putting out.

Also we update this topic periodically on the hospital open door forums and send out updates to the hospital listserv.

I will now invite Dr. (Jeff Rich) up to talk about the role of specifically one of the HACs, mediastinitis following coronary artery bypass graft.

Dr. (Jeff Rich): Thanks (Lisa). Good morning to everybody and happy holidays to everyone. And thank you for being here. It's a large crowd sounds like both from in the audience and on the phone.

I think mediastinitis really represents the tension that exists in this policy. And I have to personalize it because I do cardiac surgery and I understand what mediastinitis is. And then I have to live with that definitions that are applied and come out of this policy, is it reasonably preventable, and understand that in the practice of healthcare delivery when I do CABGs , I know that eventually a patient will have mediastinitis.

And a lot of that speaks to the fact that we do want to have risk adjustment. I think that we do want to refine the policy as time goes on and that this is an evolutionary process, that we would very much like your input on how to make it better for all of the conditions that we're listing.

It's clear that we don't have all of the answers. But we have a starting point and it's a statutorily mandated starting point. And I hope that you understand from the presentations by now or get the impression that this is a complicated process.

It's not something that everybody at CMS woke up one day and decided these were the conditions. It went through a vetting process and a lot of very thoughtful discussions both from outside sources as well as internally.

We do obviously need risk adjustment in many of these indicators. And I think that what (Tom) had asked me to talk about is what - how I would personalize it and how I would sort of tell you about my experiences in dealing with this at least in the state of Virginia.

As you know, I was a former Chair of the Virginia Cardiac Surgery Quality Initiative which was a consortium of all the surgeons and hospitals that were delivering cardiac surgical care or are in the state of Virginia.

And over time, it's been about ten years that we've been together and it's a quality improvement organization and we share our concerns about the complications and the outcomes that we see in our patient population. And we share our experiences in an open way about the results that we get.

And you can see from the institution to the institution, one institution will be better than another in for instance mortality or strokes and/or mediastinitis.

And probably five years ago it was identified that our institution was the best performer in the state for mediastinitis. And we did presentations and shared our protocols with the institutions are around the state.

And this is all anecdotal. But in the state mediastinitis on the index hospitalization, remember, it's on the index hospitalization as defined by the STS database. It's not soft tissue infection. It's not sterile sternal (dihistine). It's mediastinitis. We had four hospitals reporting no occurrence before we started adoption of the protocol and went to eight hospitals or nine hospitals with no occurrence in an annual period of mediastinitis.

Now recognize that mediastinitis is an event that occurs less than 1% at a time in our patients as indicated by the STS database. And so you already have a good fighting chance of getting from less than 1% to zero.

And I don't - and I looked at the data this weekend when I was back at home, the most recent data. And our hospital has had some cases of mediastinitis after that.

So it will come and go. But the important thing is that we hope that this policy will crystallize in your mind and catalyze the provider community to sort of

begin looking at the protocols that they have in the hospitals for all of these conditions. And we hope that by doing so we can drive improvement as close to zero as possible.

We are not saying these are never events. We are saying they're reasonably preventable. And I think that Chelsey and others from around the CDC and in other places here in the CMS community would agree that although it's not perfect, it's a starting point.

And we do want to refine it. We do want your input to help make it better. And we hope that you'll join us in that effort. Because we think that in the next phase of this we would move to what (Tom) has described was a value-based purchasing system where we have performance measures that can introduce risk adjustment into them.

We hope that as we move into ICD-10 we'll have a better way of risk adjusting patients and that we can create models, even risk adjusted models through our claims database without having to collect this data in a chart in an extracted way that will allow us to provide risk adjustment to look at a benchmark for occurrence of some of these things and then to provide incentives to either achieve that benchmark or super achiever it and get beyond it.

So with that I think I'll turn it over to Herb Kuhn.

Herb Kuhn: Well thank you to each of the folks who is on our first panel here. I think the preview to the level of expertise and attention that's gone into this particular policymaking and that you'll continue to see throughout the day.

At this point this panel is going to take their seats back out in the audience and



we're going to have another panel which is the coding and information experts, (Mattie Who) and (Sarah Chari Lasso) from CMS and (Donna Pickett) from CDC.

I would just mention as they're coming up as well that (Ann Haddox) was on the line. And unfortunately technology was working against us today. So she wasn't able to give us her welcome from CDC but sent that via email. So thank you for understanding.

(Mattie Who): Good morning. I'm (Mattie Who). And I work in the CMS Division of Acute Care. And what I'm going to discuss is very familiar to those of you in the inpatient side of things. But hopefully it will give a little bit of background for those of you from the outpatient side and for this afternoon to set the stage.

So earlier you heard Dr. (Valuk) mention the three statutory criteria that the inpatient folks had to deal with. And one of those had to do with the conditions that are selected must trigger a higher payment.

So as Dr. Kelly ran down a list you might have noticed that most of those conditions were complications including some infection that can be designated as what we call CCs which stands for Complication of comorbidity or an MCC, a Major Complication of Comorbidity.

And all the diagnosis within the ICD-9 (stem) classification system may or may not have that designation.

Now the important thing for the inpatient side has to do with the MS DRGs for the HAC provision. The MS DRGs which were implemented last year for the year 2008 may or may not be split based on severity levels.

So for the conditions that are selected it's important that the MS DRGs that they be assigned to has that split so the HAC provision works correctly.

Now for the inpatient setting present on admission is defined as being present at the time the order for inpatient admission occurs.

So any conditions that developed during the outpatient encounter including the emergency department, observation or outpatient surgery are considered to be present on admission for inpatient purposes. And of course that will differ for outpatient which we'll discuss this afternoon.

Now the next couple of slides talk about the indicator reporting option. The POA indicator must be assigned to the principle diagnosis and all secondary diagnoses including any external cause of injury codes or e-codes that would be reported as an additional diagnosis.

There are five POA indicator reporting options, Y, N, U, W and 1. The Y would be assigned to a code to indicate that that condition was present on admission. The N is assigned to indicate no, that condition was not present on admission.

The U is assigned to indicate that the documentation in the medical record was insufficient to determine if that condition was present on admission or not.

The W indicates that the provider was unable to clinically determine whether or not that condition was present at the time of admission. And a 1 assigned as a POA indicator means that that condition is exempt from reporting.

Now this slide discusses the conditions that influences payment adjustment.

So right now CMS will pay for the CC or MCC conditions for selected HACs that are coded as a Y or a W. We would not pay for the CC or MCC conditions for selected HACs that are coded as an N or a U.

And this next slide illustrates some examples for the stroke DRGs. The stroke DRGs have three severity levels. So across the top we have an example. And these MS DRG assignments are examples for a single secondary diagnosis.

So we start out just listing MS DRG 66 as stroke without CC or MCC. And the average payment would be approximately a little over \$5000.

Now if the patient comes in and they're diagnosed with a stroke and they happen to have one secondary diagnosis of an injury, that injury happens to be a CC and it's coded as a yes for the POA, the final DRG would be MS DRG 65 stroke with CC. And you can see the average payment to the right-hand column.

Now if that same patient came in and the injury was not present on admission you could see the payment would be MS DRG 66 stroke without CC or MCC.

And the next example you have a stroke payment patient that happens to have a stage three pressure ulcer that was present on admission. That would result in an MS DRG 64 stroke with MCC. And you can see the difference in the payment amount goes up to \$8000.

If that same payment had a pressure ulcer that was not present on admission it would result back to MS DRG 66 stroke without CC or MCC. And you see the payment adjustment as well.

And now I'll turn it over to (Sarah Chari Lasso) to talk about the life of a

claim.

(Sarah Chari Lasso): Hi. Good morning everyone. I'm going to talk about the life of an inpatient claim. And hopefully this will be a quick overview. But I'll try not to get too technical.

Basically the hospital, your IPPS acute care hospital will submit a claim to the Medicare contractor. About 99% of claims are electronic for Medicare especially in the institutional setting.

And in terms of POA they'll report that POA in the K3 segment of the electronic transaction.

So once the claim comes into the Medicare claims processing system which we call FISS, Fiscal Intermediary Standard System it will go through some very initial editing such as validating all the claim elements are filled out et cetera.

This is where we have our first set of present on admission editing. Effective for discharges on or after April 1 of 2008 we instituted three edits in terms of present on admission.

The first was just to validate that for every diagnosis on the claim that there was a POA present. And in addition - so when - a 1 to 1 match, one POA for every diagnosis.

In addition we wanted to see that the present on admission indicator was also valid. So one of the valid indicators that (Mattie) indicated.

The third we're looking for is that the end of the POA stream ended with a Z

or an X. And those factors will come in in my next couple of slides.

If any of these sort of elements fail the claim is returned to the provider for correction and resubmitted.

After the claim passes all of that we'll go into the Medicare Code Editor. And this software module is developed for CMS by 3M. And that is a system that basically validates and edits ICD-9 coding information for us.

Once all our ICD-9 coding looks good, the claim will pass through to our grouper. And grouper basically is our software that assigns that DRG. It assigns it on the principle of basis and diagnosis coding, demographic information such as the patient's age, facts and discharge status.

For October 1 of 2008 fiscal year '09 we made some modifications to the grouper to look at hospital acquired conditions.

So again, we're going to do some initial editing in the grouper to ensure that the present on admission indicator is included for all diagnosis. And at this point we're going to really need to look at the stream indicator which will be defined as the end of the POA segment.

We're looking for a Z for inpatient hospital acute care and an X for non-acute care inpatient hospitals.

And basically this is going to signal the grouper as to what kind of logic to apply. With a Z we're going to go to the hospital acquired condition logic. If it's an X we're going to go apply the logic in the old method and apply the DRG.

Just as a side note we do - all hospital claims go to the grouper regardless of whether they're paid on that payment system on the DRG system.

The grouper then reviews all the ICD-9 codes and looks at all the hospital acquired conditions to see if they're present. And the codes as they're defined from the hospital on final rule.

Then the grouper is going to adjust the DRG assignment based on whether it's a hospital acquired condition and looks for the presence of the N which is not present at admission or unknown. And this happens when there are no other CC's or MCCs present.

So once we have our DRG we move on to Pricer. And Pricer is a software module that's developed in here and houses CMS that's installed within our standard system for claims processing. And Pricer calculates reimbursement under the IPPS payment methodologies that are outlined in the final rule, the IPPS final rule.

Once we have a payment, the claim moves along its path to the common working file.

And CWF is sort of like the last step of the active claims processing system. CWF is verifying patient eligibility, spell of illness, beneficiary utilization, deductible information, make sure that there aren't any other claims out there for the same patient on the same dates of service -- this kind of thing.

And then finally it authorizes payment if everything looks good.

Once our claim is paid it moves into national claims history which is the - sort of the bucket where a lot of our researchers pull data from. It also moves into

MEDPAR system which is used in setting the acute care PPS rates.

The remittance advice will also go to the provider. We have a summary notice that goes to the beneficiary. And the claim information also goes to the provider statistics' report. And that is also used in cost reporting. And then finally the claim is passed to other payers as appropriate.

So for more information we have two on claims processing type instructions. We have CR change request 5679 which is on (PAC) in POA Web site. That sort of describes how we implemented POA last year.

And in CR 6189 this is the fiscal year 2009 IPPS changes. And that will include some of the HACs and how the grouper works with things like that. Thank you.

(Donna Pickett): I'm (Donna Pickett), the National Center for Health Statistics, part of the Centers for Disease Control and Prevention.

The next few slides I will be covering reporting and guidance for the reporting of present on admission indicators.

The ICD-9 CM guidelines which are a part of the ICD-9 CM classification and adopted as a HIPAA standard are updated annually in conjunction with the update to the ICD-9 CM classification itself. The guidelines are posted on the MCHS CDC Web site and are also published as part of the American Hospital Association's ICD-9 CM coding clinics.

The POA indicator information was published in - beginning in 2007 as part of the guidelines update and was updated again with the October 2008 update to the coding guidelines.

In the body of the coding guidelines there is a statement that we believe is very important which is why we have a slide here to bring this to everyone's attention assuming that everybody hasn't memorized this by heart anyway.

And that is that it's a joint effort between the healthcare provider and the coder to achieve complete and accurate documentation, code assignment and reporting of diagnosis and procedures.

The guidelines, that would be the main body of the guidelines as well as the POA guideline, it's not a substitute for the provider's clinical judgment. And again, this is something I'm sure everybody knows. But it's always nice to restate it and have it in black and white when one needs to refer to it.

Moving to the next slide, resources for POA Coding Guidance. When we did our presentation last year December 17 there were some questions about where people should go to ask questions about POA indicator reporting.

And since that time we now have the cooperating parties which is the American Hospital Association, the American Health Information Management Association, the National Center for Health Statistics and the Centers for Medicare, Medicaid Services being able to provide guidance on the reporting of POA through the American Hospital Association's Editorial Advisory Board for coding clinics.

With the third quarter issue of coding clinics this past 2008 we now are publishing questions in coding clinics providing advice for reporting of POA indicators.

And again, what we're looking at in terms of the guidance that we are



providing, we'll be looking at questions that have been received from the many people that do write to the American Hospital Association who have provided a question and also documentation in support of that question.

In other words, as in the past with other coding clinic determinations and advice, we're not looking for what if questions or a free thinking of how do you do this if. We're looking at actual records and documentation to make those types of determinations.

And we will be continuing as part of the coding clinic publishing questions related to present on admission as questions come in. So I think that's important that everybody knows that there is now a process whereas last year there was no identifiable process for handling the types of questions that had come in previously.

Herb Kuhn: Okay at this point we're going to have our morning panel. So I'd invite Chelsey and Joe and (Jeff) back up to the table here to receive comments.

I want to thank all the presenters for staying on target with the length of their presentations. That created a little bit of a cushion for us here so that we don't have to be particularly rushed in this particular comment session.

So let me just review the ground rules. We're going to ask for comments first from Baltimore. If you would limit your comment to 2 minutes then that will give us a chance to take as many comments as we have here in the room in sort of a first round.

Then we'll go to the phone and then we'll have the operator queue up comments for us and take commenters from the phone.

We will then potentially return back to the room in Baltimore depending on how many comments we have from the phone and take additional comments. And the same people who spoke in the first round can speak again and then back to the phones if we have time.

Recall that we're also going to be taking comments at the end of the day. So if it in fact we get into a situation where not everyone who's in the room or on the phone who wants to make comments on the inpatient hospital acquired conditions provision, if they don't get a chance we can take comments again at the end of the day.

So with that we would take the first commenter at the center aisle microphone please. Yes sir?

(Robbie Bawish): Good morning.

Herb Kuhn: Please introduce yourself and note your organization.

(Robbie Bawish): My name is (Robbie Bawish). I am a clinician and a researcher at Baylor College of Medicine in Houston.

As a triple board certified physician and internal medicine infectious disease and spinal cord injury I experienced a major problem with a variety of inserted medical devices.

And I very much applaud the drive by CMS along with your partners in CDC and (Arch) to change the autopilot status as Mr. Kuhn has so cleverly labeled.

I also would like to illustrate my perspective on this issue by using one of the examples that Dr. Kelly from CMS mentioned. And that's mainly infections

that's treated with Cardiac Rhythm Management Devices, CRMDs which include both defibrillators and pacemakers.

As many of you know we have witnessed a major increase in the frequency of usage of these devices. Over a period of seven years between 1996 and 2003 there was a 50% increase in insertion of these devices. But during that same timeframe there was a disproportionately higher increase in the number of infections. It tripled.

At the present time we estimate that about a half million such devices are inserted in the States, 20,000 cases of infection results from those insertions, and the current annual cost of treatment of those cases of infection are about \$1 billion. So we must do something about that.

Now when I looked at the list of conditions which CMS has already included to be effective for being non-reimbursable as of October '08 it's mentioned three infectious complications -- catheter, (straight BTI), (baso) catheter, blood stream infection and mediastinitis after CABG.

All of these three conditions have had published clinical guidelines for prevention of infection.

For some reason in the area of infections associated with pacemakers and defibrillators, we as clinicians and researchers have done very little. We don't have published clinical guidelines. We don't have standardized definitions of infection. And we do not report rates of infection on a systemic - in a systematic fashion.

And therefore I think that it would be you very wise to establish clinical guidelines, establish clear definitions of those infections, establish processes

to monitor the rate of infection as well as monitor the compliance of healthcare providers with these guidelines.

Only then I think it would be very justifiable by CMS to hold providers accountable for infections because of something they have failed to do or accomplish.

So in summary I think this is a major problem. I think it's going to continue to expand. And I certainly applaud your efforts to do something about it, not just to reduce the cost of health care but very important way, I think this creates a golden opportunity to improve patient care as well.

Herb Kuhn: Thank you for that comment. This is primarily for us to hear your input. But we may engage in a bit of discussion as well.

If there's any questions for clarification or if Chelsey would want to comment on guidelines, process or anything relevant, this would be the time.

Chelsey Richards: I would just say thank you for your comments. I think that the prevention of the types of infections that you're talking about, the principles are scattered amongst the number of guidelines.

But it is an interesting idea that we can certainly talk within HICPAC about whether to have a focus guideline on that particular area. So I appreciate you bringing the topic up.

(Michelle): You know, (Jeff) a month ago actually the United Kingdom through its NHS, the National Health Services established guidelines that specifically address infections arising from defibrillators and pacemakers.

So I think it behooves us to do something similar to that and actually something better than that.

Herb Kuhn: Thank you. Next, commenter please.

Dr. Barry Eisenstein: Good morning. Thank you for the chance to speak. Because I'd like to be concise so I'm going to use notes. My name is Barry Eisenstein. I'm an Infectious Diseases Physician, Former Hospital Epidemiologist, Former Infectious Disease Division Chief and presently Senior Vice President Scientific Affairs for Cubist Pharmaceuticals, a leading anti-infective company located in Lexington, Massachusetts.

I'm also Clinical Professor of Medicine Harvard Medical School, Editor of the Journal of Antimicrobial Agents Chemotherapy.

Cubist supports CMS's value based purchasing initiatives and agrees that it is critical for healthcare providers to establish procedures policies to combat events that are reasonably preventable.

