MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHERINE BAICKER, PhD
KATHY BUTO, MPA
ALICE COOMBS, MD
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
HERB B. KUHN
MARY NAYLOR, PhD, FAAN, RN
DAVID NERENZ, PhD
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
CORI UCCELLO, FSA, MAAA, MPP

B&B Reporters
701 Copley Lane
Silver Spring, MD 20904
301-381-2005

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P R O C E E D I N G S

[9:44 a.m.]

DR. CROSSON: Okay. I think it's time to begin. I'd like to welcome our attendees for this morning's discussion.

Once again we are going to pick up on our continuing work on the impact of pharmaceutical costs on the Medicare program and its beneficiaries.

I'm going to make a couple of opening remarks here before we get to our presentation. I think it's fairly obvious to everyone that even since our last meeting, the issue of drug cost has become a subject of increased public awareness, both through the media and also through the injection into the American political process. As a consequence, I think there has been an increase in sensitivity and passion among all parties involved, and we're fully aware of this.

We also are concerned about the impact of drug costs on the federal treasury and on the out-of-pocket costs for our beneficiaries. But we are a nonpartisan deliberative body. We have been working on drug costs for more than a year, and we'll continue to do so. We do not

blow with the winds, whether those are media or political winds. We approach topics through thorough research, analysis, careful deliberation, and the development of recommendations which are supported by facts.

We have a plan and a schedule. Those of you who have been following our work have a pretty good idea, I think, what are the issues that we have on the table currently.

In order to think through some of those issues, both with respect to Medicare Part D and Medicare Part B, other issues such as the potential impact of the 340B program, we need as a Commission to have a full understanding of the broader world of Medicare, the pharmaceutical industry, and its impact on both the Medicare program and beyond so that we can then focus on our mandate, and that is to deal with issues that affect the Medicare program and its beneficiaries.

So we are going to proceed with our work plan. You will see these issues that we have discussed previously coming up at future meetings. But, in addition, this Commission I think will be over time making suggestions and potentially leading to discussion of other approaches to

deal with the question of the impact of Medicare costs on the program, the federal treasury, and its beneficiaries.

In the end, as always, our work will reflect deep research, thorough analysis, and careful consideration in the process of developing recommendations, which I think we will see later in this term and beyond. We consider this problem to be of such impact that it is clearly a multi-year piece of work for this Commission.

And with that, Rachel and Shinobu will take us through the context of Medicare drug spending.

DR. SCHMIDT: Good morning. Our talk this morning is the second of two presentations that provide broader context around Medicare's payment policies for drugs.

Last month we discussed the magnitude of Medicare drug spending across all payment systems. We said that in terms of the measurement concept used in CMS' national health expenditure accounts -- a final purchase, retail concept -- about 13 percent of Medicare spending in 2013 was for retail prescription drugs. When we considered a broader measurement concept that also included drugs used as intermediate inputs for services at hospitals, nursing

facilities, and so forth, about 19 percent of Medicare program spending in 2013 was for drugs and pharmacy services.

Many of you had additional questions for us, but we hope that you can wait until next month's meeting for answers because we've got a full agenda this morning. But, briefly, let me deal out Warner's question about what the 19 percent looked like in 2007. The answer is that our estimate was, again, 19 percent in 2007, so the proportion spent on drugs did not change even as the Part D program was ramping up.

This slide shows you how we will work our way through this presentation. Let me say at the outset that this is a really sprawling topic, and we are extremely aware that many of you know a lot more about some of these issues than we do. So for this presentation even more so than others, we look to you for help in getting the details and the sense of balance right in this discussion.

Let me also note that in the interest of time, we had to condense some of the slides from your mailing materials into fewer for this presentation.

There are two general categories of medicines

we'll talk about this morning. Most medicines are small-molecule drugs, shown here on the upper right by aspirin. Small-molecule drugs are synthesized through a chemical process and can usually be manufactured at low cost. After an innovator has marketed a brand-name small-molecule drug for a period of time, other manufacturers may enter the market and produce what are often nearly identical generic versions at much lower prices. The Hatch-Waxman Act of 1984 laid out how and when generics may enter.

Biomedical science has moved toward developing large-molecule biologics, depicted on the left by EPO. Biologics are synthesized from living organisms or tissues, they are much more complex, and they provide more targeted treatments for conditions like cancers and autoimmune diseases.

Biologics are typically injectable or infusible, and they often require special handling such as refrigeration. Because of their complexity, biologics cost more to develop and produce, and unlike generic drugs, manufacturers of biosimilars cannot make exact duplicates of the reference product. Even the innovator may see small changes in their own reference product as they produce it

over time.

The first biologics have been around since the early 1980s, but it wasn't until 2010 that the Biologics Price Competition and Innovation Act laid out a pathway to approve biosimilars. The Food and Drug Administration approved the first biosimilar in March 2015.

The federal government plays many important roles in drug development. It supports biomedical research -- most notably through the National Institutes of Health -- by directly conducting studies as well as through extramural awards. The government needs to ensure that new drug products are safe and effective. It also provides protection to innovators so that other firms can't immediately jump in and compete away economic returns. Otherwise, there wouldn't be much incentive to invest in developing new drugs. Ultimately, though, it's also important for other manufacturers to enter the market so that there will be price competition. So government needs to find a balance between encouraging innovation and promoting entry of "me too" and generic drugs.

Key tools that the government uses include financing and the award of temporary monopolies. The

government finances basic research that provides the underlying knowledge base for developing drug therapies. The government also uses tax credits and grants to encourage private entities to conduct R&D. Most relevant to the Commission, the government is a major payer for biopharma products through federal programs like Medicare and Medicaid.

Probably the most important government tool is its power to award temporary monopolies. Developers first apply for patents when they've found a new compound, but well before they've gathered all the data they need to get approval to sell it. Later in the development process, the FDA grants marketing approval to sell the drug after reviewing clinical studies about its safety and effectiveness. So, typically, FDA approval happens well into a drug's patent life, and the remaining length of patent protection depends on how quickly the developer can gather evidence about safety and effectiveness. Additionally, the law around FDA approval provides for a period of exclusivity that holds off competition from generics and biosimilars. The federal government also tightly controls the resale of drugs among domestic

purchasers and prohibits most personal importation of drugs from other countries.

This slide is a schematic of the development process for innovator drugs and biologics. Basic research helps us understand the mechanisms of disease and helps identify therapeutic targets such as genes and enzymes. As research moves into discovery and preclinical trials, developers may evaluate thousands of compounds, narrow those down, and screen them for efficacy and toxicity.

Before developers test a compound in humans, they have to file an Investigational New Drug application with the FDA. If approved, clinical trials on humans proceed in three phases that gradually involve larger numbers of volunteers to evaluate the drug's therapeutic effectiveness and side effects. Once the developer has filed a New Drug Application or Biologics License Application, the FDA reviews the evidence to make an approval decision.

Typically, there are issues to resolve such as which indications have enough evidence to be listed on a drug's label. Note, though, that even if a specific indication isn't on a drug's label, physicians can still prescribe it "off label." After the drug is on the market,

the developer and the FDA monitor use for additional information about safety, effectiveness, and risks.

You can see that this process is long, and relatively few compounds make it all the way to FDA approval. So this process can be very costly. When analysts estimate the average cost of developing a new drug or biologic, they typically include the R&D costs of both successes and failures. Estimates of the average cost also typically include the cost of capital -- what investors give up when they tie up their resources in development projects. There is a lot of variation in biopharma development costs, but one recent study by researchers at Tufts estimated that developing an innovator drug or biologic costs an average of $2.6 billion: $1.4 billion in research and development and $1.2 billion for the cost of capital, which has been a controversial point.

