CENTERS FOR MEDICARE AND MEDICAID SERVICES
MDS 3.0 Town Hall Meeting Conference Call
Leader, Robert Connolly
ID #244453
06/02/03

Date of Transcription: June 3, 2003

Cheryl: Good afternoon. My name is Cheryl, and I will be your conference facilitator today. At this time, I would like to welcome everyone to the MDS 3.0 Town Hall Meeting. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer period. If you would like to ask a question during this time, simply press *1 on your telephone keypad. If you would like to withdraw your question, press #. I would now like to turn the call over to Mr. Richard Lawler. Mr. Lawler, you may begin your conference, sir.

Dr. Lawler: Thank you very much. Good afternoon, everybody, and thank you very much for joining us today for our town hall meeting on the MDS 3.0 instrument. We have online already over a hundred callers and we're expecting the regional offices will be online as well, and I'd like to take a moment to advise the regional offices that also they can phone in on the phone call-in number in order to bring up questions when the question-and-answer period comes up, and wanted to briefly remind them to keep their phones on mute during the call.

The MDS instrument today, the feedback that we get will be used to advise the validation process and provide us with important information regarding both clinical improvements and overall provider burden; so we hope to have a very informative meeting and elucidate lots of concerns that are brought forward today. To begin, we're going to have Lisa Hines address the goal of the meeting and provide an overview of the MDS instrument.

Ms. Hines: Good afternoon, everybody. It's nice to see a bunch of friendly faces, and a lot of hard work has come out of the audience as well as that that's come up on the stage so thank you all for participating. Thank you all for your help throughout this process. I'm sure for many of us it seems like we would never get here. It's been a long couple of years to get to this point, and it's pretty exciting today to finally come to the town hall meeting and we've gotten to this point.

There's been a lot of hard work on a lot of folks' parts, and I'd just like to take a second to thank them. You're going to hear more from Bob Connolly, Mary Pratt, and Lori Anderson as part of the team, but there's a lot of team members out in the audience and I'd like to see if I could see them without my glasses and ask them to stand up as well. Tina Miller from Center for Medicaid and State

Operations. I have to put my glasses back on. We have Rosemary Dunn from CMSO as well. Rita Shapiro from our staff. Ellen Gay from the Center for Medicare Management, our payment folks. Also Dana Burley and Sheila Lambowitz from CMM. Did I catch everybody that's here so that you have faces with names? Oh, and Anita Paniker from our clinical standards group. You'll see her name from time to time. Probably three names from the past that continue to go through in spirit -- Helene Fredeking, Cindy Hake, and Sue Nonemaker -- have put in a lot of time. We may have faces that change, but certain philosophies have stayed the same in many cases to keep the integrity of the instrument together. As you all know, a care planning instrument turned into a payment instrument turned into quality indicators and then quality measures, so we are multi-faceted and continue to grow.

What I would like to do is just tell you a little bit about where we came from, where we are, and why you're here today. This is to let you have an opportunity to provide input into the MDS 3.0 development. Many of you have seen a draft instrument. Putting the draft instrument out was the decision that we made to give you something to red ink. We didn't want you to start from square one. There were lots of pieces of the instrument that were very good. There were things that we needed to make HIPAA compliant because we, too, have to adhere to the government rules. There were some clinical areas that we wanted to clean up, certainly after we started doing quality measures. So we took a stab at using all the comments, going to the experts, and then the field and got something down on paper so that it would be easier for you to comment on. This is surely not set in stone, the instrument that you've seen on the website. This is why you're here. We want your comments. We look forward to having comments because you are real world users and we need to make this useful. I think our mantra through all of this is to maintain the clinically relevant utility of the instrument so that the facilities are not just filling out the MDS to fill out the MDS. We want to make it useful in the day-to-day operations. So we welcome any suggestions. If you get home and think of something, you will be informed on how to send things in during a later portion of the presentation. We are all very open, as many of you know. Email, phone calls; if something comes up or an idea pops in your head -- some of the greatest augmentations to our instruments are just a thought that someone has -- very practical and very concise -- and we welcome that.

With that, I apologize. I'll be disappearing every once in awhile but, as many of you know, you can always get me. LHines@CMS.hhs.gov. We do answer email. You will hear from us. My phone number is (410) 786-0045. And I apologize; I have a niece graduating from high school and while this is very near and dear to my heart, and has been three years in the making for me, her's has been 12 years. So I'm going to flake out a little bit early on you this afternoon, but I will be around and I'm certainly available by email or phone if you do miss me this afternoon. With that, I'm going to turn it over to the real experts -- to Bob, Mary, and Lori -- to take you through the rest of the presentation. Thank you all very much for the time out of your day, for your insights, and for your comments. Thanks.

Dr. Lawler: Bob Connolly and Mary Pratt are the MDS 3.0 co-leaders on the development team, and Lori Anderson is the MDS IT coordinator.

Mr. Connolly: We'd like to welcome you. We've seen many of you at other meetings and, as you'll hear from the story that we share of how we developed it, it wasn't really any one person; it was a combined effort. And, as Lisa said, hopefully from today and from our validation team you'll be able to help us move this instrument further. As Lisa had said, we do have a team at CMS and, as you'll hear in the presentation, this instrument has a broader impact than just assessment in care planning and that's I think one of the reasons why we really need as much input from you as possible.

As I think about it, I started out going to nursing homes to visit my uncle when I was eight years old, and I think it's funny how what goes around comes around because now I've got the gray hair and I'm getting closer to the qualification; and I think in this era of the baby boomers needing nursing homes that we really need to step up our information systems, we really need to support you as providers, and we really need to move forward together.

In terms of the beginning of this instrument in the first slide, in 1987 OBRA required a comprehensive assessment and we at CMS created the Minimum Data Set (the "MDS"), which was specified by the secretary, and the RAI (the "Resident Assessment Instrument") was implemented in 1990. As I inferred, the original use was for care planning. Now it's moved on. In 1998, we implemented the PPS system and, with Lori's leadership and her

team, had an electronic submission process. In 1999, we initiated the Quality Indicators with the excellent work at University of Wisconsin. And in 2002, the Nursing Home Quality Initiative came into effect in which we now publish on the Nursing Home Compare Website--selected measures for every nursing home in the country. It's also been used for ongoing research and policies, and we realized that the way you and nursing homes submit to us had to be upgraded so our IT platform really needs to be worked on as part of this process. And Lori will speak more to that point.

During 2002, we received input from a large number of provider groups, professional organizations, and technical expert panels to come up with an instrument for the first version developed in January of 2003. Since that time, many of you have heard our voices and some of you have seen us talking at various professional groups. We've had web access. We've talked to the states. We've talked to professional organizations. We've used email. The real emphasis of this is that we want your input and we are listening. In terms of these recommendations, we, on the development team did not really say no/yes to many things. We pretty much put as much in as we could because we realized that we needed the validation contractor and their expertise.

In terms of the meetings that we've had, the themes that we've heard is there a way to take the MDS, which has so many items, and through dropdown boxes that everything isn't needed to be completed on every resident assessment. Could we put more of the detail into a RAP ("Resident Assessment Protocol") and not so much into the MDS as a way to reduce burden? Can we kind of figure out better triggers than we have right now in the Resident Assessment Protocols and certainly pain, quality of life, mental and cognitive status are a part of that. Can we use the RAP data items to rule out a condition or continue care planning?

Now, Mary and I will go through each of the sections that changed more significantly. This is Section A. The rationale for changing Section A was to reduce tracking forms, to serve the multiple users that are now using the form, and to add important information. So we combined from MDS 2.0 AA, AB, AC, AD, AE, into Section A. And the famous AA and AB -- for those of you who work with this -- that we put this into A.11 (a), which is the type of facility, was it nursing home or swing bed. A.11 (b), we have a work group of pediatric practitioners who are trying to

develop MDS items under each of the domains of care since right now pediatric residents use a geriatric assessment tool. We have A.11(c) for primary reason of assessment, and A.11 (d) scheduled assessment, A.11 (e) OMRA, and A.11 (f) swing bed or clinical changes.

The next area that we spent a lot of effort and had an excellent opportunity to look at through your input and through technical expert panels is Section B. We improved the clinical relevance; used standardized instrument and better-organized items look at cognitive behavior. We combined cognitive and behavior items into one section. We held a mood and behavior panel including Laurie Loftis, who is here in the audience and you'll hear comments from her -- and Joel Stein from the University of Pennsylvania. This panel helped us look at cognitive and behavioral items and later, mood; and what they indicated that for indicators of confusion and disordered thinking, that we should use the confusion assessment method and this would be used to trigger a RAP -- that we know that delirium can be terminal or a serious problem and we needed to move forward with that. We added B.5 hallucinations and delusions that we moved from Section I.

For behavioral symptoms, we recategorized them with the help of our expert panel, and they now include wandering, verbally aggressive behavior, physically aggressive behavior, non-aggressive behavior, and resists care. And we're looking at further modifications that you have provided to us.

The last section that I'm going to talk about is mood, and in order to address mood we're trying to look at improving clinical relevance, obtaining residents' voice -- and you'll hear this later with quality of life -- using a standardized instrument and better organizing the items that we have. Because we're not changing the payment items, we're still using indicators of possible depression and sad mood from 2.0, but we're also trying to use the geriatric depression scale. So what we've done is we have five questions from the geriatric depression scale that are in Section E. There's a lot of research on these five questions, and in fact Paul McGann, who's one of the geriatricians on our staff, was part of the research that found that these five questions are good triggers to do the full geriatric depression screening. The five screening questions would be asked of residents that are able to answer and are not confused or not comatose. And if they were triggered, then

we would do the RAP with the full GDS.

So I'll now turn it over to my colleague, Mary Pratt, to talk about quality of life.

Ms. Pratt: I came down here rather quickly. I had my lunch in my hand and I was sort of running down here, and I forgot two very important things that I live with here at CMS. One is the latest draft of the MDS 3.0 instrument that I carry around. And then myself and the rest of the MDS team are often seen carrying around our 2.0 manual. And not having it here with a group of people like you, I feel really vulnerable right now because you'll see me -- I'll go and I'll look up something if I have a question, and I'm digging through the manual. I feel much safer with it. So I'm a little on edge without it and I hope if you ask me a 2.0 question, you'll, "Oh!" and there's a manual out there, that would help. Thanks. Bear with me on that. But on with the 3.0 -- let me get this machine here organized. We want to update you, as Bob said, on some of the newer sections and highlight them; and then some of the other sections that sort of remain constant, we certainly can comment on those but we didn't really need to highlight them in our presentation.

But we wanted to let you know about the quality of life section. We thought that more information needed to be shared, and more information will be shared as we move along. But this was a real early bit of work that CMS contracted with the University of Minnesota back in 1998 to begin looking for evidence and ways to measure and hear the residents' voice with respect to their quality of life. There was a large-scale study conducted in a hundred nursing homes in six states. We had almost 3,000 residents that were interviewed. And out of that were developed 11 domains of quality of life and scales for each domain.

Now as part of the design elements, some of the things that were key to our study in understanding these concepts were that we wanted to hear directly from the residents. And we didn't want cognition to be something that ruled out a resident's voice. So only those residents that were considered comatose on the MDS were removed or excluded from the sample. All other individuals in the nursing homes were at least approached for interviews. There were some simple conversational screens to help exclude residents further, and there were a number of responses that if they

were unable to give us usable responses they were also excluded.

Now the questions that were done on the design, were used more of a scale -- 1 to 4 -- type of response, and then they were turned into more of yes/no response for the MDS. Some of the significant findings that we had were that both better and worse conditions of cognition residents could respond adequately. The patterns were generally similar across cognition levels and, on average, 60% of the residents could respond. And, of course, as the impairment levels rose, so did the time on which the interview time would take as well; but the outcome of the results was that the residents could respond. We found that there were items that were both useful at a resident care planning level and at a facility level of analysis. We could look across facilities and measure variations among facilities.