In particular Cubist believes that CMS should continue to exclude staph aureus septicemia and methicillin resistant staph aureus commonly referred to as MRSA within the definition of a HAC that would trigger nonpayment or reduce payment by Medicare as a reasonably preventable condition.

To date CMS has not included staph aureus septicemia or MRSA on the HAC list because CMS has recognized that they are not reasonably preventable conditions.

As has been noted in previous comments, CMS in the FY 2009 IPPS proposed rule providers and payers cannot always determine whether the septicemia or

MRSA infections were hospital acquired or whether the patient had already been colonized by the infecting bacteria in the community prior to the patient's admission to the hospital.

Upon reviewing these comments CMS determined that these conditions could not be labeled reasonably preventable and chose not to include both staph aureus septicemia and MRSA a under HAC.

Given CMS' previous difficulty in differentiating between community acquired and hospital acquired staph aureus and given the risks in morbidity and mortality for the patient and the complexity of successful treatment, Cubist respectfully recommends that CMS continued to not include these conditions as HACs but rather put them in the W category that essentially then would preclude Medicare payment to the provider for treatment.

In closing, I would also like to ask that CMS consider expanding Medicare coverage of home infusion services. And I recognize this perhaps belongs in the afternoon discussion as much as the morning to include payment for services and not just payment for the infused drugs.

As you know, antibiotics used to treat MRSA require daily intravenous infusion over many days. And infusion requires extra supplies and supervision of the healthcare provider.

Currently Medicare fully covers infusion services provided in the costly hospital setting but will only pay for the drug in the outpatient community setting and not for associated infusion supplies and services.

So there's a mixed incentive then to keep the patient in the hospital even though that's more expensive.

If CMS were to allow full coverage of home infusion services and the drug, Medicare would realize significant cost savings and benefits for those patients who could remain in the home for treatment or more readily be transitioned to outpatient care thereby obviating the need for extended and costly inpatient hospital visits. Thank you for allowing me to speak.

Herb Kuhn: Thank you for your comment. Regarding points that were made in rulemaking about staph aureus septicemia and MRSA, we remain hopeful overtime that the guidelines will improve the evidence about the preventability of the conditions through the application of evidence-based guidelines will improve. And we did indicate we will be revisiting potentially some of the candidate conditions that were previously rejected. So I appreciate your comments.

Dr. Barry Eisenstein: Thank you.

Herb Kuhn: Next commenter please.

(Tanya Altaris): Good morning, (Tanya Altaris), The Consumer Purchaser Disclosure Project. I just want to thank you for all your presentations and say that we sincerely support CMS' effort at reforming payment policy to improve patient safety.

It is very aligned with the goal, the patient safety priority area as described by the National Priorities Partnership which states that all healthcare organizations and their staff will strive to ensure a culture of safety while driving to lower the incidence of healthcare induced harm, disability or death towards zero.

They will focus relentlessly on continually reducing and seeking to eliminate all healthcare associated infections and serious adverse events. So I want to

thank you for expanding on the list of HACs that could potentially be in the IPPS.

A few comments. One is that we strongly encourage public reporting of all the non-paid events from hospitals as well as the present on admission data that's collected.

And then in the - on the issue of risk adjustment some of the HACs are considered never events. And in those cases we would suggest that risk adjustment is not necessary since they should never happen.

They, you know, the challenges in some of the other HACs is that they are not necessarily 100% preventable. And we understand that there is a need for risk adjustment. But a never event, the condition of the patient should not necessarily be something that is risk adjusted.

Herb Kuhn: Thank you for the Consumer Purchaser perspective there. Next commenter please?

Dr. (Tammy Lindstrom): Good morning, Dr. (Tammy Lindstrom) on behalf of the Society for Healthcare Epidemiology of America. Thank you for the presentations and great overview.

We'd just like to say that like CDC (Shea) strongly supports the concept of value-based purchasing. We think that aligning reimbursement with quality of care makes sense and is likely to lead to improved and wider adoption of evidence-based prevention strategies.

We also agree that metrics related to quality measures aimed at reducing healthcare associated infections in particular should include both process and



outcome measures.

In December 2007 CMS indicated the intent to collect data and analyze the implementation of POA codes and the new HAC measures for reimbursement. And (Shea) believes this is a very crucial step to ensure the credibility of the process and also to verify the reliability and impact of these initiatives.

And this analysis should include careful study of unintended consequences of HAC exclusions.

For example, nonpayment for the current HAC catheter associated UTI could lead hospitals to screen patients unnecessarily on admission in an effort to document the presence of bacteria in the urine and that is present on admission. And these patients may subsequently receive unnecessary antibiotic treatment which could fuel the development of a resistant organisms or even clostridium difficile infections.

Further, (Shea) believes that healthcare associated infections are better suited to consideration as part of a rate based value based purchasing model than as never events because even though recent literature shows that they can be drastically reduced by implementation of evidence-based practices they're complex and rely on a lot on patient based factors as well and not universally preventable even with implementation of all known evidenced-based practices.

And finally (Shea) would encourage CMS to continue to adopt a framework for rulemaking that's transparent and emphasizes the selection of measures that have sufficient evidence base.

We urge an implementation timeline also that ensures adequate testing and

validation of any future measures and allows time for institutional process change and builds in the evaluation of impact for any future added measures. Thank you.

Herb Kuhn: Thank you for those comments. Regarding your points about the potential unattended consequence of stimulating unnecessary testing and treatment, our expectation is that this policy will simulate collaboration between hospitals and the medical staff of those hospitals to determine the approach that that institution and the affiliated professionals will take in terms of testing and treatment.

We're hoping that the evidence-base will inform that decision-making rather than some knee jerk reaction based on the financial provisions of the payment policy.

But your point is well taken about the need to monitor for unintended consequences.

And certainly one of the themes you've heard from the folks here on the panel is that we are also in favor of rate based measurements and incorporating rate based approaches into our payment model specifically the hospital value based purchasing model that was submitted to Congress a year ago.

Would anyone else like to comment? Okay great. Thank you. Next commenter please?

(Tom Schneider): Good morning. My name is (Tom Schneider). I'm with (Common Tech), a manufacturer of wound and skin care products. Our products are very frequently used in patients who are at risk of developing pressure ulcers in institutional settings.

I'd like to just make the panel aware of an issue that has caused a lot of confusion for our customers and see if I could just clarify the intent of the policy as it regards to pressure ulcers.

We heard this morning and were reminded that only Stage 3 and 4 pressure ulcers are considered MCCs that impact MS DRG payments and POA reporting.

However, we've been made aware of by our customers that there is advice in the current issue of the coding clinic that has confused this issue somewhat for hospital coders.

And the issue, I'll provide a scenario and then maybe ask a question to see if I can clarify the intent is for patients who present to the hospital with Stage 2 pressure ulcer that deteriorates or progresses to a Stage 3 during the hospitalization.

It has always been my understanding that that would not be considered a Stage 3 ulcer present on the admission. ICD-9 code captures stage at the time of discharge, whereas the POA indicator as we heard this morning indicates that a condition was present at the time the order for inpatient admission occurred.

So I believe there's confusion over this. I don't believe it's confusion over the content of the FAQs in the coding clinic which I think are very accurate and very helpful. Rather I think there's an interpretation of that guidance that's out there among our customers that's confusing the issue somewhat.

And I'm wondering if I could just ask to clarify my understanding of the

intent of the policy that a Stage 2 pressure ulcer present on admission would not be treated the same way as the Stage 3 or 4 pressure ulcer present on admission.

Herb Kuhn: So thank you for your comment and your question. The purpose of today's discussion is to primarily receive input. There may be some questions for clarification that the panel is prepared to answer or they may refer questions to another setting that may be more appropriate for answering.

But given that, would any of our coding experts who are present on the panel want to answer that question?

Thank you (Donna).

(Donna Pickett): Actually I would like to take that question offline and have you submit the question back to the American Hospital Association's coding clinic for ICD-9. I think that way we could get the background information from you. And it would be easier for us to understand it as opposed to me trying to answer it on the fly.

(Tom Schneider): I appreciate that and I'd be happy to follow-up with you on that.

I guess in terms of providing feedback and input in keeping with this morning's sessions I just say this is the sort of issue that really emphasizes how important it is for the coders and the physicians to collaborate, and that I really don't know with respect to all these conditions that that's currently happening because the source of coding advice is not always consistent with the intent of the policy in my experience.

So I think to the extent we can provide further clarification it would be very

helpful for our customers. So thank you for that.

Herb Kuhn: Thank you for raising that. I mean clearly with the advent of something as new and big as a nationwide reporting of a present on admission indicator and also associated with a policy like the hospital acquired conditions policy there are going to be some questions that will need to be answered, and clarified along the way.

And as (Donna) has pointed out, there are mechanisms for doing that. So thank you for raising that.

Leah?

Leah Binder: Good morning. My name is Leah Binder. I am the CEO of the Leapfrog Group. We represent employers and other large purchasers of healthcare benefits in the private sector.

I want to commend CMS for your efforts in value based purchasing and in particular around hospital acquired conditions and assure you that this from the perspective of the Leapfrog Group and the employers and other plan sponsors we represent, this is a major priority. And we intend to align with you and hope that you will align with our efforts in this area.

It is a priority not only because of the direct costs associated with hospital acquired conditions but also the indirect costs that are hitting employers quite hard. And those are costs of productivity losses and of course there are costs in human suffering that are hard to quantify but are also very important I think to all of us.

So one of the key issues for us in supporting value based purchasing and the

kinds of approaches that you're taking is that not only do you begin to address some of the system changes necessary to address the particular hospital acquired conditions that are - that you've outlined, but in addition, you've put the issue of hospital acquired conditions on the top - on the front burner for CEOs and other leadership in hospitals.

And systems changes can affect not only the specific issues of hospital acquired conditions but many other conditions as well.

What we know from our survey, the Leapfrog hospital survey that Dr. (Valuk) referenced, what we know is there are still major problems in patient safety in American Hospital. And it is a continual source of frustration for employers and others.

And we would like to see better transparency about where these problems are occurring and we would like to see more efforts like yours and like ours to ensure that value based purchasing puts major system change on the top priority for hospital leadership.

So again we thank you, commend you and we stand ready to support you in any way we can to make this - these changes happen and even more aggressive changes in the future.

Herb Kuhn: Thank you for that comment. We're somewhat limited and the specific conditions that we can select through the statutory requirements and how our payment system actually works. But your point about the systems impact and how looking at specific conditions but then playing out the improvements across the organization can have a much bigger impact than just these ten categories of conditions that have been selected.

Okay. Next comment please?

John Shaw: Hello. I'm John Shaw and I'm the President of Next Wave in Albany. We do health policy research and consulting in fiscal and quality issues.

And first I'd like to thank everybody involved in the process. You're doing a great job. I actually agree with everything that's been said so far and the direction we're going. I've been working and hoping for 35 years to really get the alignment of payment and quality in place. And we're getting closer and that's great.

But on the other hand I also have the luxury and the burden of working down in the practice level as well in helping providers implement and react to these issues. And we're finding some disturbing facts down there.

And I think some of it's been alluded to before but I wanted to just focus on one specific area as an example. And that's the venous thromboembolism, the pulmonary embolism and DVT that is currently a HAC.

When we look at the data we find that there are evidence based guidelines. And many VTE events can be prevented.

The problem is the HAC methodology doesn't have a way of telling which of those events can actually be prevented.

So to illustrate, you're lucky on this side of the room you have implemented all of the evidenced-based guidelines, you've implemented them 100%.

On the other hand, on this side of the room you're in the bottom 50th percentile and you have a long way to go to implement the prevention

guidelines.

So let's look at the data. What we find when we run the data is there's virtually no difference in the numbers and percentages of pulmonary embolism and DVT on either side of the room. How can that be?

Part of the other problem is because you're so good at preventing these events all of the high risk patients are going to your facilities. And there's a wide variation in the risk of people getting those events 10, 20, 30 to 1 in some cases.

So basically what's happening is the high risk facilities are treating more of the high risk patients and the residual non-preventable numbers of cases are about the same as the preventable numbers over here. And that's problematic.

We have many hospitals that have 100% implementation on the Medicare compare website for the VTE prevention processes. On the Medicare compare website for the VTE prevention processes. But they're basically getting the same numbers.

So what do we do about the issue? Part of the problem is the tool itself. The HAC tool as it stands does not have any risk adjustment in it. And so our recommendation is actually maybe not even for people in this room - or perhaps so.

So my recommendation is for those in the current and incoming administration and those in Congress. And that is we have an issue with the HAC tool. There's an old saying that if the only tool you have is a hammer everything looks like a nail.

And the problem we have is we've got a very complicated system that we're



trying to fix. And so it's kind of - we have a system that looks like it's in need of complex neurosurgery and we're handing CMS a hammer to fix it.

So what I'm strongly recommending that the administration and Congress do is expand and allow CMS to allow to have the value based purchasing tools that can easily incorporate risk adjustment into the mechanism and move in that direction so that we can take the tool and make it appropriate to the job.

So the HAC works well for never events. Fine. Make it never events or not pay at all with the current proposals. But if you have areas like infections, like DVT that you can prevent some but not all we don't want to encourage bad things happening.

Twenty years ago I was at the other end of security boulevard on the day that mortality scores were released. I came back from that meeting with several large books with everybody's mortality scores. They were not risk adjusted.

We didn't see any movement in quality for ten years after that because it basically said if you have a hospice or do complex cancer or cardiac care you have high mortality rates. And if you have maternity, newborn, and pediatrics you have low. We know that. Let's not repeat the same issue.

Man: Thank you. I think there may be a couple of follow up points here from the panel.

Man: Yeah I just want to say that we completely agree with your concern about DVT and PE with regard to its reasonable preventability. And we've had lots of conversation both within the agency and outside the agency about it.

We tried to limit that exposure if you will by choosing only two elective

procedures to associate it with. We certainly didn't want to say that DVT and PE in general were reasonably preventable in all hospital patients. So we did a (unintelligible) to risk adjusted in that respect.

But we share your concern and we certainly would look forward to more dialogue about it.

Man: Yes on that particular point I went to and had followed the NQS panel that worked jointly with the joint commission looking at this area. And the concern from the technical panel was not the high risk surgery areas that almost always have implementation of the guidelines. The concerns they had were the silent clots that occur in the medical population we don't know about that kill people.

And so the risk adjustment that works is that most of the people that get PE now do have other conditions so that the number of cases is lower. But I think the focus is not on the population where we need more compliance.

Man: I think you heard me say before that risk adjustment is important. And I agree with you. I think the issue of risk of moral hazard that you talked about is going to exist no matter what we do even with risk adjustment.

I think academic institutions would appreciate that because they tend to get the sicker more desperate patients and so that will be a bigger factor for them. And no risk adjustment model is ever perfect.

But to answer your question your two charts for me I guess the answer your data is wrong. And until you can prove that your data is right then your data may be wrong as an answer to one of your questions.

Which I'm saying tongue in cheek but it is what we hear all the time and I think what you hear out there in the community and in professional societies who actually collect and analyze data. It's difficult to do. So I think that data aggregation and data analysis is as important in this process as anything.

And then finally recognize that the HAC policy - you say we have a hammer and everything looks like a nail but we have a legislative mandate to create something within the payment systems - in the structure. So the payment systems here are very complicated and they are written in statute most of them. So we have to work for what we have.

And so the tools we have are those. We think value based purchasing is going to be a breath of fresh air if we can the legislative authority to move forward.

Man: So our bottom line on the relative precision sophistication of rate based measurements is in agreement with yours. So that's also consistent.

Man: And I just want to reiterate that I agree that your tool is constrained by the law that gives you the opportunity to do it. And that's why I directed my concerns and the solution back to Congress and so on.

Man: So Miss (Mindy Harmon) our operator we're going to take one more comment from the room here in Baltimore. And while we're queuing up that comment if you would please queue up the phone comments and then we will turn to the phones after the last in-person comment.

Operator: Okay. At this time if you have a comment you may press star and the number 1 on your telephone key pad.

Man: Yes ma'am.

(Cynthia Sylvia): Thank you very much for giving me this opportunity. My name is (Cynthia Sylvia) and I'm program manager for education with industry - (Gaymart) Industries. We make support surfaces for patients who are immobilized to prevent pressure ulcers. I'm also a certified wound, ostomy, and continence nurse for let's say over 25 years.

I would like to first off commend the efforts of the CMS and the CDC with value based purchasing to really put the focus on prevention. Speaking for my colleagues I can say that for many many many years we have all been very much in favor of preventing rather than treating pressure ulcers. And now the system is working with us in order to incentivize this prevention.

I would like to make one comment recommendation that the hospital acquired conditions for pressure ulcers be expanded from stage 3s and 4s to include unstagable and deep tissue injury. I can say that I'm speaking for many of my colleagues in that respect.

I think that some literature that is there, the evidence and the expert opinions and the consensus appears to be that both unstagable and deep issue injury are full thickness wounds which is what differentiates 3s and 4s from 1s and 2s - full thickness versus partial thickness.

And also the fact that the National Pressure Ulcer Advisory Panel of which (Gaymart) Industries is the founder -- Dr. (Thomas Stewart) founded that -- also has differentiated stage - has refined 1 through 4 in 2007 and also defined deep tissue injury and unstagable as the fifth and sixth stages of pressure ulcers.

So they are recognized by the NPUAP as being recognized stages of pressure

ulcers and as being full thickness wounds. I think I'm going to be brief. That's my point. Thank you.

Oh one comment that I'd like to say there may be in the future I could see an unintended consequence being suddenly we have many more stage 3s and 4s being documented than currently are being documented. Thank you.

Man: Thank you for your comment. Any response from panelists?

Man: Well I think that if this stimulates better documentation that's a good thing. Maybe we're under reporting stage 3s and 4s and this will get people to actually look more closely at the patients that arrive at their institutions.

Man: Okay at this point Ms. (Mindy Harmon) we're going to turn to the phone lines and take our first comment.

Operator: Okay. Before your comment please state your name and your organization. Your first comment comes from (Dana Butcher). Your line is open.