In spite of the risk and cost associated with developing medicines, many biopharma companies do not appear to have had difficulty obtaining access to capital.

This slide shows the process for innovator drugs and biologics, but there are different processes for generics and biosimilars. To get a generic approved,

companies usually refer to the innovator's clinical trials and then try to demonstrate that their product is equivalent. For approval of a biosimilar, the manufacturer has to demonstrate that it is highly similar to the reference product through analytic studies, animal studies, and clinical studies unless the FDA determines that some of that process isn't necessary in a specific circumstance. One estimate puts the cost of getting a generic approved at $1 to $5 million over three to five years. Good data are generally lacking for biosimilars, but one manufacturer estimates that they take eight to ten years to develop at an average cost of $100 to $200 million.

FDA's approval process triggers periods of exclusivity, giving an innovator manufacturer temporary monopoly power in setting prices. The first type is called data exclusivity, during which firms that would like to introduce a generic or biosimilar may not use the innovator's clinical test data as part of their application to the FDA. The length of this period depends on the type of product: five years for new small-molecule drugs, three years for new indications of a drug that's already been approved, and 12 years for biologics. If a follow-on

manufacturer was willing to conduct their own trials and pursue FDA approval, in some cases they might be able to challenge an innovator's patents and introduce a competing drug.

The second category is called market exclusivity, which refers to an explicit period of protection before the FDA may approve a similar product. For example, the Hatch-Waxman Act of 1984 provided incentives for manufacturers to introduce generics by granting the first generic producer to achieve FDA approval a 180-day market exclusivity period. That first generic producer might not be able to charge as high a price as the brand-name drug, but the market exclusivity keeps out other generic competitors for a six-month period.

Over the past several decades, we have seen that generic competition can dramatically lower prices for small-molecule drugs. However, we should not expect as dramatic an effect of biosimilars on the price of biologics.

When the FDA designates a generic as "A rated," it's considered therapeutically equivalent, and in most cases pharmacists can substitute the generic for the brand

without involving the prescriber. This ability to substitute generics for brand-name drugs has led to rapid downward pressure on prices. On the left is an estimate by the FDA of how the average relative price of a drug is affected as the number of generic manufacturers increases.

By comparison, producers of biosimilars face substantially higher costs to bring a product to market than producers of generic small-molecule drugs. The FDA approved the first biosimilar product this year, and more applications are under review.

How much of an effect might biosimilars have on the prices of biologic products? The Congressional Budget Office estimated that prices may be 20 percent to 40 percent lower than reference products, varying by product and over time. Several European countries have already been using biosimilars at prices 20 percent to 30 percent below those of innovators. So far, Medicare's payment rate for the first FDA-approved biosimilar, Novartis' Zarxio, is about 3 percent lower than the payment rate for Amgen's cancer drug Neupogen. However, the biosimilar has only been available since September, and CMS doesn't yet have average sales price data for it. Once CMS does have ASP

data, Medicare's payment rate is expected to go down.

There's a lot of variation in the number of new launches of innovator drugs and biologics from year to year, but generally in recent years it has been increasing. One noticeable trend is that the number of orphan drugs has been growing. Orphan drugs target an indication affecting 200,000 or fewer patients, and the government provides incentives to invest in developing orphan drugs through tax credits and market exclusivity.

New launches are not only affected by how much companies invest in R&D, but also by the pace of the regulatory review process. For example, the FDA has developed approaches that are intended to speed up its review of drugs for serious conditions that fill an unmet medical need or demonstrate improvement over existing therapies. Despite these newer approaches, some analysts continue to have concerns that the FDA process is too lengthy and expensive. Other analysts have concerns that too many new launches are incremental, improvements of existing drugs, instead of instead of first-in-class products, or that FDA's expedited approaches and the use of surrogate endpoints to evaluate effectiveness have led to a

review process that is too lenient.

Several new launches have implications for the Medicare program either because of the drugs' high launch prices or because a potentially large group of beneficiaries may be prescribed the drug. The most notable example includes hepatitis C therapies, which may lower the viral load and stem the progression of disease for infected patients but at prices that led to a double-digit spike in Part D spending in 2014.

Over the past several months, the FDA has approved the first of several PCSK9 inhibitors for familial high cholesterol as well as a new treatment for heart failure. In each of these cases, the new launches have been viewed as promising therapies for serious conditions but at high prices. The extent to which physicians prescribe these new treatments and whether plans and PBMs control dispensing will have strong implications for Medicare.

A number of other therapies in the development pipeline may also have important effects on the Medicare program, including next-generation immunotherapies for cancer and new compounds that aim to stall the progression

of Alzheimer's disease.

High launch prices for new drugs and biologics pose enormous challenges for Medicare and other payers. On the one hand, to the extent that a new therapy represents a real breakthrough in treatment, access to the treatment may extend a beneficiary's life or improve quality of life. On the other hand, because there are few published results of head-to-head trials of therapies, it can be hard to know the merits, risks, and relative value of a new therapy.

Let's look at a couple of recent analyses that put this in perspective. This chart shows trends in the pricing of 58 anticancer drugs approved by the FDA between 1995 and 2013. Each point shows a different drug, and you can tell when it was launched by looking along the horizontal axis. Higher amounts on the vertical axis mean that the drug had a higher price relative to its survival benefits. The study found that newer drugs were not necessarily associated with greater survival benefits when compared with older drugs. The regression line shown above suggests that after adjusting for survival benefits and general inflation, launch prices for oncology drugs have increased by $8,500 per year. In other words, there has

been an upward trend in launch prices of cancer drugs independent of additional treatment benefits.

Today we're at a point in time when specialty drugs make up a large share of what's in the development pipeline. There's no one definition of a specialty drug, but generally they are expensive. Medicare Part D uses a threshold of $600 or more per month. Not all specialty drugs are biologics, but biologics are often specialty drugs.

This chart is from a study that asked the question: What happens to insurance premiums as beneficiaries begin to use the types of medicines that have prices similar to those emerging from the development pipeline? The authors assumed a simple insurance benefit design where the enrollee pays out of pocket until they reach a $3,500 cap. Next they estimated what would happen if a new drug became available at a price of $100,000 per treated patient. The chart shows that even if this drug is used to treat a relatively narrow percent of the covered population, it can have substantial effects on premiums.

MS. SUZUKI: There are many factors that may affect drug prices. For example, on the demand side, a

shift from out-of-pocket to an insurance can decrease price sensitivity and increase demand, and a shift from private to public insurance could affect prices.

A consolidation in the insurance industry may provide insurers with more leverage when negotiating rebates and discounts with manufacturers. Discounts and rebates mandated by law for certain federal programs could affect both launch prices and how quickly manufacturers raise prices on existing products.

The aging of the population can affect demand and drug prices as more and more people receive their drug coverage from Medicare.

On the supply side, a shift towards more complex biopharmaceutical products, such as specialty drugs and biologics, would tend to put upward pressure on prices. Policies that encourage development of treatments for smaller disease populations can shift the pipeline towards more expensive therapies.

The cost of borrowing and patents and temporary monopolies granted by the government can also affect prices.

Consolidations or specialization within the

biopharmaceutical manufacturers can reduce competition for specific therapies and increase the ability of manufacturers to raise prices or launch new drugs at a higher price.

Finally, changes in the drug supply chain can affect incentives faced by individual actors as well as the relative power in specific markets.

The next few slides will provide an overview of drug supply chain, focusing on the retail slide. I will briefly summarize the roles of each sector and then show, using a very simplified example, how drugs and payments flow through the retail supply chain.