We also did some other testing with family proxies and with staff to see if their perception of the resident's quality of life was similar to the resident's. While the family's perception was slightly closer to the resident's than the staff's perception, neither one of them was that strong in predicting the resident's response. Fifty-four items were used in the original instrument, comprising 11 quality of life scales. And then here are some of the statistical properties that show that they developed into good scales, that there was a high correlation with satisfaction, emotional well being, and being in a private room. And confirmatory analysis to identify that, yes, those ten domains were able to stand as separate domains.

We also did some preliminary studies on the collection of the data by facility staff. When the study began, we had research nurses, go in and conduct the interviews with the residents. We wanted to understand some of the implications for nursing home staff -- particularly nursing staff, social work, and activity personnel -- and their ability to collect like responses from the residents. And we were able to see that there was very little difference between the researchers and the facility staff in getting similar responses on the test and retest.

So from that body of work came a request to the University of Minnesota to come up with a scaled down version for possible use in the MDS 3.0. We wanted a smaller subset of items that were developed from the 54-items. And they developed two potential

scales. The one that you see in the current MDS has subscales. I think there were – how many domains that are represented? Maybe three or four domains represented, and you can get subscales for each of those domains within the 14 items that are collected. The other format was a set of questions that yielded a single score on the quality of life. And we changed the Likert scales into more of a binary response format.

We'll move on to the rest of the sections and talk about Section G where we met with a number of therapy groups and clinical groups in open door meetings. In that section what we've done primarily is combine the self-performance and support provided scales, trying to make it a little more user friendly for staff to collect information. We've changed from test for balance-to-balance related transitions. And you see the associated questions with that. And we've added neuromuscular skeletal impairment to look at range of motion and motor control. And we've added a stamina question as well.

In Section I we have done some work to improve the accuracy of coding the information, and we've partnered with the AHIMA group, the American Health Information Management Association, to provide us some expertise in the drop down menus and the tables, and the whole ICD-9 structure. Currently, as you know, in the versions of 2.0 that the ICD 9 codes are not up to date, and the plan is to update them soon for the 2.0. And in the 3.0 we would update those on an annual basis to have them complete. We've also combined I1 and I2 and made it a simpler format.

In Section J we've begun to do some more work at looking at aspects of pain. We've brought together some evidence-based research out of the Agency for Healthcare Research and Quality -- contracting with Catherine Jones at the University of Colorado to help with better measures of pain as well as pain management. We've begun the use of more standardized pain scales to help assess resident pain, and map them into a score for the MDS so that based on the resident's needs and the scale that best fits the resident and the facility, that information could then be calculated and used on the MDS for quality measure information. We've added pain behaviors and pain interfering with functional status to the section as well.

I'm going to turn the monitor over to Lori Anderson who is going

to take just a quick minute or two to let you know about some of the system impacts that the states and vendors would be interested in understanding more about.

Ms. Anderson: I'll just very briefly take a few minutes to go over some of the high level implications of converting from the old MDS 2.0 to the MDS 3.0. We know that once we do the conversion we still have to supply the reports, the quality indicator reports, resident rosters, delayed and missing assessment reports that we currently provide to facilities and our state agencies. Now in order to do that, we know we have to do a conversion of the MDS 2.0 databases to the 3.0 format. And the process by which we're going to use to convert, we're still analyzing that. We do know a few things. We know that at least for a short period of time we will provide a conversion tool at the state so that if a submission file comes in the old format, we will convert it to the new format so that facilities don't have to be ready on implementation day one. We are, as I said before, insuring that all of our conversion plans will result in generation of reports that are needed and applications that are needed.

The RUGS impact – We will have a new grouper, however, we are making every attempt to keep the existing RUGS model, but vendors in facilities will have to use the new grouper that we will provide. The state agencies may have a lot of programs they'll need to revise as the result of our changing from the MDS 2.0 to the MDS 3.0. Many states use the MDS 2.0 in their Medicaid payment system. They have custom grown some quality applications outside of our quality indicators. We are attempting to communicate with the states so that they have sufficient opportunity to plan for those changes and make those changes in the timeframe for implementation.

We do plan to maintain Section S for those states who have custom needs as well as custom quarterlies. Should we take items off of the MDS 2.0 that a state today uses for their Medicaid payment systems, for example? They will still be able to collect that data via Section S once MDS 3.0 comes up. We will be, of course, creating a new RAVEN tool. We also hope to create additional DLL's with the RAVEN tool to better enhance our help functionality. RAVEN, at a minimum, will allow a facility to look at residents that were created in the 2.0 format and bring them up in the 3.0 format so that they can continue their assessments on

that resident. And we will have to rewrite our quality indicator applications as well as our quality measures because although we have attempted to keep all of the payment items on the MDS 2.0 the same or comparable so that the grouper model doesn't need to change, we will have to redo the quality indicators somewhat. And we intend in the future to run them on a national platform instead of the state platform.

And I'll turn it over to Bob to go over the communication.

Bob Connolly: We just wanted you to know that we now have an MDS website. It's **www.cms@hhs.gov/quality/mds30**. So that is a place where we have right now the Power Point slides that you're hearing today from Mary and I, and later will hear from RAND. We're going to put a summary of all those who gave us formal comments. We're going to eventually put up the data specifications there. And as we revise the instrument, we will have it there.

The other thing, feedback is critical. And we have an e-mail address that many of you used to either register or send comments. Write to: mds30comments@cms.hhs.gov. So with that we would like to now turn it over to RAND. The RAND Corporation is in Santa Monica, California. And we're very lucky to have two excellent co-principal investigators; Deb Saliba is a geriatrician, with extensive background in working with nursing homes and research. Joan Buchanan is a Ph.D., Health Services Researcher. Again, these are two of the leaders that we were able to have work with us on this project. So we feel our validation will be strong. And I'd like to turn it over to Deb Saliba.

Dr. Saliba: I'm used to speaking loudly because I'm used to speaking to my geriatric patients, so let me know if I blow you out on the mike. In the next few minutes I'm going to describe our evaluation plans to look at the revisions to the minimum data set for nursing homes. Bob introduced us as the evaluation team. I'm an Investigator in the VA Center of Excellence, as well as at RAND. And Joan – I'm fortunate to have Joan who has 20 years of experience in health services research, who is currently in the Department of Health at RAND. We're very fortunate to be joined in our research efforts by two subcontractors. Our lead quality improvement organization in this effort is going to be the Colorado Foundation for Medical Care, and Laura Palmer is the Project Director there. And then we're getting assistance on our instructions and care guides from

Care Link and Joan Kwiatkowski has been very helpful as well.

When we set our to design an evaluation approach, we had some criteria that we felt was very important to accomplish in our 17 months that we have to do this. The first is that whatever tool that we end up with needs to reflect current knowledge. And by current knowledge what we really mean is that it needs to reflect the experience of current users of the tool, as well as what we have learned about how to measure these types of topics and issues in nursing home patients.

The second criteria is that it be relevant, that it be clinically relevant to the care that goes on in nursing facilities. The third is that these reports be accurate, that the information that's within the tool is accurate and reflects - is consistent across facilities in that accuracy. The fourth is that we really take into account the burden of data collection with the tool, and try to make it as parsimonious, but still as useful, as possible. And finally, we were charged with trying to maintain the ability to perform current functions, specifically being able to maintain generation of quality indicators and quality measures, as well as the RUGS. So I'm going to go through the four phases of our evaluation approach, the first being how we plan to get input from experts, both clinical users as well as researchers with the tool.

In the first three months of the project, we've already gotten written feedback. We've received over 100 commentaries from the website that Bob showed you just a few minutes ago. And what we're doing with that data – Nick Castle from our RAND's office, who is a Health Policy Analyst, is leading the effort to summarize and synthesize this information. And we're going to be developing – we are developing an item-by-item matrix and synthesis. And what we hope to use this feedback for is to guide our technical expert panel discussions of changes and issues within the tool to help it guide our own revisions as we go through specifically item by item to make revisions, as well as give us some more information about what needs to be elaborated on or addressed in the instructions. Then also the town hall commentaries today. Again, Dr. Castle will be doing a qualitative analysis of what themes emerge today within your comments and discussions.

We also are planning a structured literature review where we're

going to focus on the psychometric properties of the different scales within the tool. A literature review will be actually looking across several different topics within the MDS. The topics that we're going to select - we can't do every topic – so our criteria for selecting the topics for literature review will be to look at items that are new or have significantly changed in the MDS such as pain, mood and behavior and delirium, or items where feedback indicates that measuring the construct is not going to be easily addressed by just simply changing the words that are currently there or maybe a few clarifications in instructions. And we hope that we will use this literature review to help guide our validation panel discussion and review.

So we're planning two types of expert panels in the process of our project. The first is a technical advisory panel, which we will have working with us throughout the project. The members of this panel we hope to identify are folks with experience with nursing home care delivery, management and quality improvement. They'll be provided, as I alluded to before, the item level summary of the stakeholder feedback. And we're going to ask them before they come to meet with us to help prioritize topics through their utility and care within nursing homes, as well as to identify items that are going to warrant further discussion because of the challenge that they present or the potential burden that they present within facilities. We'll meet together for two days, and then at the end of that meeting, we'll ask the participants to reprioritize those items for utility and their needs, and also their need to develop additional care tools to help with those topics in nursing homes. Finally, we'll have ongoing follow-up with that group and seek their input on a continuous basis with monthly telephone conferences throughout the evaluation process, and a summary and input after the evaluation process is completed.

We also will have a validation panel between months four and six of the project. And this is the group that's going to deal with that psychometric property piece of this. So we're looking for folks for that panel that are experienced with evidence-based nursing home research and scientific review. And they'll be the ones receiving the literature review or the performance of the items in scale. And what they're going to be asked to do before coming to their meeting is to rate the item construct and criteria and validity, and to prioritize items that require additional validation before the national evaluation. And their meeting structure will be a formal

rating process that will be probably a full day of rating work prior to the meeting using sort of a modified Delphi process that we successfully used to build consensus in the past. They will meet again and discuss their votes. Typically what we'll focus in on are those votes where there's a lot of discordance, a lot of disagreement between the members because we can't discuss again all 400 something items. And then they'll re-rank the validity of items after the meeting. We plan to use them at periodic telephone conferences during the design and construct of any validation activities that they suggest that we conduct.

On to the second phase. I'm going through this pretty quickly, outlining what we're going to do. Let me move on to the second phase, which is our pilot testing activities. We plan to conduct the pilot tests in both community and VA nursing homes. We've been very fortunate that the VA offers long-term care services, and Dr. Christo Hojlo, who is the Chief of Nursing Home Services at the VA, has been very enthusiastic about supporting our efforts to improve this tool. The pilot activities are going to focus primary on looking at the clarity of the items and instructions, whether the items agree with each other and are consistent, and the best order for the items in order for the tool to function effectively. We'll test some of the skip patterns that are going to be in the tools, again testing for their ease of use, but also minimizing error. In time when we introduce skip patterns, we may actually increase the chance for there to be error when people fill out forms. So we really want to be sure that we keep that in the pilot activities. And then finally, in testing the instructions. What we hope in the instructions for the new items that we're going to develop, that we can make clearer what the intent of the item is because we think that will facilitate completing some of the items in the tool, as well as provide a little bit more guidance on what the information sources should be for completing a particular item.

For the third phase of the national evaluation, our sample frame for that will be 50 nursing homes distributed regionally. We're aiming for a mix of hospital-based and freestanding facilities, and for profit and not for profit. Our targeted resident sample is 2000, again short-stay and long-stay patients. And we'll have an algorithm that we'll be providing to the nursing facilities who are participating to be sure that we capture a mix of admission MDS assessments, quarterly assessments, and annual assessments. Our training for evaluation is targeted to take place in month seven.