(Dana Butcher): Yes hello. I was reading through the candidates for the hospital acquired conditions. And my thought comment is that I see that there are provisions for identifying whether a condition is present on admission or not.

However there's really no -- and I don't know if there is in the future -- there's no way to annotate or give direction if a patient is being non-compliant. And in the brief time I've had doing DRG validation I have seen some very interesting things that patients do that unfortunately hospitals don't have any control over.

And the reason why I bring this up is because part of the things that are on the

possible candidate for the acquired conditions are dehydration and malnutrition.

And I'm just wondering if there is in the future - will there be something that allows the facility to direct or annotate that the patient is being noncompliant, that it's kind of something that's out of their control. Thank you.

Man: What is your organization please?

(Dana Butcher): I apologize. Tri-West Healthcare Alliance.

Man: Great. And thank you for your comment. There certainly in looking at the potential candidate conditions certainly a number of considerations around each of them. You've raised a potential consideration around a potential candidate or two.

And we would encourage you and others as we go into our next round of rulemaking to watch what's proposed and the discussion around each of those conditions and comment at that time as well.

(Dana Butcher): Thank you.

Man: Our next comment please Ms. (Harmon).

Operator: Your next comment comes from (Jennifer Schevik). Your line is open.

(Jennifer Schevik): Hi (Tom) it's (Jennifer Schevik) at the America Medical Association. And first off I just want to thank you and your colleagues for hosting this session today.

My question then -- you might've already touched upon this earlier but I was late joining the call -- is what are the agency's plans to carefully monitor and/or analyze the implementation of this program in terms of any additional costs or impact on providers hospitals as well as patients.

I think this is an important question to ask now because considering that this might be expanded into other care settings I think it's important to be armed with that information before, you know, such a policy is indeed expanded.

Man: Thank you for joining (Jennifer). The question was about our monitoring for the impact and as we've also heard from other commenters the potential unintended consequences that might be associated with a new policy provision.

Part of it is going to depend on the funding that's available and we're always exploring options for the application of funding to priorities such as this. I don't know if any of the other panelists would like to comment further on our plans for monitoring and evaluation at this point or whether that would be premature considering that those are likely contracting actions.

Okay. Thank you for that important point (Jennifer). Operator can we have the next comment from the phone lines please.

Operator: Your next comment comes from (Elizabeth North). Your line is now open.

(Barbara McIntyre): Yeah this is (Barbara McIntyre) sitting in for (Elizabeth) at Baptist Hospital East in Louisville, Kentucky. One of the questions has come up with HAC is if you have one do you -- even though I have not seen this in the regulations -- do you expect us to remove the charges from the claim that are associated with the potential diagnosis and/or procedure?

Man: Okay (Sara) would you like to address that?

(Sara): I know for non-covered services, you know, we would like to see those charges in non-covered. I'm not sure if this is like a more broader question because I think we have to look at how the charges flow into the DRG payment system.

And, you know, in some cases the services were performed. So, you know, the charges should be there. So I almost think that this might require us to have some discussions internally.

We have not addressed how to bill the charges for hospital prior conditions. But I think that's something we should look into.

Man: Great. So thank you for raising that important question. It sounds like one that we haven't run across to this point. I would remind everyone that we do have information resources about this policy and its implementation on the CMS website at [cms.hhs.gov/hospitalacqcond](https://cms.hhs.gov/hospitalacqcond) -- all one word hospitalacqcond.

And we have a number of resources there to help answer questions. And there's a page called educational resources. And with (Sara)'s acquiescence I think we would plan to update that page with the answer to this particular question when we process that through our internal mechanisms.

(Barbara McIntyre): Can I ask one more quick question.

Man: Yes if you would speak up please. It's a little bit hard to hear.

(Barbara McIntyre): Yes I'm sorry. One thing that was on your handout that I'm not sure I'm



clear on is you state that if a condition develops during an outpatient encounter - say I come through the ER or I'm in surgery and I fall or I develop a UTI and I'm subsequently admitted as an inpatient that's not considered a HAC, correct? I mean, you would mark it as a POA?

(Donna Pickett): This is (Donna Pickett). The definition for what is considered present on admission is consistent with the definition that was developed by the National Uniform Billing Committee and so it flows through directly to the guidelines.

And there is information I believe in the NUBC manual that addresses that. And unfortunately I don't have that material here with me. But that certainly could be a question that you could send by December 31 that we could try to respond to.

(Barbara McIntyre): Thank you.

Man: Thank you. And again for those of you in the room and on the line this is a policy level discussion primarily today where we're seeking your input on the conditions that have been selected via the potential additional future candidate the mechanisms for determining POA and for ultimately making payment as well as the idea of expanding this policy to other settings of care in this case the outpatient hospital setting will be our primary discussion topic for the afternoon.

So we are wanting to provide resources for the answer and answering specific questions for example about how the POA indicator should be coded in certain instances. But that's not the primary purpose of today's discussion.

Operator can we have another comment from the phone please?

Operator: Your next comment comes from (Sonya Haley). Your line is open.

(Sonya Haley): ...from Yale New Haven House Assistance. I have two questions please. The first is a very short one. It is all the HACs never events?

Man: Okay I'll answer that question. And then when you ask your second one if you could speak a little bit more loudly directly into your receiver please.

(Sonya Haley): Sure.

Man: The answer to your question is no. Not all of our hospital acquired conditions are considered never events. And that's if you look at the National Quality Forums list of serious adverse events that are commonly referred to as never events.

There is a substantial crossover as you might expect because at base both policies are about patient safety. But the criteria for the selection of conditions for our hospital acquired conditions policy - the statutory criteria that we've repeated several times today and the criteria that the National Quality Forums Committee use in selecting the serious reportable events were not exactly the same. And so even though there's overlap not all of the HACs are never events.

(Sonya Haley): Thank you. My next question is if a hospital acquired condition were to result in a long length of stay and if the DRG were to be downgraded because of the complicating diagnosis the case more easily result in a cost outlier status. Would Medicare then require an audit of charges?

Man: So the question is about the relationship between the HAC payment policy and outlier policy.

(Sonya Haley): Yes.

Man: Would anyone on the panel like to address that question? Okay. Well I will then. The HAC payment policy works specifically as described in statute which is that we can no longer pay the higher DRG the complicated the major complicated condition DRG when the condition is present as a secondary diagnosis.

That is a distinct approach from outlier and to my knowledge outlier is not adjusted based on the occurrence of a hospital acquired condition.

Man: That's correct.

Man: Good.

Man: And there is an indirect effect I think because some of your outlier charges will not be part of your outlier profile as a result of the HAC.

Man: Right.

Man: You're right - directly there's not. And I wanted to go back to the first question about never events. I mean, there's some confusion about are these never events or not because of what's occurring in other alliances and in other organizations.

But from a standpoint of payment policy these are all HACs. They fall under the HAC payment policy. We have three never events -- wrong patient, wrong site surgery, and wrong operation -- which will have an entirely different payment policy attached to them that we're working through.

It doesn't look at all like the payment policy we're talking about here. So the conditions you see here from a functional standpoint in terms of payment they are HAC.

(Sonya Haley): Thank you so much.

Man: And I would just add regarding your outlier question I think from a practical perspective it's highly unlikely that any outlier patients would not have another CC or an MCC present. With the implication being that other CC or MCC would still generate the higher paying DRG. Operator our next comment from the phone line please.

(Sonya Haley): Thank you.

Operator: Our next comment comes from (McDalia Aponte). Her line is now open.

(McDalia Aponte): Yes. Good morning. I am with (SAIC) in software development and I support the coding compliance editor. And I just have a quick question. I know you said that this effort - you're looking at extending them to the outpatients. What about - would this include nursing homes in the future?

Man: Not at this time although we would be interested in your thoughts about expanding this policy to the nursing home setting.

(McDalia Aponte): Okay. Can I use that e-mail address to send additional comments?

Man: Please send your written comments to the mailbox [hacpoa@cms.hhs.gov](mailto:hacpoa@cms.hhs.gov).

(McDalia Aponte): Got it. Thank you so much.

Man: Thank you. Okay.

Operator: Your next comment comes from (Christy Sarasen). Your line is open.

(Christy Sarasen): Good morning. And thank you for taking my call. The question I have relates to information that came out in the final role as far as CMS soliciting comments for preventable re-admissions and possible incentives to beneficiaries.

And I'm thinking at this point it's probably not tying in but at some point in the future it probably will. And it was - it came back to me as a result of the question that came for non-compliant patients.

And I just wanted to mention that it is very frustrating that there's no recognition of circumstances that do happen as a result of a patient's non-compliance and to really reiterate the importance of keeping that in mind as we go forward not just with this but either with these incentives that we're contemplating for the beneficiaries for the preventable re-admissions.

Man: So an important point about a potential unintended consequence related to non-compliance. That's one of the most common that we hear about our hospital value based purchasing initiative as well as our physician value based purchasing initiative.

A couple of responses - one is that the provider really is in a position to have the most influence over patient compliance beyond the patients themselves. So the kind of education and emphasis that are given to the importance of compliance is I think a part of the incentive that we're talking about here.

But regardless I think there is an understanding that there will be a certain amount of non-compliance. And one of the potential solutions is to actually involve the patient in the value based purchasing initiative such that there's some incentive for them to comply with the treatment plan.

And there are certain ways that that can be done. Some of them are already in use in the private sector. And that's something for policy makers to consider for the future of Medicare and value based purchasing as well.

(Christy Sarasen): Thank you. I have one other quick question. Is there somewhere we can get a recording of this listening session?

Woman: The recording of the session and transcripts to go along with it will be posted to the hospital acquired conditions web page within the next couple of weeks.

(Christy Sarasen): Thank you.

Man: Thank you.

Operator: Your next comment comes from (Aseef Pasek). Your line is open.

(Aseef Pasek): Hello. Thank you for taking my call. My question - I work at a community supported hospital in Bellevue, Washington, as a clinical data extractor in the quality of clinical effectiveness department.

And largely our population of doctors are independent contractors. And I wondered if you had any advice on how to help them adapt the evidence based practice and encourage them to - because largely when we fall out we don't make these things and with the loss of money is ours to endure they are the ones that are making it impossible.

For example prevention of DVTs and the evidence based practice shows large amounts of Heparin or Lovanox that they will not write for. We then see the effects of, you know, having the DVTs occur and then we don't get paid for it.

But is there anything in plan to get their compliance in this?

Man: One of the very important aspects of this payment incentive is encouraging hospitals and their medical staff to work together. It comes up in setting the treatment approach for that institution and their professional staff working in collaboration as well as in the documentation that leads to the accurate coding. So we hope that that will be encouraged.

Having said that, having been a vice president of medical affairs previously in my career I know the difficulty in working with the hospital management and the medical staff to make that happen.

So I could only just encourage you to continue your efforts. And hopefully this payment policy will give additional backing to those in hospital management who are attempting to work with the medical staff for the provision of evidence based services within their facility.

Maybe other comments about how to accomplish that?

Man: Yeah that's a great question and it's a very important one. So right now we're talking about financial disincentives to the hospitals. But if we -- and I'm speaking very generally here -- what if this payment policy was extended to physicians and they were held jointly accountable for not only their income but the hospital's income, would that provide the stimulus that you need? I don't know.

But I'm a big supporter of physician hospital collaborations. And I'm a big supporter of joint financial and clinical ownership in the healthcare system. And think that in the evolution of these policies when we hit value based purchasing you may have a fully mature program where hospitals and physicians are held jointly accountable for the similar performance measure on which a portion of their payments is based.

And that's been tested in the private sector already and I think it works. And you will have physicians in hospitals talking together a bit more than they do now I think if we could develop a system it really provides the right incentive for the right reason and try to create some joint ownership here going forward.

Man: At this point I'd like to return to the room here in Baltimore and see if there are any additional comments from the room. And if you're in the queue on the phone lines please stay in the queue and we'll return to the phone lines after we take a few comments from the in-person participants here in Baltimore.

(Danielle Lloyd): Hi. My name is (Danielle Lloyd). I'm with the (Premiere) Healthcare Alliance. We're an alliance of more than 2,000 hospitals with our goal of sharing knowledge to both improve quality and reduce costs.

As you saw in the previous slide we are the private sector partner with CMS in administering the (HQID) program. We also have a new program called (Quest) High Performing Hospitals Collaborative where one of the pillars of that program is reducing harm through a collaboration of over 160 hospitals.

So we wholeheartedly support CMS's efforts in the area of value based purchasing programs. We've obviously submitted extensive written comments so I'll highlight a couple of things here. I guess one of the advantages of being



one of the last speakers is that I get to underscore a bunch of what other people have said already.

But in particular the hospital prior condition policy as it has been alluded to previously is a very bland tool. And we would like to see CMS move to a more refined system that more fairly exerts pressure on hospitals.

And so we want to make sure that if a hospital provides the right care to the patient and they still end up developing a hospital acquired condition that they're not unfairly penalized.

And in particular the way we think is best to go about that is as (Lisa) covered is moving to a rate based system within value based purchasing. Now that being the ideal goal we also know that that is not the current construct that you all are working within.

So within that current policy we do encourage you all to move towards the population based risk adjustment and certainly to continue researching the individual level risk adjustment. We think that that is the best way to refine the existing tool that you have.

In choosing new measures we certainly believe that CMS has more than satisfied your legal obligation to select two conditions. So we think that the agency at this point should step back and assess how this policy is unfolding.

Since it's just started you all have chosen a number of conditions. We need a bit of time to see how this is going and also provide some more time to for instance continue amassing the evidence base, disseminating these guidelines. We think CMS should play more of a role in education of providers.

We need more to time to work with our clinicians to understand the guidelines, to improve our coding, for CMS to create on creating new codes and tracking possible unintended consequences as one of the other speakers pointed out earlier.

We're not going to give you comment today on specific measures although we will say that we do have some major reservations with a number of the conditions that you all considered previously. And we would refer you to those comments and certainly we will put this all in writing again.

But we do think many of those are not ready for prime time and that perhaps this is a good time to step back for a minute and see how things are going before we implement any additional conditions.

Man: Thank you for that comment and the continuing theme of rate based measurements as a preference.

(Jennifer Fairberg): Hi I'm (Jennifer Fairberg), Association of American Medical Colleges. And as (Danielle) got to underline, I get to exclamation point what has been said already and really appreciate the direction that you're going in risk adjustment especially for the types of patients that we are seeing at our member institutions.

Wanted to make one comment and one question as far as the measures for future that you're looking at. Wanted to make sure that there are standard definitions associated with those measures.

I know one measure under consideration is a ventilator associated pneumonia. And there is a lot of, I know, work being done as far as the definition as far as that's concerned. But there still isn't a standard definition and before anything

like that were to be implemented that would need to be updated.

The question that I have is in relation to another candidate measure being the failure to rescue measure. Now this is a measure that's already slated to move forward for the pay for reporting program. How does CMS plan to potentially work this where a measure would be in two different programs?

Man: Would anyone on the panel like to address ventilator associated pneumonia and/or a failure to rescue?

Man: I'll address the first one for sure. We completely agree with you about the definitional problems with VAP. And that's one of the reasons it hasn't been selected. You know, those are issues that continue.

(Jennifer Fairberg): I'm sorry but it's on the list for potential - so it's just staying there? It hasn't been finalized previously so it just stays on the list?

Man: No actually it make it to that list because a commenter suggested that we reconsider it.

(Jennifer Fairberg): Okay.

Man: And there's no inherent conflict between having a rate based measure in a pay for reporting program and a claim by claim adjustment for the occurrence of some condition that might be related to measures.

In fact if you looked at the selected intent conditions - categories of conditions you could probably relate them back to some of the current pay for reporting measures. Interesting thought. I haven't done it but I might at this point. But I don't see any necessary conflict.

And in fact in the future as commenters have already pointed out we might be interested in preserving the claim by claim adjustment for certain kinds of conditions that very low rates, maybe have some measurement happening for those as well as others that would be included in a rate based measurement. And then the public reporting of that might take yet another form.

(Jennifer Fairberg): Okay. Thank you.

Man: Thank you. Good comments.

Woman: Hello I'm (unintelligible) from the American Nurses Association who represents the interests of 2.9 million registered nurses in the United States. Thank you so much for giving us the opportunity to listen to what your plans are and to provide comment.

ANA is very supportive of the work that CMS is doing related to pay for performance and public reporting. But there are certain considerations that we would like to express, one of which is supporting the recommendation that had been made previously by a colleague as far as expanding the pressure ulcer categories.

ANA has a national database of nursing quality indicators database that has close to 1,400 hospitals reporting. We did a pressure ulcer liability study and what we found out with nurses' assessment we had moderate to near perfect reliability.

So when you're talking about measure reporting, measure collection it's very important that you have validity and reliability when it comes to those measures.

Along with that is ensuring that there are standardized definitions. It's important that if there is substantive change that is going to be made to a definition that it's done that there is compelling evidence for that change.

You know, hospitals have to adjust for whatever reporting is going to need to be made so it's important that those definitions are standardized and they're not changed with great frequency unless there's compelling evidence to do so.

And then the last couple of points that I wanted to make is that, you know, nurses are pivotal when it comes to the assessment, the monitoring, the surveillance of patients and the reporting of that care and the reporting of quality.

So in any of these activities that are performed it's important to include the nurse. We've heard provider of care and in my mind I think of the advanced practice registered nurse who provides care. I think of the bedside provider of care.

And so it's important to include that documentation as well when you're evaluating care because it will impact the reporting of that outcome from a hospital perspective and their reimbursement.

Thank you so much for this opportunity.

Man: Thank you. Next comment please.

(Susan Bailey): (Susan Bailey) with Cleveland Clinic. I'm the coding manager. And I wanted to comment on the potential for malnutrition. That concerns me because we have malnutrition and we work hard to get that documentation for our cancer

patients who are terminal.

So that would be an issue I think we'd have to look at how to account for - the expected malnutrition and when we try to show how sick the patient is that we're taking care of.

I would also be concerned that costs could increase because it would probably force hospitals to do baseline screening on admission like total protein albumen which may not shake out to be malnutrition at all so it could be a waste of money.