Traditionally, biopharmaceutical manufacturers have fallen in one of three categories: Those who specialize in brand name patented products; in generic off-patent products; and in biologic products. In addition, manufacturers of brand name drugs also market their products through direct-to-consumer advertising and detailing or direct marketing by sales representatives to health care providers.

Manufacturers set list prices that are typically used as a starting point for price negotiations among the

different actors in the supply chain. Where to set a list price depends on the availability of close substitutes, expectations about the size of rebates and discounts to purchasers, and prices of other products in the same therapeutic class.

Manufacturers may negotiate rebates and discounts with Pharmacy Benefit Managers, or PBMs, working on behalf of health plans or employers. Manufacturers make other types of payments to PBMs. For example, they commonly pay a fee to PBMs for a favorable placement on their formularies. What a manufacturer receives for the sales of its product -- of drug products -- reflects prices, discounts, and rebates that are negotiated by various actors in the supply chain.

It is often more efficient for pharmacies to get their stock through wholesalers. Wholesalers provide a link between pharmaceutical manufacturers and over 60,000 pharmacies and outpatient dispensing outlets throughout the U.S. Manufacturers can ship bulk quantities of products to the relatively small number of wholesale warehouses instead of shipping to thousands of individual outlets. Wholesalers store the drug products and then sell and

deliver the products in much smaller quantities to their customers. Wholesalers help smaller pharmacies by pooling their purchasing power to negotiate with generic manufacturers.

The wholesale sector is highly concentrated. In 2013, three companies generated about 85 to 90 percent of all revenues from drug distribution in the U.S.

Revenues for the wholesalers typically come from the spread between what they pay to purchase drugs from manufacturers and what they receive in payments for the sales of those drugs to the retail and non-retail customers. They can also earn discounts, such as prompt pay discounts and fees on services they provide to their customers.

Retail pharmacies can be chain stores or independent pharmacies, food and big box stores, and mail order pharmacies. They serve about three-quarters of the consumer market for prescription drugs. The remainder is served by non-retail providers, including hospitals, some HMOs, clinics, nursing homes, and federal facilities.

Pharmacies stock a wide range of single-source drugs so that they are prepared to immediately fill most

prescriptions on demand. Because of this need, they do not have much leverage to negotiate rebates or discounts with manufacturers of single-source brand name drugs. For multiple-source drugs, they can choose which manufacturers' drugs to stock and dispense, which provides them with leverage to negotiate rebates and discounts.

The pharmacy sector is fairly concentrated among large chains. In 2013, the top five dispensing pharmacies accounted for about 65 percent of U.S. prescription dispensing revenues. Still, independent pharmacies have held on to their market shares.

Pharmacies make money on the spread between what they pay to purchase drugs and what they receive for the sales. They typically earn higher profits off of the spread they get for generic drugs.

Pharmacy Benefit Managers administer drug benefits on behalf of health plans and employers. They build pharmacy networks and play a key role in negotiating payment rates with pharmacies and negotiating rebates and discounts with manufacturers.

The formulary is one of the main cost containing control mechanisms to manage drug use and spending of their

customers. The amount of cost sharing, which drugs are covered, how much members must pay for each tier, and whether prior authorization is needed for a particular drug are all determined in discussions between the PBM and the health plan or the employer.

The formulary is also used to negotiate rebates and discounts with manufacturers. PBMs have the greatest leverage for brand name drugs with close substitutes, because manufacturers typically pay rebates in exchange for a favorable placement on a formulary or based on the market share that the manufacturer's drug receives. Manufacturers are unlikely to provide rebates or discounts on products with no competition unless the PBM can make a credible threat to exclude their products from coverage.

The market for PBM is concentrated, with about three-quarters of the prescription dispensing revenues accounted for by four PBMs.

There is a real complexity in how PBMs operate and where they get their revenues. We think their revenues come primarily from manufacturer rebates and fees they receive for managing the drug benefit. In some cases, they may take on an insurance risk and make money on the spread

between what they pay to the pharmacy and what they receive from the payers.

As prescription drugs move from manufacturers to wholesalers to retail pharmacies and to consumers, a complex set of market transactions take place along the supply chain. The type of transactions and prices paid at various stages depends on whether it is a brand name drug with patent protection, a brand name drug that is off-patent, or a generic drug.

Here, I will show an example of how the payments flow for a brand name drug with patent protection. Although the various transactions do not necessarily take place sequentially, I will go through this hypothetical example, starting with the pharmacy counter.

In the simplified example, a PBM manages a drug benefit on behalf of an insurer. The beneficiary pays a monthly premium to be enrolled in the plan. The PBM and pharmacy negotiated a price of $88 for filling the prescription. I will come back to the other negotiation by PBM in a minute.

The copay amount for this drug is $30, so the beneficiary pays $30 at the pharmacy counter. The

remaining $58 is paid by the PBM.

The pharmacy had paid $83 to the wholesaler to stock this drug, so it makes $5 on the sale of this drug, which is the spread between what it received from the PBM and the beneficiary and what it paid to the wholesaler.

The wholesaler had purchased this drug from the manufacturer for $80, so it makes $3 on this drug, which is the spread between what it received from the pharmacy and what it paid to the manufacturer.

The manufacturer sold the drug to the wholesaler for $80, but since it had negotiated a rebate of $6 with the PBM, the net revenue for the sale of this drug is $80 minus $6, or $74. Notice that the net cost to the PBM for this transaction is $58, offset by the $6 rebate it negotiated with the manufacturer, or $52.

We would be happy to answer any questions or provide clarification on the material presented to you today. For your discussion, you may want to provide comments on the material or their implications for Medicare that would be relevant for policy discussions that we will be having during this cycle.

DR. CROSSON: Thank you, Rachel and Shinobu. As

usual, wonderful, thoughtful, clear presentation.

So, we are going to do our normal thing. We are going to have clarifying questions, and then after that, I will ask if there are any Commissioners who would like to jump out in front and start the discussion. I apologize. I might have done that earlier, didn't. And then we will have our discussion.

So, I think the centerpiece here is in view of what we have had presented, as well as your understanding of the work that we already have on the table, what are the implications for either the existing work we have on the table that we did last year that we began in September, or other ideas that you have that we should consider that have an impact on Medicare beneficiaries or the Medicare program and the Treasury going forward, so that as we develop our full program over this year and probably well into next term, we have an understanding of where this Commission would like to go.

Clarifying questions. We will start here with Rita.

DR. REDBERG: Thanks, Rachel and Shinobu, for an excellent chapter. It certainly is complex.

My clarifying question is just on what was page seven of the mailing materials, but if you would just remind us of the definition for orphan drugs, and also if you could tell us if there is any tracking for how many prescriptions are written. Do we know how much of that is actually on-label or off-label?

DR. SCHMIDT: I think there is more complexity than I'm able to give to the definition of orphan drugs, but I think you can generally think of it as designed for an indication that serves a patient population of 200,000 or fewer people.

In terms of tracking the degree to which prescriptions are on-label or off-label, I'm not aware that we do such a thing.

DR. REDBERG: I'm just wondering, do we know, for example, how commonly more than 200,000 prescriptions would be written.

DR. SCHMIDT: I don't know off the top of my head. I know that there were some -- we were talking this morning, there are a couple of drugs that started out as orphan indications and now, I think, are used more widely than was originally -- the original indications suggested.

DR. CROSSON: Herb.

MR. KUHN: So, also on Slide 7, I was curious about the issue of biosimilars. So, you mentioned that the European experience is 20 to 30 percent lower for innovators, but Medicare's first initial is about three percent. I'm assuming that, under Medicare, the referenced biologic as well as the biosimilar have separate codes, billing codes, is that correct?