We'll use gold standard nurses who have experience with collecting the MDS in nursing homes, and they'll receive five and a half days of centralized training with our quality improvement organization in Colorado. We're also recruiting 50 facilities, and the nurses in those facilities will be trained as well. The person within the facility that will be targeted for training is the MDS Coordinator, and they will receive two and a half days of training within each region. Throughout the entire evaluation period, there will be a 1-800 information number that will be operated by the Colorado QIO, and we will be tracking all queries that come in so that we can again go back to that information at the end of the evaluation period and use it to help further refine and improve our items.

One of the primary focuses of our national evaluation is to look at the reliability of the items within the tool. And basically by reliability, what we really mean is that if two different people administer the same item, do they get the same answer. And we really believe this is the first step in understanding the performance and precision of the instrument because it looks at the stability of the idea, as well as how clear the instructions are for that item. And it's a particularly fairness issue for the MDS items that are going to affect the calculation of quality measures of facility reimbursement.

We're going to approach reliability in two different ways. First, we're going to sort of look at efficacy, which we'll use both standard nurses, the two gold standard nurses, and look at whether they have agreement when they collect a particular data item. But even more importantly, we're going to look at the effectiveness of the tool, and that is looking at the gold standard nurse compared to the facility nurse. And we think this is really important because the facility staff may face work-related pressures and responsibilities as they seek to record resident data. And that's the data at the end of the day that we're going to be actually using. So understanding the reliability of that data is really important, and we'll do that on 600 residents within our sample.

Time burden – I refer to that as one of our main criteria in looking at and evaluating this tool. We realize that nursing homes – that residents that are in nursing homes to receive care, and assistance and that resources are limited. Any amount of time that's spent in one activity is taken away from another. But at the same time, if

there's some real important utility to having standardized assessments so that the amount of time that goes into the MDS really needs to be a balance. And we'll be quantifying the amount of time that's needed to complete the MDS, not by the research nurse, not by the gold standard nurse, but by the facility nurses who are familiar with that facility.

During months eight through eleven, we're going to be looking at the instrument functionality. We realize that it has many important uses, as have been talked about today, and we need to look and see how those are going to be preserved, specifically for the quality indicators, the quality measures, the RUGS, and the resident assessment scales that have been developed within the tool. So to do that within our evaluation activity, we're going to have the facility nurses complete the MDS 3.0 proximate to the scheduled 2.0 that they're already completing on their residents. And the responses will be assessed for comparability and classification. We're doing that for all 2,000 residents that are identified in the sample.

Then we move on to our analytic phase, months 12 through 15, and we're going to answer some basic questions just outlined here. I'm not going to go into a lot of detail about them or outline every analysis, but just the core ones. First, we're going to ask, as I said, can the MDS be coded reliably at the individual levels. In addition to looking at percent agreement, we'll look at the Kappa statistics, Pearson correlation coefficient, which are ways that we have of measuring whether or not reliability exists. And we're going to look at one of that inter-facility variation in scoring the reliability. We'll be looking at mean shifts in the QI's and RUG payments between MDS and 3.0, recognizing that some QI's and RUGS are – all the RUGS require multiple items to code. And where multiple items are needed, our audit database will - and this database contains all the component items – we'll compute the QI and RUGS reliabilities as well to provide for you. And then finally, how much time is needed to complete the tool.

We'll move on to phase four which are our final set of recommendations. We're going to consolidate the feedback that we've received from the field trials and the national evaluation because we feel this is really core to making the final set of recommendations and evaluations. We'll analyze the questions received from the 1-800 number. And we're also going to conduct

a structured survey of the facility nurses who participated in the study, again focusing on the clarity of the tool, the flow of the items, as well as their perceived burden in completing the MDS 3.0. We will have actual measures of time burden as well, as I said, and our analysis will address that. And we'll have tables that will be reporting all this data, and I'll just show you an example of one in a minute.

We'll be feeding all of this information back to our technical advisory panel, as well as our understanding of how our field experience went. And we're going to ask our technical advisory panel to discuss with us the utility of some of the more poorly performing items. So if an item is not performing very well with iterative reliability, is it still an item or a construct that's so important to you in evaluating or taking care of your patient that you think we need to retain it despite that borderline sort of psychometric type of performance. And then we'll propose final revisions.

Here's just an example of the kind of thing that our technical advisory panel is going to be going through with us we hope at the end of this project. If you look there at New Measure 2, for example, they'll get how does the two gold standard nurses agreed, what the facility to gold standard level of agreement was, and then whether it is currently used in the quality indicator item or in a RUGS item.

So in summary, I've gone through a lot very, very topically here of what we plan to do. But primarily our focus is taking feedback from persons who are experienced with the tool and incorporating it into revisions in the tool to both improve the words and instructions, to identify existing problems, to review the results of the study once they start coming back, and to identify needs for additional care planning tools within the nursing facilities. Our plan is to develop an objective evaluation of evidence from measurement approaches for selected items, and to have an objective evaluation of the impact of changes on facility functions that can be provided to CMS as well as to interested parties.

Dr. Lawler: Thank you very much, Deb. I'd like to take a moment now to discuss a little bit about the format for the rest of the meeting today. All the slides that have been discussed at the meeting so far are available on the website that Mr. Connolly mentioned earlier,

and that website again is www.cms.hhs.gov/quality/mds30. And you can download those and view those on the web during the rest of the meeting or after. For the next 55 minutes we plan to allow our 18 registered commenters to speak. We are estimating that each one will speak for about three minutes, and I will try to announce them and pronounce their names correctly before they come up. And following that, we will have approximately an hour and a half during which we'll entertain comments from both the meeting here in Baltimore, on the phone lines, and from our regional offices. And after that, if we have time, we plan to allow our MDS contractor once again to briefly comment on future plans and to wrap up. The formal comments that you'll hear today will be available, posted on the web, after the meeting at the same website I just mentioned. And also, a live recording of the entire town hall meeting will be available for 72 hours two hours after the meeting has ended. And that can be reached by telephone. And the number is 1-800-642-1687, and the conference ID number for that recording is 244453.

I'm going to go ahead and announce the first of our formal commentors. There will be three from Baltimore, followed by two from the phone and so on. I'll announce them. The first one, we'd like to ask Sandra Fitzler with AHCA to come up.

Ms. Fitzler: Hi. I'm Sandy Fitzler from the American Health Care Association. That is the Federation of State Nursing Home Providers. There's about 12,000 providers in our membership that include nursing care facilities, assisted living facilities, facilities for the mentally retarded and developmentally disabled. We represent for profit and not for profit members. We've already committed to specific comments on MDS 3.0, so today I'd like to take an opportunity to give more of the global perspective to what we feel needs to be addressed. Nursing care providers have identified that the multiple uses of the MDS complicate rather than simplify the MDS and the RAI process. The MDS attempts to meet documentation needs for clinical assessment, quality monitoring and reimbursement. The proposed MDS 3.0 adds to the multi-functional tool by incorporating sections to survey patients' quality of life and disease prevention activities. They are continually growing multi-purpose assessment allows results in the tool and process that loses clinical value. For example, clinicians completing assessments as defined by their standards of professional practice are challenged when an assessment coding must first give consideration to a

reimbursement requirement. The MDS not only attempts to deliver a one size fits all approach to long-term care services, but tries to assess the clinical needs of beneficiaries in the same fashion. There are distinct patient populations receiving care in long-term care facilities. These include chronic elderly, chronic adults, short stay, pediatric, palliative and end of life care patients. The patient populations have different clinical, reimbursement, treatment, preventive care, psycho-social and quality of life considerations. Even with recent MDS attempts to identify and segregate patient subgroups, the total remains primarily all inclusive in addressing the needs of these populations. Articulation of a current vision for MDS is needed, and the American Health Care Association recommends that the Centers for Medicare and Medicaid Services convene a panel of experts, MDS users, and other stakeholders to work with them in articulating a vision for MDS, and in identifying the short, medium, and long-range goals. Some questions needing to be addressed in articulating a vision would be what does the MDS currently accomplish and is it effective? What should the MDS do? Should future MDS serve several function and if so, what will be needed to get the job done? AHCA believes that by convening a panel of experts, stakeholders will have a better understanding around the MDS function, have an end point in mind on how the MDS should perform, and will be able to determine what short and long-term steps will be needed to achieve the vision. This approach will help to identify current roadblocks to achieving quality MDS assessments. The vision will also help identify the limitations in current MDS technology, and the infrastructure and interfaces that will be needed to get the desired results. AHCA wishes to thank CMS for this opportunity to provide comments.

Dr. Lawler: Thank you, Ms. Fitzler. And now I'd like to introduce Ruta Kadanoff with AAHSA.

Ms. Kadanoff: Thank you, and I commend you on pronouncing my name. That was very good. I am Ruta Kadanoff with the American Association of Home Services for the Aging. We represent over 5600 mission-driven aging services providers across the country. We have also submitted detailed written comments. And given the limited time, I'm going to focus on just three of our really big picture issues here. And if anyone wants to read the details, I guess it will be up on the web.

As you know, and as has been discussed already, the MDS serves many masters, and I like the term explosion that was used previously in care planning, payment and quality measurement. Unfortunately, the MDS currently doesn't really serve any of these uses as well as it might if it were really tailored to meet each of those purposes. And I see this as our opportunity to make it meet each of those critical needs as effectively as possible, recognizing that there are compromises inherent in trying to have it do all these things, but we need to try to make it as effective as it can be. Our fear is that if all of the key perspectives aren't taken into account at this time, we'll be no better off at the end of this process several years down the road than we are today. We fully understand the need to maintain the items that drive current systems, the QI's, the QM's, the payment system, but we don't think it's sufficient to say that we need to maintain current systems so that they can continue to function. We need to ask the question – what information, if we had it, could make those systems better, and make sure that those things get incorporated. Achieving this requires a lot of coordination across CMS staff divisions, contractors, and users of the tool most importantly. To outside observers who have been watching this process, we're not really clear whether that integration has been taking place, and we'd like to urge CMS to insure that the collaboration that is needed across all of those functionalities of the MDS takes place so that this critical opportunity to gather improved data, do advanced care planning, payment systems, and quality measurement isn't lost.

Second of all, as Sandy mentioned, the MDS has to meet the needs of a lot of distinct groups of residents, the same ones that she listed – the post-acute, the chronic, the palliative care and end of life population, the pediatric, and the younger disabled populations. These groups all really have very distinct needs in terms of assessment. We recommend that CMS convene an expert panel for each of these populations similar to what sounds like is being done on the pediatric side, but we don't have further details about exactly what's happening there. We'd like to see each group look at each domain of the MDS to look at whether or not it applies to that population, whether the proposed set of questions and assessment scales is the best possible one for that population or whether there are other questions that would meet the purposes better, and whether there are additional domains that need to be assessed for that population. The work of those groups should then be integrated into an instrument that has skip patterns

incorporated in it to make sure that the right questions are answered for the right patients based on some introductory set of screeners. This would help to insure that all residents' needs are being appropriately identified and addressed, and will make the process far more rationale for clinicians and insure that time is not wasted trying to make square pegs fit into round holes.

Lastly, AHCA does not believe that the MDS is the appropriate vehicle for collecting quality of life measures. We do believe that it's critical to collect that information, and we're very supportive of the goal of incorporating that information into a system of quality measurement so that public reporting can be more holistic than it is currently, focused solely on clinical information. But we must recognize that the MDS is not the only possible vehicle for collecting information about nursing home residents, nor is it necessarily the most appropriate vehicle for every type of information. And we should resist the temptation to shoehorn items into the MDS for purposes that it's not suited for.