And I would also suggest that some consideration be made to using the dietician's documentation to capture malnutrition because I think they do the best job and have the best understanding of malnutrition and that would require something coming out of the cooperating parties to allow us to use that information

Secondly just a comment on the ANA comment about the (unintelligible) I think that we really do need to look at how can we use nursing documentation. Because if we're truly trying to show the incidents of the (unintelligible) and the hospital patient we need to go to nursing because we I think most people would say that you can't get physicians to document all cases of (unintelligible) and it's vastly under reported.

Woman: Your point out nursing documentation as it relates to the coding of pressure ulcers...

(Susan Bailey): I know that we can go to them for the staging but to get just the basic documentation that pressure ulcer is present...

Woman: Okay you're referring to the basic documentation...

(Susan Bailey): Right. Because it's under reported.

Woman: Okay. Thank you for clarification.

Man: And again of course one of the important expected outcomes of this policy is to get the physicians and other professionals as well as the hospitals to pay closer attention to some of these very important things.

And we're so hopeful that hospitals and the quality professionals and so on will be working closely with the physician...

(Susan Bailey): Right. And I have a very long history of documentation improvement programs in the hospital setting and even with the best efforts are very difficult to capture.

I think - I also wanted to say that I think that something needs to be done at a very high level going to physician groups -- like the AMA -- to get physicians to understand that pressure ulcers, you know, are the responsibility and that they're very significant.

Because it's very stunning how physicians, you know, still cannot understand the significance that they have responsibility. And I think that would be almost like a public service type of campaign to physician groups.

Man: Thank you for sharing the coder's perspective.

(Jane Hartchambers): Hi I'm (Jane Hartchambers) with the Federation of American Hospitals. Thank you for the opportunity to hear the lively discussion this morning. We

appreciate that.

I'd like to comment and support comments made earlier by several of our colleagues that we are facing challenges in putting some of these programs in place and putting together the collaborative activities that we all would hope would happen between the hospital and the physician community and other clinicians in the hospital setting.

We're working very hard on that but there are still challenges that we face. We are a siloed entity right now and payment policies don't necessarily go across venues so it makes it a challenge at times.

I also would like to underscore the need for evaluation of the current program. We would strongly support evaluation of the current program to see what kinds of effect it's having both positive and if there are any unintended consequences and have a better understanding of that before moving forward with a lot of new conditions.

And finally there was a discussion earlier this morning about the HICPAC guidelines and the evidence based guidelines and some new ones that are going to be coming out.

What is the distribution process for those guidelines? How are those disseminated? And how actively are they promoted and how quickly are those guidelines - are you seeing those put into use? Thanks.

Man: The HICPAC guidelines are available on line from the CDC website for HICPAC. They're also distributed through the various professional organizations that are impacted by them.



Having said I think because of this policy and other things that are occurring it's been recognized that that needs to improve. There needs to be broader distribution.

And as I alluded to earlier there's also a process underway to simplify the guidelines. The guidelines are very detailed, very technical and very long - to try to synthesize from those shorter abstracts that we'll be able to provide information that multiple parties will be able to understand.

So we appreciate the comment and that's what we're working on.

Man: Ms. (Mindy Harmon) our operator we'll take the next comment from the phone lines please.

Operator: Okay. Your next comment comes from (Carol Ann Armente). Your line is open.

(Carol Ann Armente): Good morning. I thank you for -- it's almost lunchtime -- I thank you for the opportunity to address. I am a healthcare attorney at Legal Services of New Jersey. I've written on and speak before physician groups as well as attorney groups on HACs.

And my comment is along the lines of unintended consequences which I think were touched upon earlier I think I have a slight disagreement with a member of the panel.

I'm looking at this from the interest of consumers of healthcare. And two things - first although the regulations require that there is no direct billing of patients my concerns are because this is what I deal with on a daily basis that even though billing is prohibited by a regulation nonetheless it occurs.

And I'd like to see something built into the regulations that in some way penalize institutions that go ahead despite the prohibition to bill patients. That's the first comment.

And the second comment I think is more serious. As the HACs are set up there is as someone alluded to earlier penalizing the hospitals for all the HACs.

Nonetheless there is not a penalizing of the physicians who certainly would've collaborated or may even caused the HAC. And I'll use the most obvious non-controversial one and that's the retention of a foreign object after surgery.

I think right now we're looking at the anomalous situation in which the hospital will be penalized for that however the physician who performed the surgery will be paid by Medicare under B as opposed to Medicare A.

And it would seem to me that those two items should be linked. If the hospital will not be paid for that care then the physician who was not on staff should not be paid for that care as well. And I think that is a place to start.

We have to remember that though we all hope that better medicine will be practiced because of the HACs the impetus nonetheless was budget reduction. And certainly we can accomplish some budget reduction if we do link the physician payment to the hospital payment.

Man: So two important points. One is about the prohibition on balanced billing of patients. That's not anything that's new or unique to the hospital acquired conditions policy. It certainly continues through to the hospital acquired conditions policy.

And I don't know exactly what the penalties are for not complying with the prohibition. But I will be interested to explore that further now that you've raised the question. But regardless that prohibition is in place and we don't need additional regulation made around that in order to effect it.

And your point about aligning with the physicians that's certainly been a big theme today. And it certainly is our ultimate goal through value based purchasing to address what's been referred as payment silos by addressing harmonization or alignment of the measures as well as alignment of the payment incentives over time.

That is going to take some time, possibly statutory changes, and certainly something that policy makers are interested in doing in the future to try to help you all who are working to get the medical staff practice and the hospital services aligned.

(Carol Ann Armente): Thank you.

Man: Next question from the phone please. Operator do we have additional questions from the phone please?

Operator: Not at this time.

Man: I think everyone is getting hungry for lunch but before we break -- I just want to throw that out there -- but before we break are there any more comments from the room here in Baltimore.

Yes sir. Don't mob him just because you're hungry.

Man: Now I do understand that the selection criteria that you utilized to select a hospital acquired complication as being non-reimbursable is it high cost, high volume or both. And perhaps that is why catheter associated infection which admittedly causes about one-third of all hospital acquired infections made it on the list despite the fact that it's not very expensive to treat and it's not associated with a high mortality rate.

So what I would suggest is did you consider the possibility that in that criteria we actually are instead of paying high cost high volume or both that you actually consider high cost high volume or high mortality and morbidity.

For example we have much less cases of surgical implant related infections than catheter associated infection but yet the former infections have much higher morbidity and high mortality.

In the case of pace makers and defibrillators one quarter of those were associated another quarter will die. While as the mortality of catheter associated UTI is really very low.

So I suggest that you probably may want to consider this in the future.

Man: So the selection criteria are set in statute. But I think, you know, you could think broadly that an attention to high cost and high volume is attention to what's important to the Medicare program and to the program's beneficiaries.

And certainly the burden of morbidity and mortality are very important and are related in a way that you described to the cost and volume parameters. So even though those aren't statutory criteria those are something that through the consideration process we've paid some attention to.

Man: Yeah particularly that it could be -- I'm not saying it's not necessarily the case -- it could be more possible to actually prevent an infection of a surgical implant than it is to prevent a catheter associated UTI.

Man: Are there any other comments here in Baltimore before we take our lunch break? So I would just reiterate to all of our in person participants as well as our participants on the phone our afternoon session is going to be primarily devoted to the outpatient setting. But that toward the end of that comment period we will also be just reverting to general comments about the inpatient or the outpatient policy.

So if you think about something that you want to raise regarding the inpatient policy we will welcome those comments towards the end of the day. We will re-convene at 2:00 Eastern Time with a presentation by our colleagues from the Agency for Healthcare Quality and Research. Thank you.

So if you would all take your seats please. We're going to get ready for the afternoon session. Welcome back from lunch. It is now just a couple minutes after 2:00 Eastern.

The first order of business will be to have our operator open up the phone lines for our presentation from AHRQ. And then our operator will introduce our first speaker (Irene Fraser) from AHRQ and then (Irene) is going to turn the session over to her colleague (Ann Elixhauser).

So (Mindy Harmon) if you would open up the phone lines please.

Operator: Good afternoon and welcome back from lunch. We will now go ahead and turn the call over to (Irene Fraser). You may begin whenever you're ready.

(Irene Fraser): Okay great. Thank you. Can everybody hear me? Is this working okay? Well it's a real pleasure to be here. You know, one of the nicest things about my job in my last several years has been the increasing collaboration with the folks at CMS particularly around measurement and data and pay for performance. And so it's a real pleasure to be here.

We're going to be talking about a project that we've been working on for the next several years in which we're looking at enhancing the value of administrative data.

AHRQ has been involved for several years in working with administrative data and measures derived from that data. And we have been working to enhance that as well all along the line. And so we want to fill you in about some of the more recent developments about that.

So here's what we're going to be talking about for the next 20 minutes and we'll be sure to leave some time at the end for questions. First we're going to provide a little of background on the issue although I'm sure many of you are familiar with much of this.

And then (Ann) is going to summarize our research study that was done a year or so ago by AHRQ looking at ways to enhance administrative data. And then we'll be talking about some of the things that we have been doing to take the recommendations based on that study - to take the evidence based on that study which I think is one of the most exciting studies that I have seen in the last while and put it into practice.

So by way of background hospital administrative claims data or hospital bills are available for almost all hospitals in the United States. In 45 states most of the largest - almost all of the largest states have those.

And they provide information on every hospital stay and wide variety of information including the diagnosis when the patient went in, any procedures that were done, who paid for the stay, a lot of demographic data including in many states - in most states race and ethnicity, what kind of resources were used, usually charges but we've worked out ways to be able to express those as costs. How they were discharged. Where they went to. When they left.

So we've been working in collaboration with 40 of these states -- almost all of the largest ones -- to collect all of the discharge abstracts that the states collect.

And in some cases that's hospital association, in some cases that's state data agency that's officially part of the government. And in other cases it's a private data entity that has that responsibility.

And we work with them to standardize the data so that it can be treated as if it were from its origin a single data set. So everything is expressed in the same way. So male/female it might be M versus F in one state and plus versus minus in another state all gets standardized.

And then as part of our work with these states one of the things that we did in response actually to some requests by the states to help us develop materials and measures that would make their data more useful to them was the start to develop measures of quality several years ago.

And we now have four modules of quality indicators. Three of these are primarily focused on the hospital itself - the quality of the hospital care itself. And those are the inpatient quality indicators of patient safety indicators, the pediatric indicators, and one that's so new it's not on the slide which is the

neonatal indicators.

And then there's also a set of prevention quality indicators that are essentially reporting ambulatory care sensitive admission. These provide kind of a window on the community and a way - in a sense an outcome measure for outpatient care and preventive care and self-care.

So we developed those so those measures which were used for many many years by hospitals in order to measure and do their own quality improvement. Since these measures were released for public use a lot of organizations have started using them for public reporting.

And so this really underscored the need - it upped the ante in a way because many organizations started using them for public reporting. In fact four states are currently using them for public reporting for all hospitals in their state. And so this really upped the ante and made us say okay what could we really do to expand and enhance the accuracy and usability of this data.

So before we get to the limitations piece -- which I see is on that slide -- one thing I wanted to underscore is that there are some big advantages of this kind of data. And so our goal is to try to build on the advantages and limit the limitations if you will.

The big advantages are that the data are available, they're in the public domain. The methods are transparent. They've been really rigorously developed.

And in fact (Mark McClelland) you're the former head of CMS was originally the project officer or the principal investigator back in the day when he was still at Stanford.



Hospitals are familiar with the measures. They've been using them for a long time, there's regular updating. There's technical assistance to using them. So there's a lot of real advantages.

But there have been some disadvantages, some limitations to date in the data and hence the application of the measures. The first is that they lack some clinically important information certainly information that we would like to know and in some cases information that it's really important to know.

And it tends to be limited to what is already contained in the ICD 9 code. So we might know that a person has uncontrolled diabetes but we don't know how badly out of control that diabetes is. We may know that a person has hypertension but we don't know how the - we don't know the actual blood pressure reading.

And because these are now being used in the public domain and being used for the purpose of public reporting there have been concerns about well to what extent are they really expressing the fully accurate truth. Is the risk adjustment adequate? We don't want to penalize providers that have a sicker patient. We don't want to create perverse incentives etcetera.

So how do we go about taking this data and getting it closer to the gold standard if you will, how do we get more of the clinical data that will enable us to do that.

One step that has already been taken with the support of CMS has been adding present on admission information. And for some of the measures that becomes really really important.

So if you're going to look at pressure ulcers for example you need to know whether the pressure ulcer was something that the patient came in with or whether the pressure ulcer was something that was acquired there.

For other measures it's less significant. You know, the issue of, you know, a foreign object left in the body after surgery presumably the patient didn't come in with that. So present on admission becomes less significant for some of those sorts of things.

But the question of how to get more clinical details remained a problem. And while the electronic medical record can provide some hope for the future the goal was to figure out how can we in the short term figure out a way to get the most accurate and rigorous data possible.

And how can we as we're developing the electronic medical records be enhancing the administrative data at the same time so that at some point you're not talking about electronic medical data versus claims data you're just talking about data because it's all the same thing.

So with this back drop AHRQ sponsored a study to look at the question of how do we systemically and efficiently in a sense improve the clinical detail and administrative data. How do we get it to the level of accuracy or to approximate the level of accuracy of the clinical record.

So (Ann Elixhauser) is going to be telling you about that study. (Ann) has been involved in almost every major development related to the quality indicator.

She was originally involved in the original development of those. She was the developer of the clinical conditions software and many other measures that

have been using the data.

So she was an apt person to serve as the project officer on this study. So I'm going to turn it over to (Ann) now.

(Ann Elixhauser): Thanks (Irene). Since I'm remote I'll have to ask someone to be changing the slides there. So given the context that (Irene) has provided AHRQ sponsored a study that was then conducted by (Michael Pi) and Associates and (Apt) Associates.

And what we did there was to assess the impact of adding clinical information to the administrative record specifically for purposes of public reporting of healthcare quality.

And what we did is we examined incrementally more complex and more expensive to obtain clinical information in order to identify the most cost effectiveness enhancements to the administrative data.

Now because POA information is collected at the same time and by the same personnel who code diagnoses using ICD codes we added POA information early in the modeling process.

Then what we did is we added laboratory values at the time of admission assuming that numeric information from a single point in time would be relatively easy and inexpensive to obtain.

And given the fact that lab data are available electronically from the majority of the hospitals - over 90% of the hospitals already have electronic laboratory data. So what we're talking about here is merging two data streams -- the hospital bill and the electronic lab data.

We also assessed the impact of increasing the number of diagnosis fields. You'll see how we did that. And then we examined the impact of improving the documentation of diagnostic information using ICD codes.

Current coding rules stipulate that when there's a final diagnosis like stroke then symptoms like coma would no longer be coded. But we wanted to see what would happen if such symptoms were indeed coded. Because a stroke with coma is very different from a stroke without coma. It has a lot of bearing on the severity of illness for that patient.

Then what we did is we added information on vital signs at admission - again numeric values at one point in time but these would be less routinely available electronically. They would actually need to be extracted from the medical record.

Then finally we added more difficult to obtain clinical data. And then through cost effectiveness analysis we assessed the most cost effective enhancements to administrative data.

So the next slide shows that the study that we conducted has resulted in several manuscripts - three of which have already been published and the fourth is in press. If you're interested in more details you can find more in these studies.

On the next slide we show the source of the data. The data were supplied by the Pennsylvania Healthcare Cost Containment Council - PHC4. We're really indebted to them for having shared their data with us for this study.

They provided us with all the administrative data from 180 hospitals over a

three year period. And for all of these records they also supplied detailed clinical data that had been abstracted from the medical records using the Atlas Outcomes System which records the hospital date corresponding to each data element. So for example we knew the day that the lab test was drawn. We could then identify which lab test happened on the first day.

Now Pennsylvania didn't collect POA information at the time of this data collection so we also used New York and California data which have long collected POA information to identify which conditions were co-morbidities and if they were present on admission and which were complications that they originated during the stay. And we applied this information to the Pennsylvania data which includes detailed clinical diagnoses.

On the next slide we show the eight mortality indicators and the four patient safety events that we looked at in the study. All of these are measured using AHRQ (QI)s. This is just a subset of the AHRQ (QI)s. But they're the ones that we looked at here.

Then on the next slide as I mentioned what we did is we developed incrementally more complex models. Now the sequence that I'm going to outline today is just one of many sequences of models that we tested and that are reported in the various manuscripts that I pointed out earlier. But these really are illustrative and pretty representative of findings. So I thought that these would make most sense to you.

So in the first step what we did is we began with a model that was based just on routine administrative data and up to 8 secondary diagnosis fields. That's Admin 8 okay. Okay. Then in POA 8 we added POA information.

Then the third step we increased the number of diagnosis fields to 24 to see if

more diagnostic information was helpful for risk assessment - I'm sorry for risk adjustment.

In the fourth step we then added information on conditions that were present in the Pennsylvania clinical data but which didn't appear in the ICD cost list because of coding rules.

And these are conditions like coma, immunosuppression, chest diffusion, history of chronic lung disease. They tended to be history codes or symptom codes that didn't get coded once the final diagnosis was reached.

On the next slide the model that is called lab is where we added numerical laboratory data that were obtained on the day of admission. Then we added lab data to a model that assumed the improved coding of the claims data. And in the final step we added full clinical information.

We added vital signs, other lab data that aren't as routinely available electronically. This would be things like culture results, key clinical findings, and composite clinical scores like the American Society of Anesthesiology classification.

Now other analysis that we did broke out these clinical models in more detail. We ran separate models for vital signs and other lab results, separate models for composite scores, that sort of thing. And again the details are in the paper. But just to make it understandable I restricted it to a few models here.

So onto the results. The first result slide shows the C statistics for the mortality models. And these are mean statistics across all 8 mortality measures that we looked at. Now the C statistic is a measure of the discriminative ability of a model.

So a value of .5 is a pure guess and a value of 1 is perfect discrimination. Numbers in the range of .7 to .8 are good, .9 is excellent. Now the C statistic for the pure administrative model -- that's that first step -- was .79 which is really pretty good.