DR. SCHMIDT: Well, there's just been guidance out on this --

MR. KUHN: In the Physician Fee Schedule, they're suggesting that they collapse, is that correct?

DR. SCHMIDT: Do you want to --

DR. MILLER: Not quite. Let me just parse through it. Right now, the innovator drug has a separate code from the biosimilars, and then what CMS was proposing is that the biosimilars be put in a common code. But my understanding is that the innovator continues to --

MR. KUHN: So the referenced biologic, the innovator, would still have its own code, but the biosimilars are all lumped into --

DR. MILLER: That's what I am saying, and I

believe that's correct. I could take a nod out of somebody, and I just got it.

And, so, the second thing I would -- but, the other thing you should know is what they proposed is that the add-on, which, you know, the ASP-plus, which we've discussed many times here, will be linked to the price of the innovator, so that they're trying to neutralize the incentive to the physician about which of those they use.

MR. KUHN: Got you.

DR. MILLER: That's the thought process.

MR. KUHN: And, I'm assuming, then, what they're thinking is that creates more price competition to maybe mirror what they're seeing in the European experience of greater savings opportunity?

DR. SCHMIDT: Yes, I think that's the intent.

DR. MILLER: Certainly, the motivation is that they believe the evidence and the argument that they're making is that it creates greater head-to-head competition.

DR. CROSSON: Mary.

DR. NAYLOR: So, Slide 8. On the recent approvals affecting Medicare, you mentioned -- well, first of all, these are drugs that affect a large proportion of

Medicare beneficiaries, more than -- many more than others -- heart failure, Hepatitis C, insulin -- and then those in the pipeline related to Alzheimer's. So, they are higher price, or most of them are in the biosimilar category.

Is anyone building scenarios about the implications as we invest, as we have these approvals, the kind of cumulative effect that this has on the Medicare program in the short term? I mean, I know we have a lot to learn about what Medicare's pricing ultimately will be for, but I'm just wondering, is the FDA or some group taking a look at the cumulative impact of recent approvals and those in the pipeline?

DR. SCHMIDT: You know, I don't know that the FDA is necessarily looking at this. In the National Health Expenditure accounts, they make a projection out that's actually relatively flat growth, once we get past the bump over Hepatitis C spending. So, I think -- and I don't think that they do their projections looking therapeutic class by therapeutic class. They tend to do econometric modeling and projections in that sort of approach.

But in the coming few years, I think they did take into consideration some therapeutic classes, such as

the PCS canine inhibitors that are just coming out. And, I believe OACT told us that one thought was that there will be some degree of competition because there are two products now, others in the pipeline still. So, they thought that that competition might control growth in some of those particular prices.

But, cumulatively across all of these categories, no, I'm not aware of a broader effort. There are individual Pharmacy Benefit Management companies that have looked at particular classes of drugs just coming out, and you can see some pretty shocking cost estimates for what the magnitude might be. And there's just so many things that we don't know yet. It's hard to have much confidence in a lot of the estimates out there.

DR. MILLER: One clarification. Kim likes to have her details straight.

[Laughter.]

DR. MILLER: She reminded me that it was not proposed that the add-on be the same as the innovator, be comparable between the innovator drug. That's a matter of law.

DR. CROSSON: Kate.

DR. BAICKER: So, I thought Slide 17 was a really helpful illustration and I had a question. I like the zooming in and out -- excellent.

[Laughter.]

DR. BAICKER: That's right. Follow the bouncing price.

[Laughter.]

DR. BAICKER: So, in thinking about the implications of this for the potential role of competition in bringing prices down, it would be helpful to know which of these numbers is known to whom, you know, which, both individually and in the aggregate. Who knows? Is it just the parties to each transaction, or which of these numbers are known to competitors who might be negotiating similar transactions?

MS. SUZUKI: So, in the Part D setting, the payments from the PBM to the pharmacy are known. Those are the PD claims information. The rebates are not known. Rebates are proprietary. CMS collects the information, but it's not released.

DR. BAICKER: [Off microphone.] So CMS knows --

MS. SUZUKI: Right. The prices that are listed

for the pharmacy and wholesaler transactions and between wholesaler and manufacturers, those are usually not known. Those, we took, actually, from an estimate in CBO report.

DR. CROSSON: Okay. Clarifying questions. All right, Kathy.

MS. BUTO: So, I have three, I think, somewhat quick questions. One is the 18 percent Medicare spend that includes all settings, do we know if that number has grown? What's the growth rate like over the last few years? I know we've recently tried to figure out how to calculate that. Do we know if that's growing more rapidly now?

And then, secondly, is it driven more by price, by volume, by the growth rate? It would be helpful to know that piece of information.

My second question is on Slide 6, which is where you talk about the patent life and data exclusivity. Do you have a sense of whether patent life at the end of the FDA process is longer than data exclusivity, or do they coincide, that kind of issue.

And then the last is Slide 11, just a word about how more personalized medicine, including medicine that's developed in relation to an individual's genes or genetic

profile, what's -- I mean, do we have any experience looking at the pricing of those kinds of medicines?

DR. SCHMIDT: On the first one, the 91 percent. So that was an estimate for 2013, and actually, in response to Warner from last time, I said at the start of this presentation, it was also 19 percent in 2007. And so it was growing at about -- I think the increase, there is a slight, very slight increase, but it is growing at about roughly the same rate as overall cost in other types of Medicare spending.

MS. BUTO: Is that price driven, or did you have any sense of that?

DR. SCHMIDT: I don't have a sense yet. We're still kind of looking at that. We took that as kind of a question from the last time, and we'll try and come back to you with a better answer next time.

On the patent slide question, generally the patent tends to go first when you come up with the inventive idea of what a compound might be. A company or whoever is the innovator will tend to patent that immediately to protect it. And as we were working through that development process, it takes a while to gather the

information to prove safety and efficacy.

So for that reason, the effective patent life tends to be much shorter. I've seen estimates of 12 to 13 years, rather than the 20-year length of the actual patent. That's an average, and each drug can be quite different from one another. So it's hard to draw generalizations.

On personalized medicine, I don't know that -- are you going to try and -- nope. I don't know that we have much experience to say a whole lot about that yet, other than I guess the notion is that using more tests, including information about one's DNA. That you can figure out how to target specific therapies better, that's the notion. Whether that actually works in practice has yet to be seen. I don't know that I have a good answer for you at this point.

DR. CROSSON: Yeah. It's a complicated issue we haven't looked at because it not only impacts, potentially, the cost of treatments, whatever those are, including pharmaceuticals -- and that could be up or down -- but it also involves the cost of doing the tests themselves and what proportion of the population needs to have those tests done. And many of those tests are quite expensive in their

own right.

Clarifying questions? Alice.

DR. COOMBS: On 9, I think it was the circulated material. It actually talks about the new substances launched by year, and there's been a lot of discussion about antibiotics in terms of new antibiotics on the market, especially with these highly resistant organisms and in the hospital. I was wondering if the nonretail -- what does the nonretail industry look like compared to the retail industry in terms of growth?

And also, if you were to do a pie chart between the two for comparison and contrast, that might be interesting because I know a lot of the discussion has been around drugs that will make a difference in patient outcomes within the hospital setting. So, I mean, there's these new antibiotics that have been produced in the last 10 years specifically to address some of the resistant bugs, and I am interested in knowing if innovation is very -- what does innovation look like in terms of the hospital, the nonretail industry. So do you have any information on that kind of comparison?

DR. SCHMIDT: The introduction of new

antibiotics, you mean by --

DR. COOMBS: No, not just new antibiotics, but what the -- what does the innovation drugs compare with the retail versus the nonretail.