The two major issues we're trying to incorporate in the MDS is, first of all, that the research that Mary spoke of has documented that only 60% of residents could be included in the sample to generate scale. So I ask the question why are these questions being incorporated into an instrument that's required for every resident when at least 40% of the population won't be able to complete them. Secondly, there's not been any published research to indicate that valid and reliable data can be collected for this domain from facility staff. Mary referenced the research that has been done. The findings published to date only talk about the research team, specifically trained researchers who went out and collected the data. So I would be eager to see the details of that information. But other research that has been published has documented a significant bias when facility staff collects satisfaction survey information which is similar to the questions that are proposed. We have a host of other concerns about this section that are raised in our written comments, and I won't go into those details now, but I urge CMS and the contractors to look at those comments carefully and review those issues. Our recommendation is to drop the quality of life section from consideration for the MDS, and for CMS to convene a panel of stakeholders, carefully review the research, and to recommend options for collecting this information in a consistent way that will provide meaningful and accurate information for quality

improvement and quality measurement. Thank you for the opportunity to be here today.

Dr. Lawler: Thank you very much. And before our next caller – I mean commentor, I would like to remind everybody to please try to keep your comments to approximately three minutes. We're doing okay, but we'll just try to avoid them going too long. Next we have Francis Ann Gallagher with the ADA.

Ms. Gallagher: Good afternoon. I am Ann Gallagher representing the American Dietetic Association. We thank you for the opportunity to comment today. The American Dietetic Association represents over 70,000 food and nutrition professionals, serving the public through the promotion of optimal nutrition, health and well-being. Just about every nursing home in the country employs a registered dietician. I, myself, have spent 35 years working in long-term care.

We have submitted written comments, but today I'm just going to comment on Section K, the swallowing nutritional status. We had a number of our members who have worked several years in long-term care review this section, and they have all reported back that it is very confusing. We also then consulted with several speech therapists in different states that also found different areas of this section to be unclear. Under Category K, we recommend the addition of chewing to indicate chewing, swallowing nutritional status since it is difficult to separate chewing and swallowing problems. Swallowing problems can be the result of food not being chewed properly.

Also under Category K1, we recommend the subsections "no helper", parts one and two, and the subsection "helper", parts three through seven, be deleted for the following reasons. It requests assessment data that is not well defined or readily measured upon observation. For example, under part four it states: Subject requires 10 to 25% assistance or supervision for swallowing, and requires dietary restriction of liquid and solid textures. Does this measure refer to the percentage of time the resident requires supervision or the severity of the swallowing impairment. It includes assessments that only a speech language pathologist can complete such as say swallowing. The terminologies for diet level, minimum diet restriction, and modified diet are not defined nor are they part of the generally accepted terminology used by registered

dieticians. This data has not been demonstrated to correlate with the nutritional status across the resident population in skilled facilities. Factors that have been demonstrated to affect the nutritional status of residents in skilled nursing facilities include depression, reduced functional ability, intake of 50% or less of food served in the past three consecutive days, and chewing problems. The importance of appropriate hydration and the potential effect of dehydration for reducing the intake of solid foods are also critical aspects of care that should be included in the assessment process. A number of the factors indicated above are addressed in other sections of the MDS. Indicators that have not been included in other sections of the MDS include intakes of less than 50% for three consecutive days and hydration status.

Therefore, we recommend that Section K, swallowing nutritional status, be included in the indicators that are readily measurable on observation, and have been demonstrated to impact the nutritional status. Change Section K1 to chewing, swallowing nutritional status to reflect the following parameters. Viral would be normal, safe and efficient chewing and swallowing for all diet consistencies. One, would be required diet modification to chew and swallow foods – solid foods, a mechanical diet, cut up foods, or able to ingest specific foods only, and this would need to be explained in detail in the RAI manual. Requires modification to swallow solid foods and liquids [UNINTELLIGIBLE] liquids. Three, combine oral and tube feeding only. Four, parental tube feeding only. And five, no oral intake, NPO, and no tube feeding. Section K2, height and weight. We are pleased to see that height is only collected upon admission. Even if the resident's stature becomes reduced due to osteoporosis, the same nutritional needs must still be maintained. We suggest changing base weight or most recent measure in the last three days to the last 30 days. This measurement takes into account both skilled and nursing facility admission. Section K, foreign nutritional approach under 4E change dietary supplements between meals to dietary supplements. Residents who do not consume enough of their meal will often take a supplement at the end of meal service before they leave the dining room, and this is not being captured on the MDS. On 4F, the descriptor on a planned weight change program is a better explanation than the RAI manual, and K4, add another descriptor, 50% or more of food uneaten. Again, we thank you for the opportunity to comment and hope to continue to work with you on this instrument.

Dr. Lawler: Thank you very much. We'd like to turn it over to our Operator, Ms. Blanche, to please connect, first, Joe Ouslander with AGS.

Dr. Ouslander: Hello, this is Joe Ouslander. Can you hear me?

Dr. Lawler: Yes, we can. Thank you.

Mr. Ouslander: I'm connected. Hi everybody. I don't know who is there. I know Deb and Joan are there, so hi. I'm speaking on behalf of the American Geriatric Society, specifically with comments related to a consensus panel process that we have just completed in collaboration with the American Association of Geriatric Psychiatry. And you'll hear from Joel Streim from that organization subsequently.

This panel focused on improving mental health in nursing homes, and involved collaboration among 15 multi-disciplinary organizations. The panel focused on two conditions, depression and behavioral symptoms associated with dementia. So my comments are really directed at those conditions.

The panel process resulted in three immediate products, which will be published in the Journal of the American Geriatric Society in September. These include a consensus statement, a comprehensive literature review that was used by the panel, and a series of policy statements that have been endorsed by both the sponsoring organizations. And more products based on this process are anticipated.

The statements upon which this consensus panel achieved consensus really reinforced the importance of the minimum data set and the resident assessment protocols, as well as the importance of the modifications being developed currently. Specifically, the panel's recommendations call for improved identification of and screening for symptoms of depression and behavioral symptoms, appropriate assessment, diagnosis and referral, and the use of non-pharmacologic as well as drug treatments in the management of these conditions. The panel specifically commented on the inadequacy of the current version of the MDS for the screening and assessment of these symptoms. Thus, the plans by CMS to revise the depression and behavioral items, as well as the addition of quality of life items, is timely, and

if well conceived and validated, are likely to be welcomed by members of the American Geriatric Society and other organizations involved in this process.
Based on the panel's consensus, the American Geriatric Society would also strongly recommend revision of the resident assessment protocol. As currently constructed, they do not provide enough specific recommendations for nursing home staff to develop optimal and individualized care plans based on the MDS assessment of depression and behavioral symptoms. The AGS and other organizations and nursing home providers will certainly welcome revised, improved and validated RAPs in these and other areas of care. I'll make two final additional points.

First, the consensus statements clearly recognize the effectiveness and appropriateness of drug therapy for the conditions addressed. Barriers to the use of effective drug therapy such as restrictive formularies and attitudes about psychotropic drugs such as chemical or strength need to be addressed in order to improve mental health care in nursing homes.

And second, this consensus panel strongly endorsed the need for adequate staffing, both in terms of number and education, as essential to improve mental health care in our nation's nursing homes. Thanks for the opportunity to comment.

Dr. Lawler: Thank you very much. Operator, we'll turn it over to Mr. Joel Streim with the American Association for Geriatric Psychiatry. Ms. Blanche?

Operator: Mr. Streim has just disconnected. He was online.

Dr. Lawler: Okay. We're going to go ahead then and take our formal comments from here in Baltimore. We're next like to as Judy Peres with the American Academy of Hospice and Palliative Care to come up.

Ms. Peres: Good afternoon. I'm Judy Peres and I'm with Last Acts, a national program office funded by Robert Wood Johnson to improve caring, caring near the end of life. I'm privileged today to be presenting today the remarks of Dr. Joann Lynne on behalf of the Academy of Hospice and Palliative Medicine, Americans for Better Care of the Dying, and Last Acts.

Nearly half of elderly Medicare beneficiaries spend some time in nursing facilities while living with fatal illness, and will die in those facilities or after a short time in the hospital. Thus, nursing facilities are becoming a major part of the last phase of life for most Americans. As has already been mentioned, the MDS serves a number of functions in nursing facilities. In each of these functions, the MDS must start recognizing the critical role nursing facilities play in serving those who are living with fatal chronic illness. In that regard we are pleased with the addition of pain assessment in Section J of the new MDS.

Specifically, our organization is calling on CMS to include the following five points in the new MDS 3.0 in recognition of beneficiaries' needs in these last stages of life. One, advanced care planning. The proposed MDS 3.0 appears to have eliminated the very thin record of advanced care planning that was in the MDS 2.0, Section A10. This direction will not serve nursing facility residents well. This section should be re-introduced, and should address the following as yes/no questions. Proxy decision made clear, contact information clear, decision to forego resuscitation, decision to forego hospitalization generally, decision to forego artificial feeding hydration, decision to use sedation if essential, preference to use hospice. The first two answered as no should lead to an intervention plan. With the next five, a no should lead to an intervention plan if the new prognosis question, as we suggest, indicates that the resident is likely to die soon.

Two, suggested prognosis questions. The appropriateness of assessing weight loss, loss of ADL, and assuring adequate advanced care planning turns in part on resident's likely proximity to death. However, most residents in nursing homes have quite ambiguous prognoses until very near to death. Thus, we are suggesting useful categories in which residents should be clarified that could be added to Section J health conditions. Imminent dying, prognosis limited, might be hospice eligible, or fatal chronic illness, probably not yet hospice eligible, or stable or non-life limiting chronic illness. The first two [UNINTELLIGIBLE] should initiate a response to assure good advanced care planning for likely dying, assure good sense in management, and should remove triggers to respond to weight loss and ADL loss.

Three, if the residents in the first three categories above lie in hospice eligible or fatally ill, but not hospice eligible, then Section

I, diagnosis, should be marked as to the diagnosis contributing to shortened life span.

Four, in the list of special treatments and procedures in Section P, MDS 3.0 should add palliative care program enrollment or consultation.

Five, Section Q, discharge potential, could be reshaped to include prognostic information and the preference to stay at home through death by adding these questions. The resident may already have an eventually fatal illness, resident is likely to live out the end of life in this facility. If yes to the second question, follow-up would be determined by suggesting likely prognosis of either (1) would not be surprised if resident died within six months, or (2) course of illness would probably go longer than six months unless new health problems arise. If the resident is in the first group, additional follow-up questions about hospice can be asked. Also in this section, the MDS should ask if resident dies during this admission, are funeral plans ready. Obviously, if not, that should trigger a response.

In sum, the fact that nursing facilities now support many Americans who face serious illness and death should be more evident in some of the key data elements in the new MDS 3.0. Thank you for the opportunity to comment.

Dr. Lawler: Thank you, Ms. Peres. And next it appears that r. Streim is back on the telephone line. Operator, can we connect please?

Operator: That line is now open.

Dr. Streim: Hi, this is Joel Streim. Can you hear me okay?

Dr. Lawler: Yes, go ahead.

Dr. Streim: I'm sorry we got cut off before just as I was about to comment. I'm representing the American Association for Geriatric Psychiatry, which is a member association of 1800 geriatric psychiatrists and other geriatric mental health professionals, dedicated to improving the quality of care for older adults with mental health problems. AAGP would like to commend CMS for its recent efforts to improve those sections of the MDS specifically designed to screen for and assess the symptoms of depression and

also behavioral symptoms.

Several of the changes proposed by CMS are consistent with the recommendations of the consensus panel, just described a moment ago by Dr. Ouslander, on improving the quality of mental health care in America's nursing homes. Proposed revisions, and I'll just speak specifically to the recommendations of that panel on depression and behavioral issues, but proposed revisions to Section B, items 4A through C, are specifically designed to aid in the detection of delirium. We want to note that this is an important syndrome that the consensus panel recommended as a target for evaluation, specifically in residents with behavioral symptoms associated with dementia. So we applaud the inclusion of this.