Then we - when we added POA information the C statistic went up to .84. When we added lab values it went up to .86. The full clinical model only got up to .88. So you can see that adding laboratory values gets us remarkably close to the full clinical model in terms of the discriminative ability of the model.

Now the patient safety model showed a very similar pattern but I don't provide those results here. Now onto the next slide where we look at hospital bias. Because the fee statistic is really a pretty abstract concept and doesn't have any inherent meaning. I mean, a .79 or a .84 doesn't really mean something specifically.

We wanted to look at what these changes meant in terms of being able to correctly designate hospitals as high quality or low quality. So what we did is created a measure of how hospital rankings would change with the addition of more clinical information.

The folks who are there are actually seeing a graph. The folks who are line you're just seeing the words. But let me provide you a little interpretation here.

The bottom line here is that we compared all of the models, you know, the step-wise progression of models to the full clinical model and we asked, okay, what percent of hospitals would be mis-assigned in terms of their quality score if we used less than complete clinical information.

And we did this - folks who are there and actually seeing the graph we did this at varying levels of stringency. So at the most stringent level with just administrative data about 45% of hospitals could be potentially mis-assigned in terms of their quality score.

When we added only POA about 35% of hospitals were mis-assigned. When we added laboratory data we're down to only about 18% of hospitals being potentially mis-assigned. And when we also improved ICD coding only about 5% of hospitals are mis-assigned compared to the full clinical model.

So you can see again that the addition of laboratory data and the addition of POA gets us remarkably close to a model that is based on painstaking abstraction of the medical record.

So the next couple of slides -- one labeled numerical lab data -- this slide provides details on which specific clinical data elements played a role in the model.

I won't go into the details here but you've got the information. What's key here is we're talking about 20 or so lab values at one point in time that we were talking about adding here.

The next slide shows you the vital signs and other clinical data and how many models each of those data elements played a role in. And the next slide shows you the abstracted key clinical findings.

And what's important here is that 14 of these key clinical findings -- coma, malnutrition, immunosuppression -- have corresponding ICD codes that could potentially be coded.



So the next slide talks about the results of the cost effectiveness analysis. Here what we did is we looked at the marginal cost associated with incremental additions of clinical data. And the focus here was on the cost burden to the hospital. What would it cost the hospital to provide this information?

Now costs remained relatively low for adding POA and lab information because the POA information is obtained at roughly the same time as the abstraction of the medical record happens for ICD coding the lab information would be available electronically and wouldn't require an additional foray into the medical record.

But costs increased dramatically when we added the detailed clinical information. So adding POA and lab data has the smallest incremental costs for the improvement in clinical specificity that we get.

So in summary what we're finding here is that administrative data can be improved at relatively low cost by two major additions -- adding POS modifiers and adding numerical lab data on admission.

And if it were possible to improve ICD coding or change ICD coding to allow for more complete coding we could further improve our ability to do risk adjustment for quality reporting.

Now the last couple of slides just talk about some of the implementation of these results. In order to encourage implementation of the results of this study AHRQ is sponsoring pilots in three states to add clinical information to their administrative data which they already collect.

We're working with Florida and Virginia and Minnesota. These are a

government agency, private data organization that receives only about 15% of its revenues from the government. It's primarily self-supporting. And then hospital associations. So there are three very different models. The pilots began in September of 2007 and they're going to finish in September of 2009.

The next slide shows the objectives of the pilots. And so the major objectives are to one establish the feasibility of linking the clinical laboratory data and the administrative data so basically merging those two data streams.

Two is to develop a reproducible approach that could be exported to other states. And three is to set the stage for integrating the clinical and administrative data streams in the future.

The next slide shows the specific activities that our pilots are engaged in. What they're doing -- they've gone through this process already -- they've identified and selected the clinical data they're going to add to the administrative data. It's primarily based on the (unintelligible) studies.

Then they're translating the clinical data from the electronic format and merging that to administrative data so they're using the (unintelligible) codes and merging that with the administrative data.

They're transferring data from up to 35 hospitals to the statewide data organization. So they're working with, you know, a good number of hospitals to get this done.

Then they're processing that merged administrative clinical data into a multi-hospital database and also collaborating with stakeholders to make sure that they get the input that they need to see what needs to be done, how it could be done, what is the most efficient way of doing it, and how does it meet the

most users' needs.

So, you know, they're working with hospital representatives and state government agencies and researchers and quality measurement professionals regional or state healthcare quality organizations are involved as well.

And then something that's been working really very well -- it's been remarkably good -- is they're engaging in peer to peer learning. We talk all together once a month where we do a lot of information sharing, a lot of dissemination of information. If one site develops a tool that they find useful they share it with another site.

That has been really helpful. And what's going to happen then is all of the sites are writing their own report and then we are going to take that report and integrate into a report that hopefully others can use to guide similar efforts to merge the laboratory data along with the clinical information. Now another - I'm sorry merge the laboratory data on with the administrative record.

So another effort that's part of the pilot projects is to develop algorithms that would screen for possible problems in POA coding. At the same time that these states are working on getting the laboratory data together they're also implementing POA coding. Many of them (unintelligible) implementing them statewide not just for Medicare patients.

And so what we've been working on as well is some screens - algorithms that would screen for possible problems in how POA is recorded. So for example one of these algorithms tried to identify elective surgical admissions that have longer than expected risk adjusted post-op lengths of stay.

So we're doing risk adjustment but then we're seeing very long lengths of stay

for some elective surgical admission. But in these cases there's no secondary diagnosis coded that shows that it originated during this stay.

So if a hospital has high numbers of cases that meet this screen - higher than average then there may be some reason to suspect some problems in POA coding. Something has to explain the long length of stay.

And it's possible that POA coding is not being done correctly in those hospitals. So we're developing these screens and they'll be disseminated as part of our report as well.

So in conclusion our study found that by adding a few clinical data elements we can really significantly improve our ability to do quality assessment using administrative data.

And we get remarkably close to a full clinical model for mortality and for the patient safety measure studies here. And through the pilots that we're engaging right now we really hope to jump start the process of adding clinical data elements to the hospital discharge data.

So thanks very much for your attention. And we'll be happy to take any questions.

Man: Thank you (Ann) and thank you (Irene) for participating in our discussion today. You know, we did want to show the breadth of what we're all after here in collaboration not only within the departments -- CMS, CDC, and AHRQ -- but also in working with the various stakeholders who are represented here.

And this is a great example of the importance of various data elements -- in this case particularly the present on admission indicator -- and how we can

leverage what we're doing around one policy like our hospital acquired conditions policy and use that the clinical improvement that we're looking for, use that for research purposes such as was described so eloquently by (Irene) and (Ann). So that was the purpose of highlighting this today to round out the discussion.

And we do have a few minutes if anyone would like to make a comment or ask a clarifying question to (Irene) and (Ann). I know that most of you came here to talk about a payment policy.

But if some of you are researchers or have interest in the implication on the present on admission indicator this would be a great time to give you an opportunity to comment.

(John Shaw): (Unintelligible).

Man: He'll turn on the microphone. Just keep speaking.

(John Shaw): There we go. Hi (Ann) it's (John Shaw) from (Next Wave). One question in looking at either vital signs or improved coding one of the major risk factors in all the clinical literature is obesity.

So are you collecting height, weight or BMI at minimum in the ICD 9 V codes as part of this study?

(Ann Elixhauser): You know, as part of the pilot study?

(John Shaw): Right.

(Ann Elixhauser): If it's in ICD code for collecting it.

(John Shaw): Good.

(Ann Elixhauser): Okay. We are not going into the medical records or trying to get any additional information beyond what's in the ICD codes or what is collected in terms of POA or in terms of the electronically available lab data.

(John Shaw): Okay. In the coding there is smoking and there is BMI back in the V codes although we've noticed that a lot of facilities don't code them. So that might be something to feed back to the participants to at least collect that information because all of the clinical literature suggests that that's a major factor.

(Ann Elixhauser): Yeah. No I think you're absolutely right that we've seen that too that there's really very poor coding of those kinds of risk factors.

Man: Okay we have another comment here in Baltimore.

(Jane Chambers): Hi this is (Jane Chambers), Federation of American Hospitals. This is really a fascinating study. It really made me start to think about a number of things. But I may have missed in the beginning is this all payer data or is this Medicare data?

(Ann Elixhauser): This was all payer data. The Pennsylvania study was based on all payers.

(Jane Chambers): Okay. And how does it relate to the charted value exchanges and to the kinds of work that's also being done through the Quality Alliance Steering Committee and their data aggregations project?

(Ann Elixhauser): This study actually predates the charted value exchangers and perhaps (Irene) can speak to that. I don't know if there's anything happening in the charted

value exchanges that's related to this.

(Irene Fraser): Right. No (Ann) is correct. This data preceded the charted value exchangers. The charted value exchanges have been - have expressed interest in it and this is one of the data measurement pieces that we've been sharing with them through our learning at work. But this occurred prior to them.

(Jane Chambers): And finally would the use of ICD 10 codes make this an easier project? I mean, could you really drive change if you had more robust coding along those lines?

(Ann Elixhauser): You know, I don't know if (Donna Pickett) is still there but she and I were talking earlier this week and we think that ICD 10 coding will make a big difference.

Man: So (Ann) (Donna) is stepping up to the mike here and...

(Ann Elixhauser): Okay. Great.

(Donna Pickett): Hi (Ann). Great question. Yes we do believe that the implementation of ICD 10 CM for diagnosis and ICD 10 PCS for inpatient procedures will definitely improve the data and give it greater value in doing all of these studies.

Man: And we have another comment here in Baltimore.

(Deb Williams): Hi (Deb Williams), (Specter) Healthcare. Loved your study. Thought it was very interesting. Question for you. On the mis-assignment - talking about the results and hospital basis, do you have a sense - is there a measure of the degree of -mis-assignment when you're talking about - are you going from like medium to high or, you know, a low and a high?

Do we have a sense for that?

(Irene Fraser): You know, the measure of hospital bias is actually a little bit tricky. Because what it's doing is basically trying to get at sort of a signal to noise ratio of, you know, the extent to which we're able to identify, you know, which hospitals are doing better than others.

It's not a pure ranking. I sort of simplified it in my description. It's not a pure ranking of hospitals.

(Deb Williams): So the original statistic -- which you simplified -- would capture that kind of information?

(Irene Fraser): That's right. That's exactly right.

(Deb Williams): All right. Thank you very much. I loved your study.

(Irene Fraser): Thank you.

Man: So it looks like we've run through the questions here in Baltimore. I assume that some of them were ones that would be shared by folks on the phone line. And unfortunately we don't have time to go to questions and comments on the phone line for this particular segment.

But I would ask (Irene) and (Ann) if they have any closing comments before we move onto our next item for discussion to please share them at this point.

(Irene Fraser): (Ann) did you have anything?



(Ann Elixhauser): No I don't. I'm done.

(Irene Fraser): Okay. Well I was just going to say a couple words by way of kind of transition to the afternoon. I know that all morning the focus has been on inpatient - measures of inpatient quality. And that certainly was the emphasis in our study.

You know, the development of data and the development of measures tend to be very synergistic. And as you move on one it makes it easier to move on the other.

We have in our genesis of the HICPAC project which was the database that helped us create these measures even though the measures now can be used with any data but originally that was how we created them.

Our original focus was on the inpatient side. But we have over the last several years really been pushing to move outside the inpatient arena. And so much of our expansion efforts have been not just adding new states but also trying to add more state data sets that move outside the inpatient arena. And we've had a great deal of success with that.

We have about half of the states' emergency department data sets as well as ambulatory surgery data. Although for the most part the ambulatory surgery data is hospital based ambulatory surgery so it's not complete in that sense. But it takes you to the margins of the hospital as it were.

And the next step will be in a month or so we'll be releasing our first ever national emergency department data that we now have enough data from emergency departments because we have the largest states captured that we can create national estimates.

So that's been a real breakthrough and is something that puts us in a position to be starting development of emergency department measures as well. So - and that's, you know, something that we have, you know, talked about with CMS and we'll be coordinating with CMS to think about, you know, what is the best way to proceed there.

I know that - in fact I've been sitting on one of the technical advisory committees for some of the emergency department measurement development work that CMS has been doing.

So I think this is going to be a rich area for collaboration in the future. And I know you all are going to be talking about emergency and other outpatient measurements this afternoon. So that seems like a transition...

Man: Thank you very much (Irene) and (Ann) for being a part of the discussion today and representing another aspect of our work under the Department of Health and Human Services.

And while our next two speakers (Carol Bezel) and (Heather Hotstettler) come to the microphones I would just note that we're very sensitive in all of our value based purchasing initiatives including our hospital value based purchasing initiative the burden of the data collection.

So to the extent that we can be looking at these kinds of administrative data sources and leveraging them for various purposes not that we would necessarily ultimately want to fully get away from clinical data sources and abstracting not that we wouldn't want to automate that but we need some combination.

And at the very least we need to be making the best use of all the information we have for various different purposes. And to the extent that the POA data helps make our administrative data much more robust for the purpose of measurement then I think that's going to be helpful in addressing the burden of reporting in the future.

So thank you again for joining us.

(Carol Bezel): Good afternoon. I'm (Carol Bezel). I'm the Director of the Division of Outpatient Care in Hospital and Ambulatory Policy Group within CMM. And we're here now to begin to shift the focus of the conversation today to talk about healthcare associated conditions in the hospital outpatient department.

And we - for those of you who are following along in the slide set the first substantial slide is Slide 89. This says extension of (IPPS) HAC program hospital outpatient healthcare. And I refer you to that as the point where we're going to be starting this afternoon's conversation.

So (Heather Hotstettler) who is going to start the conversation this afternoon...

(Heather Hotstettler): Good afternoon. I want to thank everybody for participating today. I think we had a very lively public comment session this morning. And we're definitely looking forward to hearing further input this afternoon as we discuss healthcare associated conditions in the outpatient setting.

I think as you all know in the calendar 2009 (OPPS ASC) proposed its final rules we discussed the possibility of extending the (IPPS) HAC team of reduction policy to the outpatient setting.

We discussed and received comments on four major topic areas. Those

included the extension of the policy, collaboration process, (OPPS) infrastructure, and possible payment adjustment.

We received many many thoughtful comments and issues to take into consideration. We received comments from a variety of providers, hospitals, associations, individuals, as well as other groups representing, you know, insurance plans, employers, businesses, and consumers.

So I'd like to thank everyone who submitted comments to the rules and I would thank everyone in advance for their continued participation and your thoughtful insight.

So why would CMS create a healthcare acquired conditions policy for the (OPPS)? First I'd like to give you a few fun facts about Medicare outpatient payment. At least I think they're kind of fun.

Medicare currently pays over 4,000 hospitals and 200 community mental health centers for outpatient department services under the OPSS. In calendar year 2007 Medicare received over 140 million claims for hospital outpatient services and those were the claims that we used for rate setting in the upcoming year.

Looking towards next year in 2009, the CMS Office of the Actuary, has projected that OPSS payments, including beneficiary cost sharing is going to be a little over \$30 billion. That's an increase of over 5% from calendar year 2008.

As I'm sure you all know, hospital outpatient counters incorporate a large number and a very broad array of services. Individuals often initiate their hospital encounter in the Outpatient Department. They may receive clinic or

Emergency Department visits or have an Outpatient surgical procedure or diagnostic test that preceded inpatient care.

And as more and more services shift from being predominately provided in the inpatient setting to be provided as outpatient services, the likelihood that a health care associated condition will occur, will also increase. Therefore, we think it's appropriate to adopt a policy of not paying more for medical care in the hospital Outpatient Department that harms patients or leads to a preventable Inpatient hospital stay.

And we see extending the IPPS healthcare acquired condition payment policy to - as an important and essential next step in Medicare's focus on quality and value and for aligning the various value based purchasing payment incentives.

Can we move to the next slide? I think as you all have seen this morning with our presenters from CDC and ARC, we've been fortunate enough to throughout the development and implementation of the hospital acquired conditions policy to be able to collaborate extensively with other agencies and hospital associations and policy groups and other stakeholders and we look forward to continuing these collaborations and we'd be happy to hear from and work with other interested groups that we haven't heard from before who would like to share their insights.

So, I'll give you a little bit of background about the OPPF infrastructure and then I'll let Dr. (Bassell) talk in more detail about some of the concerns and things that we're taking into consideration.

Hospital outpatient payment covers the cost of facilities, equipment, supplies and hospital staff. The OPPF payment system is based on relative cost from hospital claims that we receive for services. Those services are each assigned

to ambulatory payment classification groups or APC's.

The APC's include individual Hix-Pix codes for items and services and those are grouped based on clinical similarity and comparable resource costs. Each APC has a distinct payment rate, which is based on the median cost for the services that are included in that APC.

And two things that I think are important to note about this, hospitals often receive multiple APC payments for a single encounter and under the current OPPF payment system, there is differential payment adjustment for disease severity, meaning that more complex patients may receive - require additional services which may be then paid separately, based on the APC.

So I'll turn it over to Dr. (Bassell) and then we'll hear from Dr. (Roman) about candidate health care associated conditions.

(Bassell): Well, clearly we've already had a substantial discussion about POA today and the definition of POA has been reviewed. Basically POA is designated whether something's present on admission is designated at the time of inpatient hospital admission and that inpatient hospital admission is signaled by the physician's order.

So when we discuss this area and how to identify conditions for purposes of a potential future hospital outpatient payment policy, a number of the commenters to our proposed rule pointed out to us that events occurring in the hospital outpatient department would be POA for the inpatient admission, and in fact, that we really needed to give a lot of thought to this area.

Clearly, patients arrive at the hospital outpatient department with many different conditions and there is no indicator right now or no administrative

way to access - to identify those for purposes of hospital outpatient reporting. So this is an area we're going to be doing a lot of thinking further about.

I would say that we have some other aspects of the infrastructure of hospital outpatient claims that may be different from IPPS and potentially more conducive to some other types of approaches.

In particular, as (Heather) mentioned services are paid based on Hix-Pix codes and if there - because there are often multiple payment group payments made for a single hospital encounter, there's at least some potential for distinguishing among services used to care for a hospital or health care associated conditions and those services used to care for a patient who arrives at the hospital with certain conditions.