DR. SCHMIDT: Do you mean which drugs are being used more as intermediate inputs compared to what's more used as final product?

DR. COOMBS: Right.

DR. SCHMIDT: I don't have a good answer to that.

A lot of the -- I guess it would be things that are used in surgeries, for example --

DR. COOMBS: Right, right.

DR. SCHMIDT: -- anesthetics and that sort of thing. We don't -- I guess it's conceivable that we could look to claims information to try and understand what those are. I don't have that information at my fingertips, though.

DR. COOMBS: And then the other question I had, like a lot of the administered drugs in the clinical setting, someone comes in to get a drug administered just for observation to see if they have a reaction, and then there's associated cost with monitoring that has to occur.

For instance, someone has something like methotrexate, and they have to have a series of tests to check their liver function and things like that. Have we looked at the costs associated with drugs that are not necessarily the cost of the drugs themselves? So we're looking at drug pricing, but I'm wondering if the associated cost of some of these medication -- the innovation drugs, the associated cost may be also a cost driver. That 19 percent only includes --

DR. SCHMIDT: That's right. It includes the pharmacy costs --

DR. COOMBS: Right.

DR. SCHMIDT: -- as well as the cost of the drug themselves, but not any other services associated with that. So I do not have a number for you, but yes, that's a valid point.

MS. UCCELLO: So a quick question regarding the payments for manufacturers to PBMs. Are the terms "rebate" and "fee" interchangeable, or does "fee" really mean something else? "Fee," for some reason, just seems a little worse to me. In terms of just this formulary administration, why are they paying that?

MS. SUZUKI: So my understanding is that

sometimes there is a service fee because PBMs administer formularies, and they may offer rebates or discounts, and I'm not sure how to clearly distinguish between the different names that are attached to them. Rebates and discounts may look like a fee if it's attached to the volume of prescriptions that are dispensed. So I think there's a little bit of gray area, and maybe it's just that we don't have a clear understanding.

DR. MILLER: I remember when we were talking about this internally, and it's to the first point and maybe just one more sentence on it. There is a role that they play with smaller pharmacies where they administer their -- can you rerun that, that point?

MS. SUZUKI: So this is the wholesaler point?

DR. MILLER: I remember we had a conversation on it, and I was trying to recover what we got out of it, but let's just move on. We'll talk and see if we can get this straight.

DR. NERENZ: Yeah. A quick question on slide 5, please. I am interested in these drops along the way, particularly from 250 to 5, and I'm just curious. In the

middle of the slide where it has 5 compounds, is that literally the number at Phase 2, or for example, is it that it's 5 that survive to the far end of this series of 250 that start? Or on the other hand, are there only 5 compounds that even enter the clinical trial sequence out of 250 that were there, just to the left? Where exactly is that drop from 250 to 5?

DR. SCHIMDT: And let me say these are suggestive number that I took from a combination of sources, including the GAO study on this, but it's to notionally give you an idea that there are literally thousands of potential compounds that are being evaluated during the preclinical phase.

And then let's see. So I think probably it gets to about five compounds that start into human trials that pass the IND approval. So the percent of those that go from Phase 1 to Phase 2, they make it -- about 70 percent of those compounds make it.

And then it quickly drops off here. So going from Phase 2 to Phase 3, contingent on getting to Phase 2, about 33 percent of those make it on to Phase 3.

DR. NERENZ: Okay. That's very helpful. So the

main drop from 250 to 5 is even at the point of beginning --

DR. SCHMIDT: Right.

DR. NERENZ: -- a Phase 1 trial. It's not during the clinical trial sequence.

Dr. SCHMIDT: Correct.

DR. NERENZ: Thank you.

DR. CROSSON: Jack.

DR. HOADLEY: I have a couple of questions that may not be things that you necessarily need to answer right now, but when one was -- Kathy picked up in terms of the patent terms, and it seems like it might be useful to have a schematic that sort of relates the length of the patent, the exclusivity periods, and I know you talked about how many years. I don't know if there's any data that would show sort of a distribution of how many drugs got how many years of actual monopoly, exclusivity on the market, but it seems like that would be useful to sort of add to the context. And maybe some of those data are not available. You have clarified some of it in response to Kathy's question.

On slide 4 -- and this may not be available, but

we talk about the federal government role in research. Is there any reliable data on what share of the R&D ends up coming from federal sources versus industry sources and so forth? It's obviously not an easy question because a lot of those things get very commingled, but if there's any studies that have tried to answer that, that would be probably useful to see.

On slide 7, the graphic you put here I think is really helpful in terms of showing as you get more manufacturers, the price comes down. It seems like there's another graphic that I think I've seen that also would be useful, which is the period of time involved. I believe I remember seeing from INS the notion that the time period -- and it may be in conjunction with the number of manufacturers, but the time period, once the generic competition is allowed and once the 180 days has become more compressed in recent years than it had been in the past. And so I don't know if that's still true or if there's been some variation over time, but the sense of how quickly we get to these, you know, 23 percent or 6 percent kind of price points, it seems like it would be helpful.

On slide 9, this looks at the particular example

from oncology drugs. The other thing that strikes me is this study that was out I think earlier this year on the MS drugs where it showed that price increases for older drugs rose at a similar rate to the new entrants, and so it seems like that's a useful piece. I don't know if that's unique to MS. I don't know if we have any way to know that because there is one study done that addressed the MS side, but this is sort of going to whether prices relate to life year gained and sort of a time thing. But another interesting question is what's happening with old drug prices in conjunction with new.

And then on slide 10, was that particular study in a Medicare context, or was that in a broader --

DR. SCHMIDT: This was a broader context.

DR. HOADLEY: A broader context. So it does seem like the Medicare picture could end up looking different between the reinsurance.

DR. SCHMIDT: Absolutely, it would.

DR. HOADLEY: And so we thought about it as total costs, government plus everybody else, that might work.

And then my last comment relates on slide 15. It's sort of a little better sense of the role of mail

order. I know in Medicare, it's still pretty small. I don't have a sense of how much of the pharmacy -- total pharmacy sales are on mail versus retail, and it might be an interesting context, and how much that differs from what Medicare is seeing is something we might want to think about down the road.

DR. CROSSON: Warner.

MR. THOMAS: So on your slide 17, first of all, I think it's a great analysis, and I think it's very helpful to understand the flow of dollars. Do you have any idea of the -- and I guess the question on the relative dollars that you're using, are those the estimated margins that each of those components of the chain, chain of payments?

MS. SUZUKI: So this is a hypothetical example, but I took the example from a CBO report that did use some actual data to estimate the average for a single-source drug. So it's not completely a made-up number, but it is a hypothetical example.

[Laughter.]

MR. THOMAS: I'll think about that for a minute. I thought that was "yes" or "no."

DR. MILLER: That was masterful.

DR. CROSSON: Shinobu, have you thought about running for political office?

[Laughter.]

MR. THOMAS: I'm going to take that as a "no."

DR. CHRISTIANSON: The question was about margins, though, too. These aren't margins, right?

MR. THOMAS: Well, okay. So I guess I was -- I mean, if you look at it, I guess I was taking the net revenue as kind of the net that they were taking. You're right. It would not necessarily be the margin.

So I guess the follow-up question would be do we have any idea of what the margins are in each of those components of this supply chain process, from the PBM to the manufacturer, because one of the things we do in all of our update factors on the provider side is we're constantly looking at margins and margins of efficient providers, and I wonder if we do that in the drug area.

DR. MILLER: So you've asked this question also in other meetings, and we have some -- I don't know that we have the same or we're going to have the same kind of data that we bring to the update discussions, but we've been trying to acquire some other data and work on this question

that you've actually raised a couple of times.