Next, proposed revisions to Section B, items 6A through E, conform to the consensus panel recommendation that verbal, non-verbal and physical behavioral symptoms should be described and quantified. And we believe that this revision – the proposed revisions here move in that direction.

Next, the revisions to Section E, including the use of five report items from the Geriatric Depression Scale for those residents who do not have severe cognitive impairment, as well as preservation of the observer rated items for those residents who are severely cognitively impaired, are consistent with our consensus panel recommendations. We believe that this is likely to actually reduce some of the staff burden in assessment, and should improve the reliability and validity of the depression scale items.

For Section I we recommend the addition of ICD-9 diagnosis codes for major depressive episodes. Single, that's 296.2, and recurrent, that's 296.3. Of all the depression diagnoses, these disorders should be listed specifically since they have been shown to be associated with substantial morbidity and increased mortality, and are important targets for treatment. The effectiveness of these MDS items for the detection of depression or behavioral symptoms will still depend on the clinical observations of front-line staff that have contact with residents, and the translation of those observations into MDS ratings. Our main concern is that the MDS by itself cannot guarantee that staff will consistently recognize new onset or worsening of symptoms that should trigger MDS evaluation or RAPs. Therefore, staff training in the recognition of symptoms and changes in clinical status must

be a high priority in addition to the revisions to the MDS itself.

The MDS as proposed still emphasizes screening and assessment. People prior to me have commented on how it is imperfect in part because it serves so many masters. Our consensus panel pointed out that assessment must be followed by treatment, that is, assessment does the patient no good unless they receive treatment to help relieve symptoms or improve function. Policies and procedures should therefore be developed for the use of the MDS in monitoring treatment processes and treatment outcomes. While that adds to the tasks for the MDS, we feel that there's data in the MDS that could be helpful in doing such monitoring.

The consensus panel recommended that state and federal agencies should work to improve mental health quality measures and processes in the resident assessment instrument and the nursing home survey system. As currently constructed, the quality indicator for depression treated with antidepressant medication has limited face validity. If a nursing home resident who is receiving antidepressant treatment is identified on the MDS as still being depressed, then the treatment is not really effective, and it should be intensified or modified with the goal of ultimately relieving the patient's symptoms and getting them better. Although recognition of depression and initiation of treatment are components of good care, failure to change the treatment in this situation where treatment isn't working is an indicator of poor quality of follow-up care. This is another area that needs to be addressed in translating MDS data into quality indicators.

I want to thank you for the opportunity to comment on this today, and again appreciate the efforts of CMS and all the other stakeholders here today in trying to move this ahead and improve it. Thank you.

Dr. Lawler: Thank you very much. We have Ms. Janet Brown, with ASHA come up please.

Ms. Brown: Good afternoon. I'm Janet Brown from the American Speech Language, Hearing Association. ASHA is the professional association of over 109,000 speech language pathologists, audiologists and speech language and hearing scientists. ASHA has provided comments at every opportunity over the years for the development of the MDS Pack and now the MDS 3.0. Our

objective is to insure that communication, cognition and swallowing impairments are identified and addressed for residents who need them in skilled nursing facilities. ASHA is very pleased that a seven level swallowing scale has been added to Section K in the draft MDS 3.0. It's a major improvement in the tool because swallowing impairments have a major impact on the resident's health risks, nutritional status, cost of care, and quality of life. Acknowledging my colleague from AGA's comment, that's not to say nutritional status doesn't have its own set of distinct needs. The swallowing item I think really addresses a missing component of those needs. ASHA does recommend that this swallowing item should trigger a RAP other than psychotropic drug use, which is the one that is currently triggered.

Like so many who have already commented this afternoon, ASHA continues to be concerned about CMS's multiple objectives in developing a tool that can be used for screening, care planning, payment, but also quality measurement. We believe that the focus on a streamlined tool reduces the depth and breadth of items that are needed to show change over time for outcomes measurement.

ASHA is particularly concerned that four out of the seven communication items have been eliminated in the MDS 3.0. Communication is an essential functional activity. Mary's reference earlier about the importance of hearing the resident's voice attests to that very eloquently. While there are at least twelve seven level scales in Section G addressing activities of daily living, Section C on communication now only has three four or five point scales to address all of speech, hearing and language.

ASHA is particularly concerned about the elimination of an item that records the devices and aids that are used to insure optimal communication such as hearing aids and communication boards. We strongly urge that this item be restored so that there will be a clear indication on the form of how residents communicate, both for maintenance on a daily basis and for reassessments.

In conclusion, ASHA urges CMS to continue work on developing the communication items so that they have the sensitivity to reflect the level of impairment and outcomes from intervention. Unless these communication areas are identified and addressed, the resident is seriously at risk in other areas of performance in the

skilled nursing facility. Quality of care should not be sacrificed for the benefit of efficacy and efficiency. Thank you.

Dr. Lawler: Thank you very much. Next I'll ask Ms. Ann Huston, I believe, from ATRA to come up.

Ms. Huston: Thank you for pronouncing my name correctly. I'm going to relinquish 1.5 of my minutes to another speaker, so I'll be very quick. Thank you for the opportunity to present our brief comments regarding the MDS 3.0. My name is Ann Huston, the Executive Director of the American Therapeutic Recreation Association in Alexandria, Virginia. As a national professional organization representing over 29,000 recreational therapists, we have provided our comments in writing to CMS in addition to this public session. We have applied to CMS for the revisions of the MDS version 3.0 from the version 2.0, specifically the recognition of quality of life indicators, the ease of the new drop-down menus in Section I, and the recognition of recreational therapy as an ordered therapy in Section T2.

While our written comments are broader in scope, we want to focus our public comments today on the new quality of life indicators in Section F. This is a very important aspect of resident well-being, and we commend CMS for recognizing the impact of the resident quality of life on specific health conditions and outcomes. Currently the indicators in Section F reflect self-report from residents that are cognitively intact. While self-report is an important method for data collection, there are many indicators that may be used based on observable, non-verbal and/or non-expressed resident behaviors and responses.

ATRA has conducted a literature review of many quality of life indices, and recommend that CMS revisit the current research available, specifically the concept of autonomy or the individual resident's needs for choice and control. Many of these studies focus on the concept of quality of life and its relationship to clinical outcomes, functional status, and overall well-being. There are many tools currently in existence that are psychometrically sound in measuring respondent's answers for not only qualitative findings, but quantitative as well. We have many other written comments that we have provided on Section F, Section P and Section T, however, I won't elaborate them here.

Thank you for this opportunity to provide our comments. ATRA stands ready to assist CMS in improving Section F, specifically the quality of life indicators, as well as assisting in writing the RAI interpretation to complement the MDS 3.0. Thank you.

Dr. Lawler: Thank you very much. And next I'd like to ask Michelle Hilario with the California Healthcare Association to come up please.

Ms. Hilario: Good afternoon. I'm Michelle Hilario, the Transitional Care Unit and Death Coordinator of Presbyterian Hospital in Whittier, California, and I'm representing the California Healthcare Association. On behalf of its nearly 500 member hospitals and health systems, many of which offer skilled nursing facilities, I respectfully present our comments for the MDS 3.0.

Although we believe that the draft MDS 3.0 is an improvement over the MDS 2.0, most of the changes and additions reflected in the MDS 3.0 are clinically sound and appropriate for the patient population, and consistent with the promotion of quality healthcare for nursing facility residents. Although the newer, expanded sections of the MDS gather valuable information, each addition to the assessment process increases the time it takes to complete MDS. Any increase in assessment time translates directly into increased cost for providers. In addition, the burden would be greater for providers who serve a short stay population, including many hospital-based nursing facilities, which on a per bed basis conduct assessments more frequently. A number of areas within the MDS 3.0 could be improved. The CHA has the following concerns with the draft form.

Section A15, admission and discharge status code. We recommend adding swingbed of an acute care facility as an option for those facilities that both have swing beds and nursing facility beds.

Section E1B, the indicators of possible depression, sad moods. We believe it is viable to assess a resident's mood. This section could be significantly strengthened. As currently drafted, this section does not distinguish between a resident's mood as a result of care provided in the facility from those that simply reflect the resident's outlook on life. We recommend adding a second level to the question that identifies whether the resident's negative mood is a recent change.

Section F1, quality of life. This section is too lengthy and not appropriate for short stay residents. We recommend that this section not be required as part of the five day assessment.

Section H1, HI, continence and bowel control categories. Unlike the MDS 2.0 and the draft version, this section does not assess whether the resident's incontinence is a recent change. We recommend that it be added back into the assessment form.

Section L, oral, dental status. We believe that as revised this section is too lengthy. And in addition, many of the options are not appropriate for short stay residents. We recommend returning the current version of this section.

Section M3, the loss of interest. Because it is common for residents to be uninterested in activities immediately after hospitalization, we recommend that this section not be required as part of the five day assessment.

Section Q1, special treatment procedures and programs. The MDS 3.0 eliminates suctioning as an option. Suctioning requires quite a bit of skilled and qualified special care. We recommend adding suctioning back into the list of special care treatment.

Section P7, expected length of stay. Estimating how long a resident will remain in a facility is more art than science. The answers for this section would be of questionable value. Obtaining physician compliance with completing the section will be highly problematic, and we strongly recommend deleting this section.

Section S, preventative health. Section S2 and S3 are not appropriate for short stay residents. Obtaining this information for residents who are in the facility for merely a few weeks is very difficult, yet if the facility is unable to obtain the data, the RAP for infection control will be triggered. We recommend eliminating this section.

On behalf of the California Healthcare Association, I would like to thank you for hearing our comments, and commend MDS – CMS for all the work that has been put into the development of a revised MDS.

Dr. Lawler: Thank you very much. Next I'd like to ask our Operator to connect Ms. Marcia Nusgart with the Coalition of Wound Care Manufacturers.

Operator: Please go ahead. That line is now open.

Ms. Nusgart: Thank you so much. Good afternoon. My name is Marcia Nusgart. I am the Executive Director of the Coalition of Wound Care Manufacturers. The Coalition represents leading companies who do manufacture innovative wound care and incontinence products. And on that note, I would like to ask Peggy Dodson, who is also on this line, and is Chair of the Coalition, to give our comments. Peggy?

Ms. Dodson: Yes, thank you. I hope you can all hear me. My name is Peggy Dodson and as just mentioned, I'm representing comments specific to Section M of the MDS relating to our recommendations. First, we'd like to commend the committee on adopting many of the recommendations that were provided by the national pressure ulcer advisory panel for Section M. And in particular, we would like to mention that the adaptation of the new description for pressure ulcers staging, and the definition and scoring of the non-stageable ulcer with the product tissue are very important in the MDS revision. These are important for clinicians as these type of wounds are quite often problematic for the clinicians when they could not in the past be able to classify that.

In addition, we are pleased with the addition of arterial ulcers and diabetic foot ulcers. We find this a very positive feedback to the MDS. Unfortunately, some of the other recommendations the NPUAP has made, in particular to stop the process of reverse staging, and to account and score for the [BACKGROUND VOICES COMING THROUGH] [UNINTELLIGIBLE] was not adopted. We feel that these recommendations are a priority, in particular, when reverse staging is contrary with clinical practice. In addition, providing preventative measures and products such as skin barriers, incontinence barriers, and pressure relief devices are critical to reducing skin breakdowns and healing, and the overall cost of Medicare that the healthcare system are incurring.

Our specific recommendations today in Section M is in order to help with stopping the practice of reverse staging, one of the recommendations that we are making is that potentially, as is

similarly done in the OASIS document for the home health PPS, would be to add some questions related to the stages that would define the progression of wound healing, rather than the reverse stage. In OASIS, for comparison, there are questions that are added to each stage of ulcer that refer to the progress of healing. Those added definitions are things such as non-healing, early or partial granulation, or fully granulated. The Wound Ostomy Incontinence Nurses Society has issued guidelines for the OASIS to advise clinicians how to properly use these definitions in the OASIS document, and we feel that using the same scale as is used in the OASIS would be appropriate for the documentation of wound progression without reverse staging. It would also enable CMS to be able to change the scoring as the wound progresses, and move from fully granulating tissue up the scale without doing the reverse staging. We feel that this reverse staging is certainly contrary to good clinical practice fraught with errors and confusion, and we feel that this is an important area that needs to be changed.