So, that provides us with some potential ideas about ways in which we might address down the line a payment adjustment in such circumstances. We do clearly feel that identification of conditions or identification of services related to care for certain healthcare associated conditions needs to be administratively manageable for hospitals.

As (Heather) mentioned, we had 140 million out patient- hospital outpatient claims from 2007, so there's a high volume of claims that hospitals need to prepare and the challenges associated and issues associated with that are things that need to be taken into serious consideration, as we think further about development in this policy area.

We also had a discussion in the final rule of the issue of continuity across sites of care, given that right now as I mentioned before, a condition that develops in the hospital outpatient department would POA for inpatient admissions, we have some concerns about that provider and their accountability for the care

that's provided in that single institution, because clearly many patients come to the hospital outpatient department and initiate their care there and the timing of the physician order may not be precise in - it will be precise, but it's relationship to the care that's provided may occur at any point in time.

And so that's another area that we're thinking about and would welcome input into the challenges associated with any policies that might address that particular situation.

Moving on other concerns that are especially of interest in the hospital outpatient department, because of the nature of the ambulatory care, obviously the attribution of conditions is particularly significant as we think further about this. Encounters are typically of short duration, so patients may be there for, you know, a short period of time, very short as in, you know, half an hour, or to some extent some care -may observation services may be given to the patient over one to two days.

So the encounters are of a variable duration, but in fact, there are some very short encounters. Patients may also be seen in multiple departments or areas of the hospital during their encounter or with multiple encounters all in the same day of service and that needs to be taken into consideration.

And clearly ambulatory patients, even over a single day, let alone multiple days, may be seen in multiple hospital and non-hospital settings, including labs and physician's offices.

And so all of that is our -make the nature of hospital outpatient's payment policy consideration distinct and different from inpatient policy. And clearly there are also the issues just like there are for inpatient payment policy of provider versus patient factors and there was a substantial discussion this



morning of issues of risk adjustment which again, may or may not, be a significant in the hospital outpatient department given that, again more complex patients may get more services. That may not always be the case, but it may the case sometimes.

So we had a discussion in the final rule of - and in the proposed rule, in fact, of payment adjustment considerations. I'd like to point out that unlike the IPPS, the law doesn't prescribe a specific payment methodology for consideration in this case. Therefore, we are - don't experience - would not experience at least currently, some of the limitations that were discussed with respect to the IPPS payment policy, because the constraints are not tight. So we thought just as the discussion this morning for inpatient (unintelligible) about various payment adjustment methodologies including claims-specific approaches which would be following upon the current inpatient model.

Clearly we've discussed and would consider a payment reduction or non-payment for some or all services related to the care for healthcare associated conditions. And such adjusted rates could be derived from a variety of methodologies.

And we had a number of comments to the proposed rule where commenters discussed some of these alternative methodologies. And those include looking at claims for hospital outpatient services within/without healthcare associated conditions; looking at the IPPS DRG payment relationship; considering payment at the rates paid to hospitals that don't meet the quality reporting requirements for a given year.

Under the OPSS hospitals that don't meet the quality reporting requirements receive a two percentage point reduction to their update factor for that year. And there were a number of other methodologies that commenters brought to

our attention.

I also mentioned before the potential for hospitals to identify certain services and the charges associated that were related to healthcare associated conditions care. And some - we had some commenters who mentioned that hospitals could not collect deductibles or copayments for (HAPAC) related services.

So all of these again follow upon the claims-specific methodology that the inpatient program has used to date, and are areas that we will be thinking about. And as was mentioned this morning, these types of claims-specific approaches might be particularly valuable for (HAC) event or sentinel events which you expect low to no occurrence in the hospital outpatient department.

We've also had a discussion and are thinking about hospital-specific approaches, essentially a rate-based approach. And we could consider establishing a hospital rate of healthcare associative conditions and defining a benchmark above which a hospital payment adjustment would be made for some or all services provided during a period of time.

This might have some potential benefits. The hospitals might not actually have to specifically identify the services that are related to care for the healthcare associative conditions.

And even moving further, which is not a point we're at right now, but a number of commenter's suggested moving in this direction to consider episode-based payment across a continuum of care. Clearly that has many additional complexities.

So we're very interested in thinking further about the rate-based approach as

was mentioned this morning for the inpatient program as well given that it allows one to consider, I think, a wider variety of conditions for which we would not necessarily expect the occurrence to be zero or very low.

Particularly given the issues that I've mentioned before, I think that this is an area that we are going to think further about. And we certainly would be interested in the comments from you all about that area in particular.

So I'm going to turn it over to Dr. (Roman) now who's going to have a further discussion of the conditions in particular that we mentioned in the proposed rule and some other thinking we've been doing about conditions that could be appropriate for hospital outpatient care.

(Sheila Roman): Thanks (Carol). I'm (Shelia Roman), Medical Officer in the Hospital and Ambulatory Policy Group. And I'd like to thank everyone for coming today.

As you can tell from the two previous speakers, we're at a very different stage than the hospital-acquired conditions program that you heard about this morning. And that we've really not proposed any policy but just spoken about how extending the hospital program to the outpatient program might look and might begin.

So with that I want to reinforce that any of the conditions that I speak about today are not selected conditions in that some of the conditions that you heard about this morning were selected conditions. So we are really very interested in any feedback that you can provide to us on any of the conditions that I'll mention today or any of the types of conditions that we would be thinking about for the hospital outpatient setting.

I'd like to also further emphasize that we realize the complexity of the

outpatient setting in that patients can receive more than one encounter, that they will receive encounters over time which has implications about our measurement. So that it's a very different setting than the hospital setting.

Additionally patients will be receiving anything from a radiology service to a clinical service to a surgical service to an emergency service. So it's a very broad array of services that, you know, we will be attempting to cover in this program.

As Dr. (Bassell) previously mentioned we don't have the same specific statutory requirement for payment methodology. And that, you know, presents both good news and bad news as we move forward. But generally from the perspective of hospital associated conditions for hospital outpatients' settings, it allows us to broaden our view of conditions that we might consider.

On this slide the initial criteria for a possible candidate, hospital outpatient, hospital associated conditions which I'll probably refer to as (HAPAC) from here on out. We certainly wanted to lay forward for your comment some idea of the framework that we might use very early on in a program that was looking to identify (HAPAC).

And obviously we looked first at the IPPS (HAC) conditions that were statutory. But as I said we can go much broader than that. But we would be considering the volume, the cost. And I think, as someone pointed out this morning, built into that may lead us into some of the other issues that have been brought up such as disease severity, morbidity, and mortality.

We are not encumbered by the DRG system. That said, you know, our payment system is lacking some of the infrastructure that has been built in to the DRG system for payment.

And finally we will be considering reasonable preventability. You know, I think that is important. And we'll be talking and thinking about that both from an event-based and a rate-based perspective as has been previously alluded to.

Initially to start, we feel that conditions should occur during, and result from, care (provideness) single, hospital outpatient encounter. At CMS we probably do have the capability to follow patients linearly over time. But I think as we initially bring this program forward, we will be looking at conditions that occur during and result from a single (HOP) encounter.

We will be looking for conditions that initially are not likely to require longitudinal examinations of a beneficiary's healthcare experience. And we will also be looking for conditions where the - conditions that are present when the patient presents to the hospital outpatient requirement or rpoA life and disease severity will have little influence on the occurrence of that condition in the hospital outpatient setting, and finally where the provider attribution to the hospital is clear.

In the proposed and final rule, we did look to the IPPS (PAC) program and listed and proposed and then stated in the final rule that we would be looking at and considering the four candidate (HAPACs) that are listed on this slide, including foreign objects left in during surgery, air embolisms, lead incompatibility and trauma including fractures, dislocations, intracranial injury, crushing injuries, burns and electric shock.

We had commenters give us several ideas for other conditions. And one of the comments clearly was to extend beyond the IPPS conditions. And one of the suggestions was to, in fact, look at conditions that were adverse events leading to death and disability.

And as we looked to adverse events that are codeable, that fulfill that requirement, there are a number of candidates where we could broaden conditions. And those might include use of contaminated drugs; use of contaminated devices; use of contaminated biologics provided by a healthcare facility to a patient in a hospital outpatient encounter.

Also malfunction of a device in - during patient care in a hospital outpatient encounter. Any incidents in which a line designated as an oxygen line or other gas is contaminated by toxic substances would be considered. Complications of anesthesia would be considered -- we do perform in the hospital outpatient setting a large number of ambulatory surgical procedures -- and finally postoperative hemorrhage.

As we move forward in the program and consider where we might go for other (HAPACs) for consideration both in the short run and also thinking toward the future, I'm - I want to point out another suggestion that a commenter made which was to think about medication errors. And conditions related to medication administration and medication errors in the hospital outpatient setting is somewhere where we clearly want to go.

We do know that the literature supports that there are hundreds of thousands of medication errors made in hospital-based clinics every year. And we do think that this is an area that is very ripe for examination.

Medications that would be considered for a first look and medication administration errors that we feel would be codeable would include antibiotics, antineoplastic agents, anticoagulants, fibrinolytics, opiates, sedatives, anesthetics, cardiac arrhythmic, insulin, and drugs affecting the autonomic nervous system.

For hospitals probably insulin and Coumadin or anticoagulants, they're probably the leading cause of medication errors in the hospital setting.

As we think ahead to a time where we have an infrastructure which can support a linear evaluation and a longitudinal evaluation of a patient's encounter over time in the ambulatory setting and when we have a present on encounter for POA like type of indicator for encounters in the hospital outpatient setting, we can think toward conditions that are related to hospital outpatient surgery or other procedures and infections related to hospital outpatient care.

And some of the surgeries and procedures that we would be considering, we would also initially look to the IPPS (PAC) program. And would look to evaluate for the hospital outpatient setting such things as deep vein thrombosis associated with orthopedic procedures that are now being performed in the hospital outpatient setting and other events that are clearly related and specified in the record as complications due to procedures such as liver failure, acute renal failure or acute renal insufficiency, and cardiac complications resulting from cardiac procedures or complications resulting from gastroenterologic procedures.

And related to infections we would also be looking toward catheter-associated urinary tract infections, vascular catheter-associated infections. There are many different types of catheters that are placed in the outpatient setting and are challenging given that patients are at that encounter a short period of time and then have their device in place for a longer period of time.

But we think that this is an area that deserved attention. And I think has received a lot of attention this morning from one of the commenters.

Devices particularly implantable devices and infections associated with these devices need attention and we would be thinking and asking you to comment on how we would incorporate into (HAPAC) program these types of conditions where there is not - where the condition is not present on admission. But that the condition develops over time and is related in some way perhaps to the placement of the device or the catheter or the vascular device that's placed in the patient.

And finally there are conditions related to patient care that we would like to consider. And some of them if we have a present on hospital outpatient encounter as patient's come to the hospital, particularly in our emergency room settings, we think could go very early into a (HAPAC) program.

And those might include dehydration, fluid overload, hypokalemia and manifestations of poor glycemic control as the IPPS (PAC) program is using, particularly hypoglycemia and hypoglycemic coma.

As we stretch further on into where we would like to see this program going and how it might relate to other settings where patients are cared for and payment systems, eventually we would like to be able to measure events related to poor continuity of care, poor coordination of care including those that might lead to potentially avoidable hospitalizations.

Obviously this is fairly complex and involves both a longitudinal evaluation of the patient as they move from different settings of care and settings of care which were paid under different payment systems.

So finally we do have a number of questions to address in getting a (HAPAC) program up and going. And we would be very appreciative of your comments



and input on these questions. We would like - we will need to know how common the conditions are in the hospital setting. Are there guidelines or prevention interventions that exist that will help in the interpretation of the term reasonably preventable?

We also would like to have them be evaluated in evidence-based so that we know how effective prevention interventions will be. And that's related to, is there a baseline in those types of conditions which are better to be evaluated on a rate-based measurement and allowing us to have some idea of how much improvement, you know, we can actually see and how far the benchmark can actually be moved.

Also can - how can we identify these conditions through ICD9 codes or through other top claim reporting mechanisms, especially a POA like indicator? And how do we resolve the (HOP) conditions that result in inpatient admission and how they might be coded. And as far as measurements, how can we and how will we be able to perform sequential evaluation of Medicare claims. And finally how do we measure event-based versus rate-based conditions?

I think as we've said here both in this morning's session and this afternoon, they're certainly conditions that appear to be sentinel that are probably better event-based and measured by - in that way. And then clearly, a lot of conditions, particularly that are relevant to the outpatient setting, will be best measured in a rate-based fashion.

And finally I've just listed some resources and information on contacting any of us about any information we've talked about this afternoon. And I thank you for your participation, look forward to your comments, and wish you a Happy Holiday.

(Tom): Very thorough and thoughtful presentations from the Hospital Outpatient Department Division here today; great background for our discussion. They've really set up a number of issues that I know that you all will be interested in having input on. So let's get right to it.

We'll start with comments from those of you who are in the room here in Baltimore. If you would limit your comments to a couple of minutes please and know that you will have the opportunity to comment a second time as we come back around for Round 2.

And after we take our comments from the room here in Baltimore, we will be taking comments from the phone lines as well. We have our first commenter.

(Chris Gersaw): Good afternoon.

Male: Would you identify yourself and your organization to start?

(Chris Gersaw): Sure.

Male: Thank you.

(Chris Gersaw): My name is Dr. (Chris Gersaw). I'm here representing the American Geriatric Society. I'm a geriatrician, currently Associate Professor of Medicine and the Interim Director of Provision of Geriatric Medicine in Gerontology at John's Hopkins. I join others who thank you for having this open session and allowing us to make our comments.

We have significant concerns with several of the inpatient HAC proposals. We've expressed those in the inpatient setting about - regarding the inpatient

setting in the past especially regarding delirium and provided extensive comments to CMS about that.

We're equally concerned about many of - as the others are in this room, about healthcare acquired condition payment policy that reduces payments to providers in the outpatient setting and could result in inappropriate penalties when providers are not responsible for causing the conditions and when they're powerless to prevent them. Expanding the current inpatient policy to outpatient settings would be premature.

We have provided extensive comments regarding falls and trauma in our written testimony. We have concerns about these being included in the inpatient HAC policy as we are even more - we're even more concerned about the potential for CMS and consider applying these in the outpatient setting.

Unlike HACs that are a direct result of medical errors or adverse consequences of medical care - falls are most often due not to the effect of medical error but rather to the effects of disease, impairments and the appropriate use of medications. In addition such incidents or injuries can occur even when providers furnish the best possible care.

At this time we feel there's no reason to consider these events to be reasonably preventable and reimbursements should not be affected. Falls, particularly for vulnerable older population, can be reduced through interventions. However about a third of older adults, those over the age of 65, experience falls in the community on a yearly basis. And this number rises to greater than 50% for those that are over age 80.

Underlying causes for falls are diverse. Research on falls and fall reduction has shown that interventions that are effective only reduce falls by about 12%.

Clearly these do not support - this does not support falling as a preventable medical condition given the state of the art. So we would urge CMS to proceed cautiously with any proposal to expand the inpatient HAC payment policy to other settings, in this case the outpatient setting. So I thank you for allowing me to make those comments. Thank you.

(Tom): Thank you for your comments. One thing that I know we heard when we were reviewing the comments on the outpatient proposed rule was that we ought to be looking extensively at what the inpatient experience is prior to extending the policy and you're certainly reflecting that here. I don't know if any of you want to say anything in addition.

Woman: I don't think so. I mean, again we are very cognizant of the outpatient setting. And again we're - we are thinking about a variety of different approaches; event-based, rate-based as has been discussed. And we certainly hear what you're saying about falls and again have made no proposal. This was just our discussion of possibilities. So we appreciate the input.

(Tom): Thank you. Next comment please.

(Barb Tomar): Hi. I'm (Barb Tomar) from the College of Emergency Physicians. And I was wondering if you could help me out with some examples about emergency department possible avoidable conditions.

I mean, I understand in the outpatient department where you've got scheduled visits to the various departments and clinics for procedures and various medical kinds of tests or treatment and the whole surgical thing with objects being left in.

I'm struggling - aside from maybe misadministration of drugs in the emergency department, I'm really struggling with what would be preventable when a person that's never been seen or heard from walks in the door with just a set of conditions and you're trying to create a diagnosis. Can you help me? I'm just trying to think how I could educate my members to work more effectively with you all on this.

Woman: I think you're right. The first thing to come to mind is misadministration of medications in the emergency room setting and that those are not infrequent. And then I think that in the list that I ticked off, I think that those occur in the emergency room on some regular basis where there are misadventures in medication.

I think other potential areas include some of the areas that I mentioned with fluid overload, where fluids are administered and not monitored as carefully as they could be. You know, I think even dehydration can occur in the emergency room setting depending on how long a patient is present with their...

(Barb Tomar): Particularly if they're boarding for days on end in the hallway.

Woman: Well that's - and that does occur with some regularity as well in the current healthcare system.

You know, I think that, you know, patients are sent from the emergency room to other areas within the hospital. And I think that that's where the area of injury and falls and trauma actually, you know, plays a role that goes beyond some of the points that were just raised. That is not just intrinsic to the patient's frailty, but maybe intrinsic to the system within the hospital of transporting a patient and monitoring a patient.

Episodes of hypoglycemia are not uncommon within an emergency room setting where a patients may have their own insulin on board and are not carefully monitored. It may not even be known that the patient has diabetes or when patients are again sent elsewhere outside of the emergency room setting, not having had a meal with insulin on board.

And those examples are applicable to other medications that patients may be receiving that may go unmonitored as they're moved around the hospital for their workup.

(Bob Tomar): Okay.

(Tom): Thank you. I'm sure that your members would have some other ideas as well.

(Tonya): Yes. Hi. (Tonya) (unintelligible), Consumer Purchaser Disclosure Project.

We want to express our support for expanding nonpayment for HACs beyond the IPPS setting and into the outpatient setting. We know just in our comments on the calendar year 2009, OPSS proposed rule. Just want to reiterate that here.

We feel that expanding this policy would improve patient outcomes and also be a step towards realigning payment to promote higher value.