So it's not as masterful as Shinobu, but not yet. But we are looking at this.

MR. THOMAS: I just didn't know, being publicly traded, if we even have any idea from the publicly traded data of what the margins are. It's just a general question.

The second question is on the concentration of pharmacy benefit managers and the wholesalers. I mean, you identify that for PBMs or 75 percent of the dispensing revenues and three of the wholesalers are 85 to 90 percent. I mean, do we have any idea how that compares to other components of the dollars distributed in health care, just how that concentration compares to other components in the Medicare system?

DR. SCHMIDT: Well, I guess I should say no, but --

MR. THOMAS: It just may be something we want to think about. I mean, it just seems like it's a relatively --

DR. SCHMIDT: It does seem like there's growing concentration across, for example, insurers.

MR. THOMAS: Right.

DR. SCHMIDT: And there's been a lot of merger and acquisition activity in many of these sectors, and as one side tends to merge and join forces, it seems like the others do as well --

MR. THOMAS: Right.

DR. SCHMIDT: -- whether that's to help in their negotiating leverage or what.

MR. THOMAS: And I know there's been some discussion of that in other parts of the industry lately, but it just seemed to me like this is pretty disproportionate to a lot of the other components of the industry, and just how does that impact the Medicare beneficiary, I think that would be the question. So those are just a couple of questions that I think could be interesting, especially as I think this is a very helpful understanding to understand how the dollar is going to pass through. I think if we understood more about what the total dollars are -- and this is one hypothetical on one drug -- do we understand what that total component of spending looks like for Medicare? For all of the Medicare dollars that roll through these areas, that may be helpful

or instructive in the future.

DR. CROSSON: One more clarifying question?

DR. HOADLEY: I was going to follow up on Warner's comment. The other thing to observe is that -- you can even see it on the examples on the slides here that there is overlap between the PBM industry and the pharmacy industry, and what you don't see here is there's also overlap between the PBM industry and the insurance. A number of the insurance companies have in-house PBM. So if we get to thinking about those things, that's just a --

DR. CROSSON: Okay. So we have about 45 minutes left, and what I'd like to do, again, is have a discussion here about what you as Commissioners see the implications being of this information as well as other information that we've had before with respect to our program going forward to deal with the question of whether the Medicare program is paying appropriately for pharmaceuticals, Part B or Part D, and whether or not the impact of pharmaceutical cost on beneficiaries is appropriate, and to entertain any ideas, either comment on work we're already doing or entertain additional ideas that we should be considering as our work progresses.

So are there any Commissioners who would like to jump out and lead the discussion? I see, one, Bill Hall and Jack, and then we'll proceed in order. Jack, we're getting towards the edge of this, but Bill, Jack, and Rita, and then we'll proceed longitudinally.

DR. HALL: This has been a very good report, and I've learned a lot from this and some of the implications.

I have two points that I would like to make, and I guess they both have to do with the components of pricing, following up on Warner's comments and maybe also Kate's about what do we know about the unknown.

From a clinical standpoint, the decision to use biologics and the complexity of monitoring biologics is immense. It's a total change from any other kind of drug therapy that's ever been there, certainly through my career.

Some of the hidden costs that affect the Medicare program -- and I'll say why it affects the Medicare program in a minute -- are that the monitoring is really extensive. And maybe we need to have a little deeper dive on what the kind of hidden costs are of using these drugs, particularly in terms of specialties, medical subspecialties that use

them, and laboratory tests, and just sort of human capital that has to go into managing patients with this. This is not like aspirin -- not that aspirin is a safe drug either.

One thing that I've noticed -- and going through these data brought this to the fore -- there has been a tremendous uptick in direct-to-consumer advertising for biologics, and my impression is or maybe my bias is that for the first time in direct-to-consumer advertising it really features a lot of older actors. So this brings it more into the Medicare sphere, and, in fact, the clinical use of these drugs. And if you pay just a little bit of attention to these ads, I would defy you to really understand what is being said in these sound bites. It's sort of like the used car market when they say the monitoring and all the things that are necessary.

So there are a lot of components to pricing that go into this, and I think we have to understand that biologics are very, very important. We should use them appropriately. But it is not just the usual components of cost. I think we might want to get a little deeper dive on that.

And the other -- I don't know if this is even

possible to do -- is looking at the consumer and out-of-pocket costs. I wonder if there's any way of getting any kind of a handle as to whether there is, in fact, an impact on the utilization of these drugs by Medicare recipients. We know the burden falls a great deal on Part D and on the Treasury, but I -- and one of the things I'd like to have us understand is are people actually being deprived, Medicare recipients, of these drugs because of out-of-pocket costs? I have not seen those data at all.

So those are just two points about trying to understand both the pricing and what the implications are in the future for managing these perhaps very important adjuncts to our medical therapy.

DR. CROSSON: So, Bill, I think all of the ideas that you have brought up are appropriate. I think certainly as we mentioned, the impact on beneficiaries and out-of-pocket costs is a big one there.

I think Alice brought up in addition the notion of, what do we want to call it, follow-on costs but additional costs with certain classes of drugs, and I think that's legitimate.

I think the issue of advertising per se, which I

know is being looked at, is something that we could look at. I think we need to understand, you know, whether or not that is something that we as a Commission can and should attempt to effect. But we'll take that under consideration.

DR. HALL: My point wasn't that we have to get into the nitty-gritty of this, but it's just an example of the complexity involved in the administration of these drugs and management of the patients. It's unprecedented in terms of the direct-to-consumer advertising. And the complexities are, if you really try to understand those ads, it's pretty difficult. For most doctors it's pretty difficult.

DR. CROSSON: Thank you.

DR. COOMBS: I just wanted to echo what Bill has said. When I asked the question about the monitoring, there are two entities that I can think of right off the bat. One is the new oral anticoagulants that don't require serial testing. In that situation, you might have some examples of where innovation has taken place which actually replace a lot of the resources necessary for monitoring, and that's one case.

On the other side, for rheumatoid arthritis there are three new biologics that have come out that are competing with methotrexate, and so what does the resource input look like in that entity? And I think, you know, we are talking about Medicare spending, but it's huge, especially with the anticoagulation in patients with atrial fibrillation and things like that because the Medicare population has such a large number of patients who are in atrial fibrillation, and you're looking at their risk stratification as to who might need it. Not everyone needs it, we know that. But I think those are the other unanticipated costs that Medicare spending on drug costs, pricing, entail. Thanks.

DR. CROSSON: On Bill's points?

MR. ARMSTRONG: So just briefly to build on Bill's point, and in particular -- and we may come back to this later, but the view of the beneficiary that you kind of brought into this, I think part of our work going forward would really benefit by thinking about -- it's sort of analogous to the supply side/demand side around pricing. I mean, our issue is costs, right? And if you put yourself in exam room or in the shoes of a beneficiary and think

about what are all of those variables that influence the likelihood that they should or will want to or ultimately will get prescribed a drug, because there's a lot of them. It's advertising. It's out-of-pocket costs or other benefits. It's clinical advice. It's shared decisionmaking. It's a handful of other things. And then, of course, it's also the supply side that will influence that as well.

But so far our analysis hasn't really given us a chance to sit in the shoes of the beneficiary and look at all the variables, many of which we could influence through payment policy, that ultimately have an impact on the cost to the beneficiary.

So, anyway, I just want to slip that in there as, I think going forward, a point of view we ought to bring into this whole conversation.

DR. CROSSON: Others on Bill's points?

DR. NAYLOR: I support what Bill has said in terms of trying to get a handle on the costs and Alice on the monitoring cost. I think that this is a new dimension as we're thinking about impact on the program.