Another issue that's problematic with reverse staging is that the data concerning the wound for residents gets skewed. When you're looking at reverse staging, the prevalent data is skewed because some of the ulcers may be documented over time as both a stage four, a stage three, a stage two, and then a stage one, which means there may be double counting, there may be miscalculation of statistical information that is used for many purposes. And we feel that reviewing the status of the statistics is an important element that is captured in the MDS, and we feel that the reverse staging needs [UNINTELLIGIBLE]. [TRANSMISSION DISTORTION]

We also feel that there is an immediate need to readjust the allocation for supplies. Currently, as you know, RUGS are assigned a standard amount across all RUGS for suppliers. And the understanding here is that that puts the provider in a situation where in some cases they're losing money, and in other cases, they may have a little extra money, depending on the type of resident that is admitted to their facility. However, this does place the providers in an awkward situation. If they're not admitting the same amount of patients that need supplies as does not need supplies, then they may very well be in a situation where they are inadequately being reimbursed for the supplies that are needed for appropriate RUGS. We feel that the data which is available

already for CMS should be used to adjust RUGS and supply allocations for the specific RUGS where the most common use of supplies is done. We feel this would be more adequate and would put appropriate reimbursement in the hands of the providers for the conditions that they're dealing with.

Dr. Lawler: Ms. Dodson, your line has cut out. I'd like to point out to the listeners that we have a little bit of technical difficulty. I'd like to remind all the callers who aren't speaking to please keep my microphones on a muted position, including our regional offices on the PICTEL system. And thank you again for keeping your comments to a reasonable period. We're trying to estimate three or four minutes per speaker. I'd like to ask the Operator next to please connect Mr. – excuse me, Ms. Wiswanath with Loeb and Troper, Healthcare Consultants.

Ms. Wiswanath: Hello, can you hear me?

Dr. Lawler: Yes, very well. Thank you.

Ms. Viswanath: I'm sorry, it's actually Ms. Gitl Viswanath from Loeb Healthcare Consulting in New York City. We'd like to thank you for the opportunity to provide this comment. This is specifically regarding MDS Section P5, physician visits, and P6, physician orders.

The MDS 2.0 users manual has always specified the various practitioners whose physician visits and orders may be included in this section, including M.D., D.O., Podiatrists, and Dentists and, quote, an authorized physician assistant or nurse practitioner working in collaboration with the physician, unquote. However, in the December 2002 revision of the user's manual, this description has been expanded and now reads, quote, an authorized physician assistant or nurse practitioner who is not employed by the nursing facility, working in collaboration with the physician, unquote. As far as we know, this apparent exclusion of staff nurse practitioner visits and orders has never appeared in the MDS Q&A's to date. Since the draft version of the MDS 3.0 does not come with a manual, and since the wording on the actual draft document states, quote, physician or authorized assistant or practitioner, unquote, we would like to inquire as to whether what we believe to be unreasonable restriction on nurse practitioners will be continued in MDS 3.0. The MDS 2.0 users manual states that this assessment

information is included on the MDS 2.0 because, quote, in some cases the frequency of physician visits and physician's order changes is indicative of clinical complexity, unquote. Nursing homes in New York State and across the country have hired greater numbers of nurse practitioners over the years for various reasons, including their reputation for having excellent assessment skills. They provide coverage when other practitioners may not be on site, and they are frankly less expensive to hire and maintain on staff. Both the nurse practitioner on staff at a nursing home and the one working independently have received the same education and utilize the same assessment and treatment skills. Both are required to work in collaboration with a physician. We believe that the current policy of allowing visits and orders by facility employed physicians and not by facility employed nurse practitioners interferes with the purpose of the MDS to accurately collect assessment data reflecting the condition and needs of the resident. We therefore respectfully request that this inconsistency be corrected in the MDS 3.0. Thank you.

Dr. Lawler: Thank you very much. And now back to our Baltimore audience. I'd like to request that Pam Bailey come up to speak for NAAP.

Ms. Bailey: Good afternoon. My name is Pam Bailey. I am the Vice President of the National Association of Activity Professionals, also the Government Relations Chair for that organization. I would like to thank the panel for this opportunity to formally address the town hall meeting. Overall, we would like to express our appreciation and our pleasure with the totally new activities Section M. A lot of good work was done on that section, and the results do show those efforts.

We do, however, need to address the deletion of the "none of the above" response in Section N1, time awake. This deletion not only affects the quality indicator for depression, but also creates the problem of falsification of records for certain clients that only fit into the "none of the above" category. Napping during the three time periods for more than one hour does not necessarily define a client as comatose. So for these certain clients who are not comatose, there is no possible answer to be given, so we strongly urge that you return that item to Section N1. In support of this argument, I would like to quote from a GPS alert publication by Lisa O'Donald under Actively Pursue Perfection in Section M. Two QI's can be triggered in Section M1, time awake, QI 4, the

prevalence of symptoms of depression, and QI 5, the prevalence of symptoms of depression without antidepressant therapy. In the Time Awake section, the intent is to discover whether the resident is bored or depressed. The RAI Manual gives you guidance on how to accurately complete this section. Interviewing the resident to discover his or her preferred activities and activity setting can help you uncover signs of boredom and depression. Just a little back-up for that particular stance.

Our membership at NAAP is comprised primarily of activity professionals who hold credentials from the NCCAP, which is our national certification council, but we have many members who also hold certifications in therapeutic recreation. As activity professionals, we would all expect to participate in the completion of Section N, however, there has been some mixed reaction among my group as to the reimbursement category, Section P2S, which permits physician orders and recreational therapy minutes to be included under therapies. This item was removed from Section T where it was previously situated for data collection purposes. We just have two questions at this time as to why this item was removed from that section and continued in the new section in the MDS 3.0, and do the data collection period results justify the move for inclusion into Section P. So those are information I would like to be able to pass on the members of our organization.

We do look forward to making future comments on other sections as the time goes along. I thank you for the opportunity to do that on the e-mail and for the viewing on the website. I would like to personally at this time urge RAND to select at least one activity professional for your tactical advisory panel. We would very much like to be included in that process. And I thank you very much.

Dr. Lawler: Thank you very much. Next we would like to ask Ms. Diane Brown to come up to speak for NASPAC.

Ms. Brown: Thank you and welcome. My name is Diane Brown. I'm on the board of directors of the National Association of Sub-acute and Post-acute Care. On behalf of NASPAC, thank you for this opportunity. Our constituents and members, those who assess residents and complete the instrument, both owners and operators who are benchmarked and paid on its completion, those who provide services and supplies to facilities, they are providing us

daily with both specific and general comments, suggestions, clinical and cost analyses regarding this revision. Formal and detailed comments for review are being ongoing, prepared and compiled. There are a few repetitive themes we are hearing that we hope serve as guiding principles for change.

We all recognize the industry has changed dramatically in the last fifteen years since 1987. Standards of care, lengths of stay, age of resident, health status, cost of care, payor sources, and payment systems are all shifting. Together we need to insure that any revision or refinement of the base document that feeds all other systems of the MDS truly reflect current industry care standards and practices. We should change and update coding that is clinically out of date, and only capture clinically relevant information. To retain coding only because it is tied to the current payment system would defeat the purpose of the instrument, and the instrument would lose significant clinical value.

Secondly, facility costs and cost centers because of the aforementioned reasons have increased, shifted, and realigned. These shifts will hopefully be recognized by the mandated refinements of the payment system. But as part of the MDS revision process, we need to identify those cost areas and to insure that elements captured on the revised MDS are reflective of care delivered, and that the cost of that care in today's world rather than 15 years ago. The recently released health care industry market update for nursing facilities presents a healthy financial picture for our industry. If the MDS assessment is to remain the linchpin of the payment system, we need to be careful to establish linkages that are not subject to wide variations in reimbursement for residents receiving the same care, same rehabilitation, and incurring the same costs, but different assessment approaches. Today it is not only difficult to obtain the additional funding authorized by Congress because of the skewed case mix index, but also reimbursement ranges currently exist of over $1,000 for a 14-day period. For example, this may occur just by choosing one assessment reference date over another, or by inaccurate ADL coding. Curbing these issues as we redesign and refine the MDS will help stabilize our industry. Lastly, a universal goal of us all is to reduce the paperwork burden.

On behalf of the board of directors, we hope to continue to collaborate with you on the refinement of the MDS and will share our comments from our membership as they are supplied. Thank you very much.

Dr. Lawler: Thank you very much. Next I'd like to ask Lisa Peterson with the University of Maryland Baltimore Campus to come up.

Ms. Peterson: Good afternoon, ladies and gentlemen. It is a pleasure to be here today to speak to you about my suggestions on how to strengthen the MDS 3.0 and improve the quality of life for skilled nursing residents. I am the Director of Social Services and Admissions at Maplewood Park Place, a continuing care retirement community in Bethesda, Maryland. My responsibilities include, among other things, the provision of all social services to the skilled nursing and assisted living population. During this past spring semester I taught a three credit undergraduate course called Social Work Practice in Aging at the University of Maryland Shady Grove Center.

I believe it is important to more effectively measure psychosocial well-being and the symptoms of depression that are more specific to the elderly. When MDS 3.0 meets that goal, it will better serve as a guide to widen more individualized care plans for mood, behavior, psychosocial well-being, and quality of life. This accomplished, social workers will be better able to alleviate psychological distress, mood disturbance, and behavioral problems. This will also help to contribute to overall feels of well-being and a sense of empowerment. Last week I forwarded to Mr. Connolly and Ms. Shapiro at CMS a list of suggested questions to add to or modify in the MDS 3.0 that focuses upon resident strengths, culture, the involvement of their family members and guardians, and their own level of self-advocacy. I believe that they will be effective in measuring quality of life in skilled nursing residents. I won't overwhelm you with the minutiae of each question that I modified or suggested.
The Office of the Inspector General has been very interested in the quality of life of skilled nursing residents. In March 2003 the OIG published the results of their study on psychosocial services in skilled nursing facilities. In this report it showed that at the 92 skilled nursing facilities that were included in the study, and of the 299 Medicare beneficiaries that were involved, 53% of the facilities did not have a social worker with at least a Bachelor's degree. Of these beneficiaries, 39% of them had care plans that did not address their psychosocial needs. Forty-six percent did not receive all of their plan psychosocial services, and 38% neither had all of their psychosocial needs addressed in care plans, nor did they

receive all services that were included in their care plan. The point was well made that skilled nursing facilities tend to have problems in identifying and properly addressing the psychosocial needs of its residents. The CMS is to be commended that it requires that all skilled nursing home administrators, nurses, nursing assistants, rehabilitation therapists, and dieticians be well-educated and licensed healthcare professionals, and demonstrates the value that the CMS places on physical health and safety. However, the residents need the same quality of care to meet their mental health, psychosocial and quality of life needs. I would like to respectfully request that the CMS reconsider the law that allows the practice of hiring non-licensed lay persons to attempt to provide social services to very diverse, medically compromised and often chronically mentally ill older adults. This job is better left to licensed professional social workers who are experts in mental health, group dynamics, diversity in culture, values, family structure, verbal and non-verbal communication skills, community resources, and health insurance.

There also needs to be a more reasonable ratio of residents to social worker or we cannot possibly hope to meet the quality of life needs of this very deserving population. Without these additional changes and modifications of the MDS, providing social services and skilled nursing facilities will be like trying to drive a car without wheels. We will continue to be stuck in the same place and not getting anywhere.