There were four criteria - or four proposed HACs that you mentioned today. They were also in the proposed rule, the CY 2009. And, you know, all four of these as you know, there are patient safety indicator measures. I would feel they're very appropriate for the outpatient setting. They meet the criteria that were outlined in the proposed rule and we're very supportive.

We encourage CMS and this goes for the outpatient and the inpatient setting, to work to align with also the private sector and with Medicaid to work on measurement reporting and providing incentives across those sectors when it comes to nonpayment for HACs. And we're also very supportive of some of the other instances that you mentioned today, specifically serious disability or death caused by adverse drug events and medication errors.

Our one concern is that among the many challenges that you would face in implementing this in the outpatient setting, we're concerned that expanding nonpayment might lead to the potential for under-coding of HACs. There's just the potential that if hospitals are not going to get paid for these events that there might be a lack of coding. And so we just encourage CMS to build an auditing process into the system. Thank you.

(Tom): Thank you (Tonya) for representing the consumer perspective. You referred to the conditions that (Sheila) discussed as proposed. They were in the proposed rule. I just wanted to reiterate what each of the speakers has said -- (Carol), (Heather), and (Sheila) that we had a discussion piece in the - through the OPPTS rule making but we didn't actually propose any conditions. We just raised them for consideration just as we're doing today as well.

In terms of this idea of under-coding, we are concerned that we wouldn't want to lose information because we're paying in a different way. So we encourage the coding community to continue to practice the coding standards as outlined in the coding guidelines and comply with the coding ethics.

We know that sometimes our approach in terms of the number of diagnoses listed on a claim and things like that sometime limit the amount of information that can be reported and so there can be some decisions that need

to be made around that. But we will be if we're able to have the funding to monitor the impact as - to the depth that we would like, one of the things that we would want to look at would be the impact on the coding practices as well. Next comment please.

(John Rigum): Hi Dr. (Ballick) and members of the panel. My name is (John Rigum) from the California Hospital Association. We represent over 500 members in the state of California, primarily acute care hospitals but we do have some other - some other members - representing members of the post acute community as well.

I think in general, the Hospital Association - the California Hospital Association is generally very supportive and has been on the record as staying supportive of value-based purchasing arrangements, both that have been proposed previously and those that are currently on the table. However we do have some concerns about the application of hospital-acquired conditions, particularly in the outpatient setting of an outpatient emergency department, for a couple of different reasons.

I think the outpatient emergency department is substantively different from the inpatient setting in ways that are fairly intuitive. But in particular it's the only - it has the characteristic of being the department of a hospital that is characteristically uncontrolled or has a lower degree of predictability in it than almost any other department within a hospital.

As those of you who know who have spent some time in an emergency department can tell you, you have no control on demand as you do in other aspects of the hospital. You can generally control the demand of - of - or control the flow of patients that come up to CCU beds, to ICU beds, to med/surg beds. But you don't necessarily have any - control or have very little



control over the patients that are coming in the doors of your emergency department.

Also in the - in emergency departments, there are a number of different providers who are potentially both monitoring patients and also administering medications. Those could be residents in a teaching facility. Those could be nurses in a community hospital or in any other range of hospital, not all of whom have a financial relationship with the hospital. But any one of whom in a hospital-acquired condition sort of policy could affect the reimbursement for medications or for procedures performed in an outpatient emergency department setting.

I'd also finally note that there's a strange interaction between hospital emergency departments and other tertiary and quaternary receiving facilities whereby patients may be treated in an emergency department and in a community hospital and then transferred to a tertiary or quaternary care facility.

So I think it's incumbent upon CMS as you consider proposals to expand the HAC policy to the outpatient department, to think about those interactions and to think about how procedures that were performed in a certain manner in an emergency department of an originating hospital affect or do not affect the reimbursement of the inpatient stay at a tertiary or quaternary care facility or even at the emergency department at a secondary facility in the event of a trauma transfer. Thank you.

(Tom): Thank you, an important consideration. We've had a couple of comments that have focused specifically on the emergency department. But I just want to remind the group that when we're talking outpatient, we're talking broader than that and maybe if we could get a ticking off of a few of the other settings

that we're also paying attention to this afternoon.

(Carol Bassell): Other settings meaning...

(Tom): Right.

(Carol Bassell): ...other types of services?

(Tom): Yes, thank you.

(Carol Bassell): So in addition to emergency department visits, many patients receive clinic visits at hospitals, particularly specialty care that runs the gamut from ophthalmology services to cardiothoracic, you know, surgery visits either in evaluation or in surgical follow up so we have the whole visit arena.

Many patients receive ongoing care for chronic conditions there such as - or acute conditions, in fact cancer being one of them. Many hospitals serve as location of care for cancer patients with cancer who are requiring a lot of drug administration services. Chemotherapy administration being very, very common in the hospital outpatient department.

In addition as been mentioned, surgical procedures are very common, basically across the spectrum of surgery, ranging from ophthalmology to ear, nose and throat to orthopedic surgery procedures to gastroenterological procedures, particularly endoscopies. That range of surgical procedures is very common.

Radiology procedures ranging from plain chest x-rays to advanced imaging, including nuclear medicine imaging, again very common in the hospital outpatient department, interventional radiology procedures including stent

placement, and the whole gamut. Many, many services are paid for. And then there are, you know, your basic services, lab services and other ancillary services that are very commonly provided.

So there's really quite a spectrum of services as many of you know, provided in the hospital outpatient department. All of these are applicable - have payment applicability under the outpatient perspective payment system to hospital outpatient department care.

(Tom): Thank you for that (Carol). I think review of that spectrum does give some indication of what we would need to be able to get our arms around here when we talk about expanding this payment policy from the inpatient setting to the outpatient setting, not only the differences in those two settings but also the differences among the various services that might be provided in the outpatient setting.

Do we have any other comments in the room in Baltimore? So while we're queuing up here, Operator if you could please ask the phone participants to queue up as well. And we'll take one more comment here from Baltimore before going to the phone.

Operator: Okay. At this time if you have a comment, please press star and the Number 1 on your telephone keypad.

(Tom): Go ahead.

(John Shaw): (John Shaw) from Next Wave in Albany. A couple observations in terms of applying the inpatient approach to the outpatient side.

One of the conditions was that there should be extra payment. And I think

what we're talking about is extra payment to treat whatever the condition that's a HAC. And so if you do that and the treatment has a HCPCS code, then you couldn't use a modifier to flag it for non-payment.

There's a whole group of the hospital HACs that may not apply easily in the outpatient side; infections, DVT, (PE), and so on come to mind because they're not going to happen and percolate in one visit one day. You might get a (unintelligible) if you stay long enough in the ER. But in the other settings I don't think so.

And so where I really think the bulk of the opportunities are going to lie, is what you talked about in terms of hand-offs, communication, coordination of care, and continuity of care over time. Those are really part of the National Priority Partnership focus areas on where we're going to get the biggest bang for the buck going forward. They're also the most difficult to try to measure because then you have to match together various settings.

One model to think about is just pediatric asthma because then you have, is the child controlled in the home and in the school? And is there appropriate medical oversight before they ever get to an ER or a clinic in the hospital side? And then, are you controlling it enough to get to the inpatient side?

So just think about the concept of how would you do that. But that's really where we're going to get the biggest bang for the buck in providing good care and less expensively. So look to the NPP priorities.

(Tom): Thank you. Could we have our first comment from the phone line please?

Operator: Your first comment comes from (Joseph Servia). Your line is open.

(Joseph Servia): Good afternoon. (It's Joe Servia). I'm a infectious disease physician, Clinical Professor of Medicine in Pediatrics at Albert Einstein College of Medicine New York, and Medical Director and Senior Vice President for (Paul Medical).

And as the other commenters have mentioned, I'm also very grateful for the opportunity to be able to provide comments this afternoon. And I'd like to once again express support for CMS and CDS, and no also (ARC) joint initiatives like this 2008 Medicare Listening Session.

Most of my comments pertain to the IPPS. However there may be some implications for the OPSS as well. This process of collaborating to appropriately align financial incentives with the adoption of best practices in order to improve safety and quality, as well as cost-effectiveness in healthcare is truly laudable.

In particular I wanted to offer strong support for the inclusion of hospital acquired Legionnaire's disease and infection by other water born pathogens such as (unintelligible) as healthcare associated conditions.

As recognized illnesses that complicate hospital stays at high cost both financially and in terms of serious morbidity and mortality in patients, Legionnaire's and other infections with water born pathogens meet each of the three criteria that are set forth in Section 5001C.

As I mentioned I'm an infectious disease physician. In 24 years now of clinical and academic practice, I have made a number of observations. And I'd like to comment on some of the relevant questions that were raised this past August in the federal register on this issue with respect with Legionnaire and other water born pathogens.

First I'd applaud the attention that both CMS and CDC have focused on this highly prevalent and yet vastly under-recognized threat to hospitalized patients. All these infections result in huge costs to our healthcare system as well as a tremendous human toll in excess morbidity and mortality.

Moreover numerous clinical studies published now in peer-reviewed literature over many years demonstrate the clinical efficacy and cost-effectiveness of a strategy of regular hospital water testing, appropriate systemic water disinfection and point of use hospital water filtration as a strategy for reducing infection risks with water born pathogens in the hospitals.

Far from rare and difficult to diagnose, infections with (*Legionella*) account for roughly 18,000 infections per year in the US according to CDC. And though likely under-diagnosed, a number of tests including urinary antigen, direct fluorescent antibody, and culture-based testing have been available to and utilized by clinicians for many years in making these diagnoses. More recently rapid duplex PCR testing has been added to this.

Even accepting the fiscal year 2007 data that were reported in the federal register at 357 cases of Legionnaire's disease each at a cost of \$86,014 per hospital stay, the savings for prevention of Legionnaire's disease alone would be over \$30 million per year which is substantially higher than that for other healthcare associated conditions that were selected in the final rule.

And in response to objections regarding difficulty in distinguishing hospital acquired (*Legionella*), I have put in my written comments the references for CDC established case definitions for determining whether (*Legionella*) is nosocomially or community acquired.

Statements about the lack of a dose/response relationship and not having existed for (*Legionella*) are simply incorrect. The Department of Labor OSHA and the World Health Organization have provided clear guidelines with respect to this.

Finally comments that the risks associated with (*Legionella*) and other water born pathogens can't be managed without possible damage to hospital infrastructures or the use of costly sterile bottled water are similarly incorrect and ignore the demonstrated use of the strategy including point of use water filtration technologies.

Once again abundant peer-reviewed medical literatures has demonstrated that such filtration may interrupt clinical outbreaks of infection due to recognized water born pathogens including (*Legionella*) in the healthcare environment, and offer a cost-effective complementary infection control strategy particularly when you use filtrations at highest risk.

For this reason point of use filtration has been recommended as a mitigation method by the WHO as well as in the recent Department of Veteran's Affairs, VHA directive for prevention of (*Legionella*) this past February.

So with respect to other water born pathogens, it's also clearly not the case that these are rare. Some of the most frequently isolated gram negative bacteria including *Pseudomonas* have been found to persist in hospital water for extended periods of time and have accounted for large nosocomial outbreaks.

A recent review of studies between 1998 and 2005 have found that between 9 and 68% of random intensive care unit water samples were positive for *Pseudomonas* and between 14 and 50% of patient infections there were due to

genotypes that were found in intensive care unit water.

According to CDC, the incidence of pseudomonas alone in US hospitals averages 4 per 1000 discharges. And the bacterium is now the fourth most commonly isolated nosocomial pathogen accounting for roughly 10% of all healthcare associated infections. And 42% of pseudomonas infections in hospitalized patients have been linked to water, with one investigation estimating 1400 deaths occurring each year as a result of water born nosocomially pneumonias alone attributable to pseudomonas.

So in summary, I would on the basis of the high disease burden and cost, widely evidenced-based prevention guidelines, and distinct identifying ICD9 codes which I've referenced in my written comments which I've submitted would certainly recommend that CMS include (Legionella) and other water born pathogens as healthcare associated conditions.

Thank you very much.

(Tom): Thank you for the thorough comments regarding water born pathogens. This, I think, is more relevant to the inpatient discussion from this morning. And so (Dr. Chesly Richards) from the CDC has rejoined us up here at the front table with a microphone. So (Chesly) would you like to make a brief comment?

(Chesly Richards): Very brief. I would just say that hospital acquired (Legionella) is an important issue. And as the speaker has articulated there are guidelines. And I think it's something that that we take under consideration.

There are complexities around determining the hospital acquired piece of it and the present-on-admission variables approach. But I think it's certainly something we can consider.



(Tom): So for those of you who haven't followed this quite so closely, we did propose in a previous round of rule-making Legionnaire's disease. And as the commenter mentioned, we did not adopt that condition based on the stakeholder input that we received.

As was indicated this morning, as the clinical science evolve, as the guidelines for prevention evolve, we will be reconsidering conditions that were considered previously and not adopted potentially in future rounds of rule-making. So we very much appreciate ongoing comments about the potential candidate conditions. So thank you very much for that comment.

Could we take the next...

(Joseph Servia): Thank you.

(Tom): ...phone comment please?

Operator: Your next comment comes from (Linda Galabiesky). Your line is open.

(Linda Galabiesky): Hi. This is (Linda Galabiesky) from Mayo Clinic Arizona. And my question is to (Irene) and (Ann). And I was wondering if there were any plans to look at pharmacy data with some of their studies.

(Tom): Thank you for your inquiry. (Irene) and (Ann) weren't able to be with us throughout the remainder of the discussion today.

(Linda Galabiesky): Oh.

(Tom): But I know that they would value your inquiry. And I would suggest that you

contact them. Their contact information is available publicly in the online HHS Employee Directory.

(Linda Galabiesky): Thank you.

(Tom): Thank you for your participation today. Do we have the next comment please?

Operator: Your next comment comes from (Carol Ann Armenty). Your line is open.

(Carol Ann Armenty): And good afternoon. And thank you again. I spoke earlier this morning. I'm the Healthcare Attorney at Legal Services. And it occurred to me that I might add for those who don't know that Legal Services represents only those who are 200% and below federal poverty level which means a great proportion of our clients at Legal Services are Medicare and Medicaid clients.

And with that, I just wanted to give my enthusiastic support in the outpatient setting of monitoring events regarding pharmaceuticals. And I think it's interesting that we have talked chronologically moving from inpatient to outpatient. And this may be an area in which we may want to move in the other direction. If we're successful in the outpatient monitoring, then perhaps that's something that we also want to look back at in the inpatient setting.

And I do appreciate also -- one other word -- the difficulty I think will be in monitoring what happens after the outpatient. And I think the suggestion was that we look at linking records in terms of look-backs for payment depending on an outpatient procedure. But I think that that is something that is highly doable. And I think that's something that's necessarily if this will be successful. Thank you.

(Tom): ...for that comment. One thing that I picked up on from your statement about

the relationship between inpatient/outpatient is that from the discussion that we had about the outpatient setting, you would recognize that we don't have some of the same statutory limit patients in that patients that we have in the selection of conditions for the inpatient setting.

So I think you're exactly right that we could certainly learn about the occurrence and how to bring conditions into a payment policy in the outpatient setting and then potentially consider that for the inpatient setting.

Next comment please.

Operator: Your next comment comes from (Nancy Foster). Your line is open.

(Nancy Foster): Thanks very much. (Tom) can you hear me all right?

(Tom): I hear you (Nancy).

(Nancy Foster): Great. And again I'll join with everyone in thanking you for holding this session and for allowing comments as you think through how to proceed with the hospital acquired conditions policy.

I want to address in particular the outpatient issues at the moment. Although some of my comments will apply to both the inpatient and outpatient setting.

And just to start broadly I have to raise a particular concern that as you think through these issues and in a sense polled hospitals, hospital outpatient department, and other providers financially responsible for certain adverse consequences to patients, it may have the unintended consequence of creating some walls between the providers. And I would think that would be an enormous disadvantage in an era where we're really trying to push towards

greater care coordination, greater integration of care.

And so I think you need to think very carefully about how this policy would work in conjunction with the other policies that are being advocated on a national level to create greater care coordination and that potential for unintended consequences.

And I say that recognizing that I think virtually all of us are eager to see greater alignment between payment and the provision of higher quality, safer care. That's the right thing to do. The question is whether this aspect of value-based purchasing is the one on which we need to focus first or at this juncture, or whether there are greater opportunities to really enhance the quality of care, the safety of the care that patients receive.

And that ought to take precedence over the amount of time and effort that is being spent on trying to figure out how to re-jigger the payment system, the coding system, every other system so that we can provide a - what - at least an inpatient system thus far has been a relatively modest financial disincentive for an adverse event occurring.

So I just raise those two overarching policies. And then would like to associate myself with some of the comments that I heard earlier from the folks in the room as well as those on the phone.

I think with the hospital outpatient department you have some significant challenges. And (Sheila) and (Carol) referred to some of those. There was a lot of conversation about whether you could create something akin to a present-on-admission or present-on-presentation code that would help to identify it. But a number of the things - the conditions that (Sheila) was talking about would not emerge until after the patient had left the outpatient

department.

And so one wonders how you were going to actually account for those things that are present in the patient but may not have been necessarily a result of the care delivered in the outpatient setting. It may have occurred as a result of something that occurred between the time the patient left the outpatient department and the time they have resurfaced in the healthcare delivery system with whatever complication of care we are talking about.

I also heard a reference in (Sheila's) remarks to the incident such as the malfunction of a device. And I know that you heard from us when that was one of the proposed conditions for the inpatient department.

I just want to reiterate that here as well as in the inpatient department that raises the whole notion of how do you know from claims information whether the hospital bore any responsibility for that malfunction? How do you know it wasn't something that occurred by the manufacturer that when the device was manufactured? How do you know what to hold the hospital accountable for?

It's why we've thought that this move towards greater integration, greater look at the episode, greater understanding of how to drive quality and safety throughout the entire episode is what's really needed. And I worry that holding any individual part of the system accountable when you can't actually pinpoint where the problem originated will be frustrating as well as cause folks to think that there's a game going on here rather than realignment of incentives with the provision of high quality care.

And (Tom) just one more thought and that is many of the services that were discussed that are provided in the hospital outpatient department are similar to services and pose similar risks to services provided in other settings as well.