I'm also thinking that in the classes of drugs

that have recent -- biologics that have recently been approved, and I don't know how we can do this, but whether or not we can begin to drill down on what is the evidence from the testing of those drugs that apply to the Medicare population. And so, you know, how many of those enrolled in the clinical trials were 75 and older, 80 and older, et cetera, particularly as it relates to thinking about one of the options that we've talked about, which is coverage with evidence. And so how much of the evidence exists, if we could have one or two cases to help us to know whether or not these drugs should be used for this population.

I totally agree on the impact on beneficiaries and the notion of taking one or two of those newly approved classifications of drugs to think about a simulation model - I don't know if we could do it -- that would say what will be the impact over the next ten years, even if it's just to one class, but what impact will it have on the beneficiary? [off microphone] On the costs.

DR. CROSSON: Okay. Further elaboration on Bill's points?

DR. HOADLEY: I do like the points that have just been discussed, and it does occur to me that on the

discussion I heard the other day on the PCSK9 drugs that, you know, where they're initially being approved with an indication of familial cholesterol problems, there's a question of figuring out who those patients are and what testing is needed to identify that they're that. And so, you know, this is coming up in a very immediate context.

I thought this was a great discussion of some very complicated issues and trying to put it in context, and, you know, I think part of what we're learning is that the issue of the next several years is a lot about the pipeline of these new drugs, very expensive new drugs, a lot of biologicals, a lot of other products that are, you know, both for smaller-scale diseases, some of the cancers, but also now with new cholesterol drugs and some of the other categories you highlighted that are going to really mean that we're dealing with high-cost drugs, which just makes it a somewhat different flavor to some of the issues. It's not that the issues of chronic multiple-drug use aren't equally important, but I think what we're seeing here is some of these additional issues. And I think it gives us some context to go back to the things that we discussed so well last year in those very good chapters on

the Part B drugs and the issues of least costly alternatives and 106 percent of average sale price and the oncology bundling and the 340B. And I think, you know, there's a lot of interest here, I think, around the table in trying to get to a point where we can reach some conclusions on some recommendations around that, and I think what this does is help to give us some context for that.

One of the particular items that I'm struck by is some of the coding issues around the biosimilars. I mean, that's clearly one of the things that could have a potential to help fix some things, and I know we commented on that on the physician proposed rule. But part of our comment there was whether there's an ability to go even further with common coding across the innovator drug and the biosimilars, and that could potentially put more price pressure on. I think, you know, that's some of the lessons of what we're hearing today in terms of things. And I think then down the road, you know, maybe not -- because we haven't discussed as much -- are some of the issues around, you know, what do the launch prices of these drugs look like? What transparency do we have in terms of how those

prices are set? Which raises some of the issues like the value-based pricing approaches. You know, that drug that a lot of manufacturers are now saying, well, we're pricing that drug given its great value to society, so maybe that's the point to say, okay, let's only give you that revenue if the value is truly going to be achieved. And so that's at least one of those value-based pricing approaches that you can kind of talk about. I think those are going to be harder to think through and not something we're going to do in the short term, but I think those are issues on the Part B drug side that we want to do on the Part D side.

Again, I think the fact that there are a lot of costly new drugs that fall under Part D raised issues, and we had our chapter last year on the risk structure, and I think, again, this helps to give us the context for that discussion of, you know, what adjustments should we make there. Again, as I've said before, I'd like to keep the sort of out-of-pocket cost side of that in the picture because the 5 percent that beneficiaries continue to pay, you know, when they are in the catastrophic range for these expensive drugs adds up to a lot of money. There are similar issues on Part B, but those are, you know, somewhat

mitigated by supplemental coverage. Part D it's all on the consumer to continue to pay that 5 percent of the cost. So as we think about the reinsurance and risk corridors, you know, we want to make sure to do that.

I also think, again, my sort of parallel to the Part B side is when we think about as new prices come on -- new drugs come on with these high prices, especially the ones that are true single-source in the category, is there -- what is the right role for the government to try to address those kinds of prices? So it's one thing when at least for hepatitis C or the PCSK9s for cholesterol, they at least look like they're multiple products, so there is some ability for the Part D plans to negotiate. If we get, you know, the next drug that comes on the market is truly only coming out of one manufacturer and it's the only drug to address Alzheimer's or whatever the next breakthrough is, then we're going to have something where the leverage is all on the manufacturer side, and we really should be anticipating how to make sure we can exercise some greater pricing leverage at that point.

So that's what I see as sort of our agenda on this.

DR. CROSSON: And a healthy-looking agenda that is.

[Laughter.]

DR. CROSSON: Jack, let me just ask you one question, because, you know, I have been thinking about this value-based pricing idea. I've seen a lot of things written about it, including some from the industry itself. Did I hear you say you think that applies only to Part B and not to Part D, or am I wrong?

DR. HOADLEY: I say it about Part B in terms of given the structure of Part D and that most of the pricing is handled by the plans, there may be questions there of whether plans could do such a thing, or there might be questions, if we're talking about this true, you know, no competitor kind of drug where that would be the kind of thing that if we introduced some kind of government role in negotiation, it could be along those lines. So I just see it's more directly a place for it on the B side.

DR. CROSSON: Directly. Yeah, got it. Okay. I agree with that.

Follow-on to Jack's points?

DR. COOMBS: So, Jack, I was just curious. What

kind of leverage would exist for a savior drug that comes out? What kind of strategies could be implemented?

DR. HOADLEY: You know, it's hard. I mean, there's been some interesting ideas having to do with some legal mechanisms that are out there. They haven't typically been used in the drug world. There are patent-type things. Some of it may more be bully pulpit. I mean, there were examples on the antibiotic side some years ago when we had all the concerns about the bioterrorism of whether the government could -- and there were some discussions, as I understand it, that happened, and then the manufacturer made some decisions. You know, some of it may go to sort of cost-effectiveness kinds of things. We've seen analyses saying, you know, what's the right sort of level. I mean, I know those are things that politically can be challenging, but, you know, should we be looking at drugs? What we don't have in a simple way is a lever, so what we'd really be trying to do is think about how would you create that leverage? I mean, it is not obvious, but, you know, what's happened in the private sector in the hepatitis C, after there were competitors, is a company like Express Scripts would come on and say, you know, if

you'll give us price concessions, we'll open up this drug with less hoops to go through. And so there are some of those kinds of things. We can say, you know, if the default is to allow this drug but only under limited circumstances, make it more available if there's a lower price. So those are the kinds of tradeoffs you have to start thinking about. But it's hard. We have to think hard about how to do that.

DR. COOMBS: I was just thinking about the diagram that we have in terms of each of those components and what kind of leverage could be implemented in each of the components within the diagram.

MS. BUTO: So one possible approach, Alice, would be -- it kind of gets back to this coverage with evidence development for a new blockbuster that you could combine something like -- this is just off the top of my head -- something like value-based pricing or risk sharing on the part of the government with the manufacturer that requires evidence that shows that it delivers what it promises. I mean, there are a number of things like that and other countries have tried it.

So I do think that the Commission longer term --

obviously, it requires some research -- needs to look at this issue of how the government can be a more proactive participant in that area.

The other thought that occurred in that same realm is, you know, Medicare doesn't proactively say X is a huge Medicare problem, we want to invite companies to work with us and NIH, or whatever. So are there some possibilities for a collaboration amongst the key government players with the industry to identify and potentially share in the risk, but also share in the profits from some new drug where -- and there was a program like this at NIH -- I don't know if it still exists -- where NIH and the companies did share -- there was some royalty arrangement. But I do not think it is widespread. So I think we could longer term, as we look at this issue over a couple of years, could look at things like that.