Thank you for your kind attention.

Dr. Lawler: Thank you very much. Next I would like to ask – and I hope I get the name right – Lavanna Shahan to come up and speak please.

Ms. Shahan: Hello. My name is Lavanna Shahan. You almost had it right. Okay. I have been a long-time care nurse for 30+ years in an ICS nursing home in West Virginia. My main concern is that the resident care, after working all this time, is taking a back seat to the paperwork. Just because we have the paperwork done, it doesn't always mean it's accurate and a benefit to us. We are losing sight of the resident who means the most. With the overwhelming paperwork we already have, this MDS will only add to the burden. It is too much time-consuming, too detailed, and is geared more towards Medicare and swing beds than to a Medicaid ICS facility which we are. We have a lot of those in West

Virginia. The nursing shortage is already an issue, and this would only complicate the problem. And who suffers? It's the resident.

The following sections I have some comments on, especially the Section E1B, quality of life. In our facility we have maybe a 25% of our ratio that can actually answer these questions. Most of them are severely impaired. And on pain assessment, J2, how do you code on C like for duration, frequency of pain? And I gave an example of a patient had a headache times one for the last seven days, and received Tylenol times one. None of the number one, two or three are appropriate. How do we code that? So that section needs to be looked at again. Again, on Section E1B, the indicators of possible depression, again, this section – what do we do with the ones that are severely impaired that can't answer these questions. And on disease and diagnosis, it is far too detailed. This information – we get a lot of residents from home, we get a lot of residents that have no family members, that don't know the background, and their doctors are just [UNINTELLIGIBLE] the information. A lot of the stuff we cannot get. So that involves time and staff again to research all this information.

On falls, Section J, it needs to be better explained. For example, we use Bacitracin on skin abrasions. We do code it as a moderate injury because under moderate injury it says a scrap, abrasion or bruise that heals without treatment in a few days. To me, that is not a moderate injury, but that's what we have to go with because you are giving some treatment to it. And then again on fractures, they're listed in two different sections and are automatically triggered. Why are they listed in two sections? And CMS already answered some of my questions about the different RAP's and the quality of life. I had a lot of questions about that, but on the slide show I got these answers. And another question is how will this affect case mix reimbursement when it's already a financial issue for some nursing homes even to stay in business. Will the time span be the same for completing this? The training of the staff is a key element. With already our nursing shortage, [UNINTELLIGIBLE] gets done in a timely manner. And our main concern is let's put the resident first. And thank you for your time.

Dr. Lawler: Thank you very much, Ms. Shahan. Next we would like to ask Laurie Loftus to come up and speak to us.

Ms. Loftus: Hi. I'm Laurie Loftus and I'm actually from Integrated Health Services. I'm National Care Coordinator there. And we have a whole team of nurses that monitor completion of the MDS, training on the MDS, patient reimbursement for Medicaid, PPS reimbursement, and also quality indicators and quality measures. We're very involved in all of that because it all comes down to the MDS.

Some of the things that we listed as issues or concerns that we had about the MDS, a lot of those have been addressed here, but just a few other ones I want to address for our group.

First off, nobody has mentioned Section A21, the attestation period for the RN to put there that the MDS is accurate. Right now we have a nursing shortage. We have nurses in New Mexico; for instance, I have nurses who are going from their building to another building to assist. If they have to document the MDS is accurate instead of complete, we're going to have less and less people who are going to be willing to do that. I know I've gone into buildings and also assisted to make sure the MDS is complete, the RAP's are complete. If I would have to go in and attest that it was accurate, I don't know if I would be as willing to do that. So that's one thing I would ask you to look at again.

Section F, the quality of life, under Section F1. Personally, and also our group feels that that really needs to either be – well, they really think it needs to be taken out. The problem that we have with that is as we have gone from – and many of us in our group have been – and the surveyors learning how to decide if the quality indicators, what they need to tag this on. Our concern is on Section F1 that that will become an issue with state surveyors who may or may not be as educated as we would like, and they'd like to look at the MDS. And they're going to come in ready to tag us the minute they walk in the door. So we do have an issue with that.

Section G, and you did answer the question that there will be a new grouper. Because to be honest, as the MDS 3.0 stands right now, the grouper doesn't fit very well into that, especially in Section G because of the difference in the way we answer those items.

Section I, the disease diagnosis, and the drop down boxes. I think they're good. I think they're tedious though. And most of our

group thought that they were tedious. And our question was how will that effect reimbursement. And also, if the tool is going to be used as research, how will it skew research numbers if our MDS nurses put down the wrong answer.

So those are some of the things that we had questions with. Basically what we would like CMS to do is make sure that when the 3.0 comes out that we have a concise manual that goes with it so there's fewer gray areas. Because right now there's a lot of gray in RAI, even the new manual. Even though it's good, there are still some issues with the grayness of it. We want to make sure that the group works with this. We want to make sure also that we have time to train our staff on how to use the 3.0, and if there's a new grouper, the new grouper. And also to make sure – we really want you guys to make sure that the states have software that works because that's an issue. That was an issue when Ohio was one of the last ones to go to the 2.0. We wait a while for everything. We were one of the last to go to 2.0. And we did have issues with just the transformation over onto the 2.0. So we would like to make sure those things are covered.

Thanks very much for asking us to come.

Dr. Lawler: Thank you very much. Operator, could you connect us with Maryanne Lyons please.

Ms. Lyons: I'm here. I'm Maryanne Lyons. I've worked in long-term care for 30 years, first as a social worker, and then for the past 20 years in administration. Today I speak to you as someone in the trenches, trying my best to balance what I would like to offer residents with what I am able to do in this community setting.

Having reviewed the MDS 3.0 we see many refinements and improvements that will enable staff to assess our residents more accurately. However, my concerns and comments are raised in regard to Section E and F, mood and quality of life domains. I certainly acknowledge the importance of these domains, but I have two concerns. I have to say at the onset that the shrinking Medicaid monies in all the states poses an ongoing challenge for today's providers between what we would like to provide and what we can manage to provide. Further, since the explosion of the assisted living market, nursing facilities have admitted sicker residents with shorter stays and more complex needs. At the same

time, today's residents are better informed and more demanding. Certainly once the baby boomer generation confronts nursing home care; they will present even a greater challenge.

From the social workers point of view, I question the appropriateness of this line of questioning given the number of losses our residents have already experienced at the time of admission to a nursing home. We get this information in MDS 2.0, but certainly in a more gentle and appropriate manner. Isn't there another way to get the information about quality of life, focusing on strengths, not on losses? Asking these questions to a newly admitted resident seems likely to trigger an emotional disaster to individuals who are in a very difficult situation, having to adjust to a new way of life within a communal setting like no other experience.

From an administrative point of view, if I had all private rooms, I do believe that resident satisfaction would skyrocket. The reality is this is not the case. Our private rooms are used for issues such as end of life care and behaviors affecting others. Also in the area of foods versus reasonable accommodation, and what about the resident, who is alert, but is on a tube feeding. What will this facility obligation be to respond? As always, we will be juggling what we want to do with what we can do, trying to do the very best with our staff, physical structure of our building, and the resources at hand.

Thank you very much for the opportunity to comment.

Dr. Lawler: Thank you very much. We next ask Cherry Meir to come up and speak here.

Ms. Meir: I'm Cherry Meir and I'm representing the National Hospice and Palliative Care Organization. The National Hospice and Palliative Care Organization is a non-profit membership organization, representing hospices and palliative care programs. The organization is committed to improving end of life care and expanding access to hospice, thereby enhancing quality of life for dying Americans and their loved ones. In 2001, NHPCO estimates 775,000 patients were served by approximately 3200 hospices. Many of those patients were residing in nursing homes. We are here to testify on the MDS because of its tremendous impact on the care being delivered to terminally ill residents of nursing facilities

with or without hospice care. It has been statistically predicted that by 2020, 40% of Americans will die in a nursing facility, and some states are currently approaching that percentage as we speak.

When a resident elects the Medicare/Medicaid hospice benefit, the resident has a consent form stating that they desire to receive palliative rather than curative care. The hospice also has a written certification of terminal illness from a physician stating that the resident's anticipated prognosis is six months or less if the illness runs its normal course. Even with this explicit documentation on the resident's record, it is extremely difficult to accomplish the task of developing a palliative care plan with the current process that's in place with the RAI. It is extremely difficult for facility staff to deviate from curative, rehabilitative, and maintenance outcomes in fear that as the resident's condition deteriorates, their interventions will be misconstrued as substandard care. Outcomes in palliative care are very different. Palliative outcomes developed and supported by NHPCO are self-determined life closure, safe and comfortable dying, effective grieving. These outcomes apply to all terminally ill patients across all settings – homes, hospitals and in long-term care.
In order to overcome the barriers to providing palliative care in the resident assessment instrument, NHPCO is proposing that a skip pattern for palliative care be included in the MDS 3.0 version. And we have included a draft of the potential tool, and made extensive comments that I have already submitted to CMS. A draft proposal – answers to these questions would initiate a note on the RAP summary sheet to instruct the assessor to develop a palliative care approach to the triggered problems. We feel that the nurse feels that they don't have permission to develop palliative care plans. And then once – then the resident assessment protocols would provide interventions that would be appropriate for palliative care as exemplified in the new protocol for pain, and the revised protocols for meeting delirium. These three new protocols have a special section that says considerations for palliative care. Subsequently, the quality indicators would be adjusted to factor out those residents in which deterioration is anticipated as the resident approaches death. This would eliminate the negative impact of providing palliative care.

In closing, NHPCO encourages that these problematic areas be addressed in the MDS 3.0 version. In support of this endeavor, if

the decision is made to include a palliative step pattern, we would be willing to convene a group of experts in the field to continue work in developing and refining the questions for this section. We appreciate the opportunity to testify and commend you on your work in improving the MDS.

Dr. Lawler: Thank you very much. And that concludes the formal comments that we had prepared for today's meeting. And next we're going to do our open microphone section. I would like to point out that we're running just a little bit behind. And that after we have the open microphone comments, we're not going to have time for any follow-up from our RAND validation contractor afterwards in order to maximize our use of the time. We're going to try to rotate between our Baltimore participants who have shown up in the CMS regional offices, as well as the telephone. And we're going to do three at each location in rotation. And when you begin speaking, please mention your name and who you represent. Let's start with Baltimore participants, and we'll take three first, and if you could line up behind the microphone, we'll start that way, and then we'll go behind that with the regional offices and the telephone participants. The Telephone Operator will assist you – explain again how to pose a question. Let's go ahead and start here.

Ms. Hinkle: Good afternoon. My name is Laura Hinkle and I represent Genesis Health Ventures. I understand that the Medicare reimbursement system is being looked at or reviewed for potential changes in the year 2005. I think BIPA (Benefits Improvement and Protection Act) mandated that, correct me if I'm wrong. Your timeline for having MDS 3.0 available would be December 2004. A change in the reimbursement system could result again in changes in the MDS. Is any consideration being given to the timeline of the two projects, and do you have any comments on that?

Dr. Lawler: Did you want to answer that? We may be able to answer that, but I want to remind everybody that this is a comment period and not a question and answer period.

Ms. Hinkle: I want a comment.

Mr. Connolly: This is Bob Connolly. And we are working with the team that's looking at payment and trying to work in parallel. Unfortunately though, their recommendations will come after we've done the

development. But in terms of communication and coordination, we have staff here – Ellen Gay and others, that are working with us.

Ms. Hinkle: I'd just like to comment that it would be good if they could coincide. Thank you.

Dr. Lawler: Thanks.