So, you know, surgical site infections, things left in during the course of surgery in the hospital outpatient department don't seem to me to be terribly different if you take it out of the hospital outpatient department and put it in an ambulatory surgery setting.

So could you talk a little bit about how this policy is being considered for the broad array of payment silos that CMS has?

(Tom): Thank you for comments (Nancy). You certainly highlighted some of the primary issues that...

(Nancy Foster): (Tom)?

(Tom): ...and subjects for discussions today such as the alignment among the various payment settings including the institutional and...

(Nancy Foster): Hello?

(Tom): ...professional alignment. The idea of moving toward a value-based purchasing model or a rate-based measurement for our performance based payment, the idea of how to accomplishment present-on-admission type concepts for the outpatient department outpatient accountability.

(Nancy Foster): Hello?

(Tom): Can you hear me (Nancy)? (Nancy) are you still there?

All right. I'm not sure if she can still hear us. It sounds like we can hear her. But her specific inquiry was about how we're looking at not just the hospital outpatient setting but other settings well.

And as was mentioned this morning in a piece that (Lisa Graybert) presented in terms of the future of the policy, (Lisa) noted that -- and it's one of your slides -- that we're looking beyond just the hospital outpatient department and the various services that (Carol) mentioned but also to other hospital settings and potentially to explore non hospital settings as well. So we would be interested in comments about that if you would like to submit those as well. (Nancy) did you - were you able to rejoin? Okay. Thank you for those comments.

Let's take the next phone commenter please.

Operator: Your next comment comes from (Linda Hart). Your line is open.

(Linda Hart): Yes (Liz). This is (Linda Hart) from Mercy Health System in Philadelphia. And excuse my voice. We have actually have a couple of questions for you. And first I also want to say thank you. I know it's been a long day but we really do appreciate the wealth and depth of information that you're providing.

We have one comment and then I also have a few questions for you. I know some other people have already raised the question about the disconnect regarding how physicians and other type of providers of care are reimbursed compared to the hospitals. And we understand that the hospital, hospital acquired condition programs is a first step. And we're fine with that.

We just want to also kind of plant the seed in order to really affect change, it's very helpful to have the provider incentives aligned.

My other question for you is regarding some billing guidance. And it's specific more to current hospital acquired conditions program. And it is,

should hospitals see billing using the DRG without considering the impact of the present-on-admission indicators even though they are currently and of course being reported, or should they be regrouping the DRG to what they think Medicare will regroup it to? And this is a question not only for Medicare but with the understanding that many other payers are implementing Medicare's program as well.

So if you can provide some guidance on that and also on whether or not there will be any appeals process so that hospitals who can document they followed a particular guideline for care. But if conditions resulted regardless of that, is there any appeals process?

(Tom):

Okay. So I'll answer the question regarding appeals and then (Lisa Graybert) has joined me here at the table. (unintelligible) a bit involved with the folks who work on the claims processing side of this. And you recall a presentation from this morning about the life of the claim. And she'll review the relevant portion of that discussion in answering your first question.

Regarding appeals, the - an appeal would be appropriate in a situation where CMS did not pay the hospital according to the information that the hospital provided us about the conditions that were on the claim and about whether or not those conditions were present on admission.

So if the hospital tells us that the condition was not present on admission or it was unknown whether the condition is - was present on admission and we pay inappropriately based on the information that the hospital gave us, then that would be an opportunity for a hospital to appeal.

There is not a not an appeal based on whether or not the hospital complied with evidence-based guidelines which I think is probably what your question



is going to. So now we'll get to the answer the claims processing question.

(Lisa Graybert): Hospitals just submit bills with the ICD9 diagnosis codes that most accurately reflect the patient's record. Once those bills come into CMS, we actually read all of the information on the claim. So we'll look at the ICD9 diagnosis codes and the corresponding present-on-admission indicator information that corresponds to those ICD9 codes.

Once we have it in our system, our grouper is programmed with logic to adjust the DRG if a hospital acquired condition is present and that hospital acquired is coded as an N or a U and that's the only CC or MCC present within the claim. So if all of those conditions are met, the grouper itself will change the DRG assignment. So you don't have to worry about doing that on your end. CMS takes care of that.

(Linda Hart): Okay. Thank you very much.

(Tom): Yes. Thank you for your question and for being on the call today despite what it sounds like might be a miserable day for you.

(Linda Hart): Thank you.

(Tom): Operator could we have the next comment please?

Operator: Your next comment comes from (Juvna Shaw). Your line is open

Okay. It looks like he withdrew his question.

(Tom): Okay.

Operator: Here he comes actually. He's back in there again. (Juvna Shaw) your line is open.

(Juvna Shaw): Okay. This is (Juvna). Can you hear me?

(Tom): Yes, we can hear you.

(Juvna Shaw): Hello?

(Tom): Yes, please speak up.

(Juvna Shaw): Okay. Hi there. Sorry. This is (Juvna Shaw). And my question is geared, I think, for Dr. (Bassell). First a comment and then a question. You know, the value-based purchasing initiatives, I think, are important. And CMS has definitely been rolling those out for the outpatient payment system. But I think one thing to consider is that we've seen a lot of changes over the last few years with those initiatives with increased packaging and the release of even more composite APCs for 2009.

And I think that the claims processing issues and some of the things that Dr. (Bassell) raised about patient seeing - being seen across different clinics and departments. I mean, I think all of those things when you put them in the hopper, I think it's going to result in a great deal of confusion in claims processing issues for providers and also for CMS unless different rules, possibly different billing guidance is given.

Some of the examples given about a patient arriving in the emergency department and then maybe being - you know, then going to outpatient surgery or being sent to another department. I think there are lots and lots of those kind of claim examples that raise questions about whether providers will

continue to be required to report all of their visits for a single date of service on a single claim.

So I know that CMS looks like they're still thinking through the claims-specific approaches in terms of payment impact versus other approaches. And I guess I would just say that, you know, from my perspective the outpatient system is so fundamentally different with being procedure driven and multiple APC payment rates being generated that applying kind of an overall reduction to the claim would seem inappropriate and unfair to providers providing a vast array of services across multiple departments.

So I guess I would just encourage CMS to maybe, you know, share different types of live claim examples where patients crossed departments. And look at those and kind of simulate payment impact that would occur. And maybe even release that to the public to think through.

I really appreciate you all allowing us to think about this with you and provide comments. But it's hard to envision those outpatient claims and to really understand how CMS would logically be able to associate individual procedure line items with a particular diagnosis that the HAC.

And so I guess I just start thinking of things like additional modifiers might be needed, or condition codes, or CMS's claims processing logic would need to be revamped in terms of how it would look at rev codes and so on.

So that's my comment and I guess just one question. I think it's on slide 94 that Dr. (Bassell) presented. Just wanted to be sure that I understood the bullet that indicates hospitals could identify non-covered charges for HOP HAC related services. I assume non-covered there doesn't mean truly non-covered, or maybe it does. Or does it mean charges that aren't related to the HAC that's

being reported?

(Carol Bassell): Well (Juvna) that was just designed to talk about the fact that we could on claims have hospitals identify subsets of charges based on - I don't know what we do coverage or non-coverage, or association with the care for the healthcare associated condition.

(Juvna Shaw): Okay.

(Carol Bassell): So it's not meant to be specific as it's stated or isolated as it's stated.

(Juvna Shaw): Okay, great. Thank you.

(Carol Bassell): Just another comment on your comments. We understand that the patients receive care in multiple departments of the hospital. We also understand it's the Medicare program, we do pay the hospital. And so some accountability at the hospital level I think is built into our thinking here. We don't provide payment to hospital on a department-by-department basis. So that we certainly know from other settings and other conversations about how that works and may happen in hospitals.

So I would like to again focus on the fact we pay hospitals for the services they provide which many times are multiple services to a patient in a hospital across departments. And as I think I mentioned we've talked about a variety different payment adjustment approaches depending on the methodology, one we're using, whether that'd be a claim-based payment approach, or an event-based approach, or a rate-based approach.

Clearly we have taken a variety of administrative steps over the last few years to adopt certain policies that have incorporated a variety of things including

claims processing logic and the use of modifiers, because of the HCPCS coding that part in parcel of the OPSS and the payment methodology we imply.

And we certainly would expect to propose to adopt any policy in this arena might well require operational changes, claim processing changes, modifiers, or other modalities to be put into place to allow an appropriate payment adjustment to be made.

I will say that we are - have been and continue to be sensitive to the hospital's issues around administrative costs and administrative burden associated with any methodologies we put into place. And again as you well know, a number of the policies that we have recently adopted require really no change in reporting on behalf of hospitals. But our logic just as (Lisa) described for the inpatient setting permits the appropriate adjustment or payment methodology to be applied with hospitals recording their stand way.

So you certainly bring up some very relevant points that we're keenly aware of and will continue to be. And appreciate your comments on this aspect.

(Juvna Shaw) Thank you.

(Tom): Thank you. Next comment please.

Operator: And at this time I don't have any more comments from the phone line.

(Tom): Okay. If you could reinstruct the callers on how to queue up if they want to make comments about the inpatient or the outpatient issues for consideration. And in the meantime, I would ask if anybody in Baltimore would like to make

additional comments on either of those.

Operator: Okay. If you would like to - or if you have a comment, please press star and the Number 1 on your telephone keypad.

(Tom): So we have a few folks here in Baltimore indicating interest. So go ahead Sir.

(Tom Snyder): Hi. It's (Tom Snyder) again with (Comma Tech). And I just wanted to make a comment about one of the candidates for the inpatient HACs that we haven't really talked about today which is (unintelligible) infection. And (Comma Tech) has supported inclusion of this condition in previous rule making cycles and continues to support its selection.

And the reason I wanted to comment specifically on this condition today is that it's my belief that since the last time this condition was formally considered in rulemaking, there have been significant advances in the evidence-based guideline available as well as some of the surveillance and clinical practices that define hospital acquired (unintelligible) infection.

So I just wanted to make the comment that in - when you're looking at the statutory criteria for selecting an inpatient HAC, it's now my opinion that (unintelligible) meets all three of the coding costs volume as well as the third which is escapes me at the moment, reasonable preventability.

(Tom): Yes, it's a biggie.

(Tom Snyder): And I just wanted to weigh it - long day, just weigh in on that one at the end of the day.

(Tom): Well thank you for that. I think that reinforces something I said a couple of

times which is that as the state of guidelines development and state of the science behind reasonable preventability advances, we will have the potential to reconsider certain things that have not yet been selected.

And similarly we haven't talked about this either, but based on those same criteria, have the ability to take conditions off the list as well.

Next comment please.

(Tammy Langstrum): (Tammy Langstrum) on representing Society for Healthcare Epidemiology of America. Just a few very brief comments. These were outlined in our written comments. But in terms of Legionnaire's disease, (unintelligible) support this as a HAC. (Legionella)'s natural habitat is water. And (Legionellas) commonly present in water supplies. But despite this, hospital water supplies that harbor (Legionella) are not commonly associated with nosocomial (legionanosis).

And the (HIC PAC) environmental guideline clearly recommend against routine testing of hospital water supplies for (Legionella). The concern is if this is included as a HAC, many institutions may react by diverting resources from infection prevention to unnecessarily screen water supplies for (Legionella).

In terms of ventilator-associated pneumonia we agree with all the comments that were made previously about the difficulty of diagnosis - clinical diagnosis of ventilator-associated Pneumonia and difficulty with diagnostic criteria and definitions. So would not support a ventilator-associated pneumonia.

In addition in terms of reasonably preventable there's some literature that suggest that under the best of circumstances given the difficulties with

diagnosis that perhaps 40% or less are preventable. So we don't think that would meet the criteria.

Just a very quick comment on staph aureus infections, septicemia. We don't support the inclusion of a organism-based HAC addition since most nosocomial staph aureus infections are related to devices and surgical site infections. Since those are already included, we think that that's a better approach and it will reduce staph aureus along with a variety of other organisms by really focusing on device-associated infections and surgical site infections more broadly, rather than focusing on a single pathogen.

And then finally we don't support the inclusion of (unintelligible) associated disease. It's now a well-recognized community pathogen as well. There are still difficulties despite the fact that CDC has released definitions to try to differentiate between hospital associated and community associated. They're still very complex, difficult to apply.

In addition we strongly support (unintelligible) antibiotic stewardship, and that is one way to reduce the risk of (unintelligible) and (unintelligible) to appropriately use antibiotics. But in hospitals even the elimination of inappropriately prescribed antibiotics would not prevent many cases of (CDAD) which develop in patients who receive antibiotics appropriately as well. So I'll stop there. Thank you very much.

(Tom): Thank you for those comments from the perspective of the infectious disease physician. Certainly infectious disease is one of the primary sub categories of conditions that we've been look at here. Are there any other comments here in Baltimore? Yes Sir, go ahead.

(John Shaw): (John Shaw) from Next Wave. Wanted to just talk briefly about infrastructure



and building infrastructure to support all of this. We heard from (Ann) today that collecting things in the administrative data track costs about \$5. And to do chart abstracts to collect a lot of information costs about \$80. So I think there's a message there that, "Gee it would be nice to collect things through the administrative data sets."

The problem is there's a couple issues there. ICD9 is old. We do want to move to I10 as soon as we can to get the ability to capture the additional information that's in there as well as to give us room for new things that develop.

In the meantime we've got a little bit of an issue with - actually, we have a big issue with Medicare routinely throwing away half the data. The (Medpart) data set that's being used to define regulations is limited to nine diagnosis and six procedure positions.

So we heard a lot of support today in doing risk adjustment so that we're appropriate. And the problem is the part that we're throwing away of the data is a lot of the preexisting conditions that tend to be the risk factors that we're going to need in order to be able to risk adjust the measures.

So let's think about - I can run all of the positions on my PC for the whole country. I would expect that Medicare should be able to do so as well. If it's a staffing issue, put into one of the economic recovery packages.

(Tom): Okay (John). Thank you for that. Certainly the infrastructure issues are huge. As we use the claims data for things that it wasn't originally intended to be used for like value-based purchasing, we're finding that those systems are stressed in various ways. And we are giving some attention to the infrastructure with the expectation that will continue moving in this direction.

And using the claims as well as the other data sources that have been talked about today to more accurately translate what's going on at the bedside and in the physicians office and in the other settings of care so that we can use that information to more appropriately tie performance with payment. Any other comments here? (Mark Hartstein), Deputy Director of our Hospital and Ambulatory Payment Group.

(Mark Hartstein): Yes. Just want to make a quick comment about the nine diagnosis and the six procedure codes that are on the claim. (John's) correct that that's the information that Medicare - we actually collect more but how much we store. We did make a proposal at the same time that we propose to move ICD10 to adopt a 5010 electronic claims transaction system that will address that issue when that's implemented.

(Tom): Good news. Okay. Are there any other comments here in Baltimore before we go to the phone lines one more time? Okay. Do we have anyone queued on the phone line?

Operator: Yes. Your first comment comes from Pinkie Scott. Your line is open.

Pinkie Scott: Yes. I was calling from Provena Saint Joseph Medical Center in Joliet, Illinois. I had a question concerning the problem of combining bills when a hospital acquired condition is present.

We - sometimes the patients leave and they are readmitted with them at 72 hour window, and those I understand have to be combined onto one bill for billing even though they may be separate records. How should we handle that hospital acquired condition? Should we just - we're putting it on the - maybe the second claim - I mean the first claim. Should we just copy whatever was on the second one and just append the same POA indicators?

(Tom): So I'm not sure that we have anyone here at the present time who can answer that question. If you would feel comfortable giving me your contact information, we can certainly get back with you on that.

Pinkie Scott: Okay.

Tom: Or we could arrange some other way to be in contact with you.

Pinkie Scott: And I have a second question concerning outpatient - inpatient only procedures that may have been performed on an outpatient basis. If the physician schedules that patient as an outpatient, are we prohibited from admitting that patient since he did not specifically order an inpatient admission?

(Tom): Okay. So I'm not sure that your question is directly relevant to the discussion today. But if there's a quick answer from one our outpatient payment experts, or as I said we can take your contact information and get back to you...

Pinkie Scott: Okay.

(Tom): ...on your questions.

Pinkie Scott: All right. Thank you.

Woman: I think just quickly, you know, an inpatient hospital admission requires the physician order for that admission. So a patient cannot be an inpatient status unless there's a physician order to support that treatment for the patient.

Pinkie Scott: Okay. When the physician bills it and he bills it as an outpatient, is his

claimed honored even though it was performed on an outpatient basis?

(Tom): Okay. So would you be interested in providing your contact information so we can...

Pinkie Scott: Yes, I would.

(Tom): ...get back to you on these questions?

Pinkie Scott: Yes.

(Tom): Go ahead.

Pinkie Scott): Do you want my phone number or email address or...

(Tom): Yes.

Pinkie Scott: Pinkie.scott@provena.org.

(Tom): Okay.

Pinkie Scott: And my phone number is 815-725-7133, Extension 3247.

(Tom): Great. Thank you very much for participating in our discussion today.

Pinkie Scott: Okay. Thank you.

(Tom): Our next comment please.

Operator: At this time we don't have any other comments.

(Tom): Okay. So I want to take this opportunity to thank everyone very much for participating in our discussion. Dr. (Jeff Rich) who addressed you earlier, the Director of our Center for Medicare Management needed to go to DC for another meeting. But he wanted to make some closing remarks.

So if we're able to connect with him at this point, we would take closing remarks from Dr. (Rich).

Okay. So apparently Dr. (Rich) was not able to call in. I just wanted to give him that opportunity. Operator is Dr. (Rich) connected?

Operator: We have not found him on the line.

(Tom): Okay. Well thank you very much. So again thanks to everyone. Great input. And we look forward to receiving your written comments even if you make verbal comments today, but especially if you didn't. The address to send your written comments is [hacpoa@cms.hhs.gov](mailto:hacpoa@cms.hhs.gov).

And we very much encourage you to participate in the subsequent inpatient perspective payment system rulemaking, and to anything that might be in an subsequent outpatient perspective payment system rulemaking in 2009. Thank you all again.

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

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