Mr. Amrhein: Good afternoon. This is Scott Amrhein and I'm the Executive Director of the Center for Continuing Care, which is part of the Greater New York Hospital Association. Our organization represents in addition to acute care hospitals in the New York Metropolitan area, over 90 long-term care facilities, all public and not for profit facilities. We want to very much express our appreciation to CMS for the opportunities that you've created for stakeholders to take part in this discussion. We at Greater New York have created an MDS improvement work group which we put together in 2001, and we submitted extensive comments in 2001 to kind of kick this process off. And have had the pleasure of working with several of the key CMS staff. We do appreciate that opportunity.

I guess the first thing I want to mention is that we want to express our gratitude and appreciation about many of the things in the MDS 3.0 draft that did reflect many of the comments that we made in many of the exchanges that we had. And in particular, I just wanted to highlight the sensitivity that's been shown to the fact that populations in our facilities are evolving. They're very diverse. And we certainly want to express appreciation for CMS's recognition that as a geriatric assessment instrument, the MDS hasn't always been, and doesn't continue to be, fully appropriate or well suited for many populations that are currently served in facilities presently in the New York area. We probably have close to 50% of the HIV and AIDS cases in long-term care facilities. That's been one issue. We also have a good number of facilities that almost exclusively serve a pediatric population. We want to commend CMS in particular for proposing to carve out the pediatric residents in terms of completing this instrument. And we do understand that the movement is towards the creation of some kind of an individualized pediatric – specialized pediatric instrument, so we think that's a very positive direction. And we encourage CMS to look at other ways in which special populations

can be accommodated.

Just one other thing, and we have a lot of items that we were happy to see in the draft, so we want to express our appreciation for the elimination of questions that we felt couldn't reasonably be answered on an initial assessment. In the 2.0, there were a number of questions basically that ask you to go back in time 90 days and make statements about changes in mood and changes in other areas. And we found that our MDS completers were having a difficult time with that, so we appreciate the sensitivity to that.

I guess lastly, we wanted to just sort of summarize our main concern and our main comments, and again, it was reiterated by many people today, about how the draft – in the draft, it's not really apparent that this product is going to be less burdensome than the current MDS 2.0. When we started looking into this in 2001, Secretary Thompson had made a statement to the public, I think to the Ways and Means Committee, that there was going to be – this was at the time when we were shortening the swing bed MDS from a six page instrument with 400 items to a two page instrument with 100. And he very much made the statement that it would be the intent of HHS to look at ways to kind of streamline the burden overall for all providers. And we think that really does need to be kind of a threshold thing that CMS looks at, and we just encourage you as you go through the validation process to not lose sight of that, and to really realize that it's not just about the convenience of providers, but it really frees up time for clinicians and caregivers to deal with residents, and that is a vital goal I think in this process. So we continue to be available to work with you. We appreciate the opportunities in the past. For example, if there is a need or opportunity on the tactical advisory panel, we would be happy to provide assistance in that regard. Thank you very much.

Dr. Lawler: Thank you.

Ms. Bateman: My name is Diane Bateman and I'm with the Washington Center for Aging Services in D.C. And I was hoping with the 3.0 that the timeframes of in the last seven days and the last fourteen days would be eliminated, but when I reviewed the draft, they're still in there. And what I find with that is that it often clouds the accuracy of how the resident actually performed overall in the last 90 days. For 85 days they required one kind of help, but in the last seven,

they didn't. And the RN's say, well, in the last seven days, they didn't do that. So you don't have any leg to stand on because the manual pretty much sticks to that. So I was wondering if there's some way they could review that and try to maybe make it not such a tight thing. And I also agree with the lady that talked about the signing for accuracy because in our facility that will cause a major problem. We've told the people who sign – who complete their sections, they are responsible for accuracy. But when people are on vacation in other areas where RN's are filling in, signing for completion, they will have a problem signing for accuracy. Thank you very much.

Dr. Lawler: Thank you. Operator, do we have any comments from our regional offices?

Operator: At this time I would like to remind everyone, if you would like to make a comment, please press star one on your telephone keypad. Your first comment comes from Rita Underwood in Kentucky.

Ms. Underwood: Hi. I would like to say thank you for having me today. And also tell the peers that are in the audience, Pam Bailey from NAAP and Diane Brown from NASPAC, I appreciated the comments. As an industry provider and also a consultant who has been in many of the nursing homes that use the MDS 2.0, the MDS 3.0 draft weighs in some concerns in the sense that it does not take into consideration some of those social service aspects. And also, by not having a complete document to review, I would also look at some extension periods with the RAP once they're developed. With that said, I agree with most of the comments today. I also would like to maybe look at some of the alternatives in the regulations and how they will be interpreted and used in the quality of life indicators that are on here. And also feel that some of those questions do not directly relate to the status of a patient such as, for example, F1M, do you clothes get lost or damaged in the laundry. A facility's performance is not what we're assessing, but rather the resident status. Thank you.

Dr. Lawler: Thank you. Operator?

Operator: Once again, if you would like to make a comment, please press star one at this time. There are no further comments at this time.

Dr. Lawler: Okay. Can we go to the open phone lines please? All right,

Operator, if you can get some people lined up in the queue, we'll see if we have further comments here in the Baltimore auditorium. Would the next three participants like to come up?

Ms. Razer: Hello, and thank you for letting me speak. My name is Teri Razer. I'm wearing two hats today. I am from the Quality Insights of Pennsylvania. We're the QIO for Pennsylvania, as well as I'm the Secretary for the Pennsylvania Association and Nurse Assessment Coordinator. I just wanted to mention that with PANAC, which is the Pennsylvania Association of Nurse Assessment Coordinators, that we held nine regional meetings throughout the State of Pennsylvania as a roundtable discussion group regarding the MDS 3.0 because we wanted to give the R-NAC's of Pennsylvania a voice. There were over 200 R-NAC's that did attend these meetings and we had a multitude of comments which I will not go through today. I will be sending those to you. A lot of those have been covered already.

Some of the things that have not – one was Section E. We do like that it was changed from the 30 days to the 14 days. Also, we have a feeling that the coding 01 and 2 was confusing with the MDS 2.0 as well as with the MDS 3.0 even though it hasn't changed. Let me give you an example. If you code a 1, that means that the indicator of this type exhibit is up to five days a week. An example would be maybe the first week the resident has five days – five times that they've had the indicator, but the second week, they have six days. What are we coding? It's a little hard to understand that way. What we have recommended is that you change the coding possibly to zero, no indicators in the last 14 days. One would be one to five times in 14 days; two would be six to ten times in 14 days; and three would be 11 to 13 times in 14 days; and a four would equal daily in 14 days.

The other area that we had a comment about was Section I. We do like the drop-down menus. We were wondering how this would be updated, if it was going to be updated annually when AHIMA updates for coding. And if so, how are the vendors going to get that to us because I know we've had problems with some vendors - I won't mention any names – of getting things updated in a timely manner which causes problems.

And also, what kind of documentation would be needed for these diagnoses? Lots of times when the physicians come in, they'll

write diabetes. They don't write any specifications. And a lot of the R-NACS have not been to ICD-9 coding, and now they're going to have to be more specific, and probably should have been before using the UB-92. You're supposed to be really specific, but what I'm finding out is that they don't know what they're doing in coding, so we need some education there.

The other comment area was K2, weight for the last three days. We would like you to change that back to 30 days. Residents are usually weighed on a monthly basis. And if you say in the last three days, I think it's going to cause some confusion. Weight gain was taken out. The nurses feel that weight gain is very important if a resident has CHF, so that's just a comment they asked me to bring up.

And also P7, expected anticipated length of time, to be filled out by the nursing home. We're lucky if we get the physicians to fill out the cert form that anticipates how long the resident is going to be there. So if you could just look at that question, we'd appreciate it. Thank you for your time.

Dr. Lawler: Thank you very much. Okay. At this time, let's go ahead and take – oh, we have another person in Baltimore. Go ahead please.

Ms. Budds: Hi. My name is Michael Ann Budds. I work with HCA. Just a very quick comment. I commend you for adding in Item #A20, the HIPPS code. That's wonderful. I think there's been a lot of confusion with the current item #T3 on the current 2.0. However, I do encourage you, and would recommend that you do automate the HIPPS code so that that billing component is taken out of the hands of the clinicians and actually put into the grouper software itself. Thank you.

Dr. Lawler: Okay. Thank you very much. Operator, could you connect our next question online please.

Operator: Your next comment comes from Donna Halston from Michigan.

Ms. Halston: Hi. My name is Donna Halston. I'm the Quality Manager at Spectrum Health Continuing Care Center in Michigan. And I just have a comment on Section G. Where does CARF- accredited associations fit in. I know that in a lot of sub-acutes like in ours, we use the STEM scoring for how people are doing functionally.

STEM scoring is the opposite of the MDS. Whereas zero is independent, with MDS seven is independent with a STEM score. So I would like to have you consider looking at that. Thank you.

Dr. Lawler: Thank you very much. Do we have any more calls online right now, Operator?

Operator: Once again, if you would like to make a comment, please press star one on your telephone keypad. Your next comment comes from John Sheridan from Ohio.

Mr. Sheridan: Hello?

Dr. Lawler: Yes, we can hear you.

Mr. Sheridan: First, I've been listening very quietly and I want to commend the committee and all the participants for the excellent feedback. I represent a company called E-Health Data Solutions. And we've made an MDS data repository for MDS 2.0, believing that no nurse should be any farther away from her data than a simple click on the Internet. And one of the comments that I would like to make is simply as you prepare the MDS 3.0 and the manual, that the manual clearly address the issues of what staff are supposed to do with regard to change in a resident condition from assessment to assessment. Many of our clients and customers have found confusion if they enter the change in resident condition on their assessment, and wonder if each assessment therefore needs to be a significant change assessment. There are currently eight rules for significant change assessment, and you might change in eight areas on an MDS and still not require a significant change from one to the other. So that's my comment. And I want to thank the opportunity to share this feedback from the many users we have of our service.

Dr. Lawler: Thank you very much.

Mr. Sheridan: Thank you. Bye.

Operator: There are no further comments at this time.

Dr. Lawler: Okay. Do we have more comments here in Baltimore who would like to speak? Going once, twice.

Male Speaker: We're all commented out.

Dr. Lawler: Operator, do we have any comments from our regional offices?

Operator: No, sir, not at this time.

Dr. Lawler: Okay. Well, I believe we're going to finish up. Let me just take a moment to thank everybody for the very insightful comments. We're obviously very pleased to have such a diverse mix of stakeholders in the providers, as well as from the beneficiary side of things. Your participation in this meeting will undoubtedly improve the nursing home MDS 3.0 tool. And we'd also like to thank Lisa Hines, who is our Director of the Division of Ambulatory and Post-Acute Care for speaking, as well as our co-leaders of the MDS Development Team, Bob Connolly and Mary Pratt, and Lori Anderson, who is the MDS IT Coordinator. And thanks again to the MDS Validation Contractor, Deb Saliba of RAND, and Joan Buchanan.

I'd like to remind everybody that an audio replay of this entire town hall will be available for 72 hours, two hours following this. And again, I can tell you that phone number one more time. That's 1-800-642-1687, and the conference ID is 244453. And I'd also like to remind you that both the formal comments presented today and the informational slides that were presented earlier in the introductory remarks are posted on our CMS website at www.cms.hhs.gov/quality/mds30.

We're just going to take one more moment and step out of our ending remarks to see if our regional offices on PICTEL would like to add any comments before we close as well. [NO RESPONSES] With the excellent lighting situation. Operator, are they –

Operator: There are no comments at this time, sir.

Dr. Lawler: Okay. How many were on the call today, Operator – telephone members?

Operator: Three hundred and forty-one.

Dr. Lawler: Excellent. Thank you very much.

Operator:	You're welcome.
Dr. Lawler:	Well, that wraps up our MDS 3.0 town hall. My name is Dr. Richard Lawler, and it's been my pleasure to assist in this meeting. Thank you very much.
Operator:	Ladies and gentlemen, this concludes today's teleconference. You may now disconnect. [END OF CONFERENCE CALL]