I just wanted to raise the question and I think it's related to Jack's earlier point that, you know, it's helpful to us in looking at the whole array of things that are available in Medicare to really make an effort through our research to identify what are the key problems we see. Is it these first launch blockbuster drugs and the pricing

of those? I think we all agree there is a problem with the reimbursement mechanism for Part B, and we've begun to address that this year. Is it a category of drugs that we think maybe some special solutions need to be addressed? We started looking at oncology last year. That's the kind of thing I know we'll be talking about. Or do we think that, you know, there is just a lack of -- once a drug gets approved in Medicare, it's just sort of "Katy, bar the door," anything can happen and costs just go up?

So I think it's important for us to do that, and I would really like to see a little bit of research on -- and I know there's research out there -- what the failures have been in Medicare, because they've looked at competitive bidding for Part B drugs, and it didn't work for a variety of reasons. I do not fully understand those, but it would be helpful for us as a Commission to understand why that didn't work. Coverage with evidence development, they've tried a couple of times, I think with a prostate cancer drug. I do not know if we think it's successful. What happened with LCA -- and we've gone over that ground a little bit, but, you know, what are the issues there that need to be addressed.

So I think at least understanding some of those issues and maybe even some of the risk sharing that's gone on with drugs in other countries to get more accountability and shared responsibility, is there something we can learn from that? So, again, I think most of these are longer-term not this-year issues, but if we can get a better definition on what we want to solve and then really apply ourselves to what are the mechanisms available.

DR. CROSSON: Kathy, I think it entirely makes sense to look at things that have been tried and not worked, because, you know, as they say -- I forget the -- but, you don't want to make the same mistake twice, because then you are truly a fool.

You know, one wrinkle on the coverage with evidence development that I've heard, and I'm not sure if this is a good idea or not, but taking a look at the difference between effectiveness and efficacy. In other words, the drugs generally are licensed based on their use in a relatively small population of patients. It provides evidence about how effective the drug is, and sometimes, once the drug is launched and is actually used broadly, it may have the same effect, it may have a better effect or a

lesser effect, and that's just one wrinkle on the same sort of idea. So, I think as we look at that, we should think about permutations of things that have been tried before, as well.

Okay. So, Kate.

DR. BAICKER: Just synthesizing what Jack and Kathy have brought together, it seems like the policy levers at our disposal going forward are thinking about how we're paying, you know, in Part B, how Part D is structured, what's covered, what's not covered, and all of those decisions can be made through the lens of are we promoting the right incentives to get the right drugs to the right patient at the lowest price possible, and that's about competition among all of these entities, it's about evidence on appropriateness of use, and that is going to play out -- it's going to manifest differently in Part B and Part D because the different ways that we purchase. But the principle that we want people competing to deliver the right drug at the lowest price available to our covered population is the lens through which I would interpret all of those nitty-gritty decisions that we're going to have to work through.

DR. CROSSON: Yes, and in fact, I think, as I heard what Kathy said, I heard it almost the same way. Are there sub -- put it in the marketplace term. Are there sub-markets that we're talking about? You know, we're talking about, for example, the market when there's a single-source drug and how that changes and how it's paid for. We're talking about the market when there are multiple competitor drugs. We're talking about, more recently, a kind of degraded market where a drug that's been in existence for a long period of time now only has one manufacturer, and then that company is acquired and then there is a new price situation with respect to that drug. And then we're also talking, at least qualitatively, about the essence of a new market related to biosimilars. Maybe it's not qualitatively different, but it is quantitatively different, for example, because of the amount of money it takes in order to develop these drugs.

And, so, I think that sense of understanding the problem, as you put it, understanding the nature of the market as it exists for that category of drugs is a very helpful thing -- thought -- on this.

DR. SAMITT: You know, what's remarkable to me as

we look at Slide 17 -- this is very helpful -- is there's another lever on here, and I mentioned this at the last meeting, that we're not even discussing, which is the prescribing practitioner. And, we struggle with how do we have leverage, how do we have influence at every level here. But, I think the reality is, is that if we can also intensify our focus on the accountable practitioner that is going to make the appropriate trade-off decisions about whether a new drug is really efficacious and whether it actually has a positive effect on a beneficiary's health over other costly alternatives like surgeries or hospitalizations, that if we can intensify the accountability at the practitioner level, that will be, in many respects, in my experience, the greatest leverage of all.

The organizations that I come from, as we look at Slide 17, we would develop our own sub-formulary that was narrower even than the PBM's formulary, because we had determined that several of the things even in the formulary were not as effective as either prior alternatives or other treatment sources.

So, I think continuing on our mission to really

shift accountability in many respects to the provider sector is going to be very powerful and we should not exclude that from our discussions about influencing drug cost.

DR. CROSSON: I completely agree, and I think although it's mind-bendingly complicated to think about, the notion of looking at the incorporation of Part D into the development of delivery system and payment changes and risk-bearing entities, so that you have risk-bearing entities, like I did in my professional career, who are handling not only the costs of Part A and Part B -- I'm sorry, A and B, including the cost of Part B drugs, but also potentially at risk for and potentially rewarded for the management of Part D costs, which we can't do right now, but thinking about how to do that would follow the general trend of delivery system reform and payment reform that we're thinking about, and I think --

DR. SAMITT: And one of the other suggestions we've made before, which may be a good entre into testing out this space, is in the ACO world. You know, do we factor in and do we have ACOs focus on Part D expenditures in addition to A and B, and is that a good way to begin to

test enhanced provider accountability for total drug spend.

DR. CROSSON: A much clearer way of saying what I was trying to say.

DR. SAMITT: Oh, sorry.

[Laughter.]

DR. CROSSON: Okay. Further on on these -- Jon.

DR. CHRISTIANSON: No, not on these --

DR. CROSSON: No, no. Jack, on your own stuff.

DR. HOADLEY: Yeah, I wanted to comment on Craig's thought. I mean, I think -- and you were picking some of this up, Jay -- I mean, there's really three settings where that plays out very differently. One is Part B, where we've already got the issues like the 106 percent that says, we're actually offering you an incentive to use the higher-cost drug, and we've talked about that.

There's Part D for the stand-alone, for the people in traditional Medicare, where we've really separated, and so the Part D plan has no relationship to the provider and the ability to sort of leverage that idea -- and that's where you get into the ACOs or other kinds of ways to try to begin to bring them together.

And then you do have the Medicare Advantage,

where at least the Part D plan is inside the Medicare Advantage plan, although they're sort of financially a bit separated. But presumably, and maybe something that we could learn more about, is within the context of MA, are they doing more -- because there's some evidence that suggests there's not that much of a difference. There is some difference in generic use that Shinobu and Rachel have seen and some differences in a few other ways. But the overall sort of spending levels and things -- but that's separate from sort of the appropriateness of the prescribing and sort of getting the right drug. And, so, maybe there's something to be learned somewhere out of the MA PD side to see whether that greater potential for integration is actually paying off.

DR. SAMITT: And what I would counter with is, and I've mentioned this before as it pertains to MA PD analysis or MA analysis in general, is not all MA plans are the same.

DR. HOADLEY: Yeah.

DR. SAMITT: So, there's a danger in sort of averaging the performance of drug utilization in MA, and maybe we want to actually look at whether the distinction

between provider-sponsored MA plans and not, or do we see pearls of opportunity within a subset of MA that can give us some guidance on drug utilization and where the opportunities could be.

DR. HOADLEY: Yeah, I think that's a great point, and it's something I've thought about, as well, is it really does matter what kind of MA plan you're talking about.

DR. CROSSON: Okay. Rita.

DR. REDBERG: Thanks.

DR. CROSSON: You've been patiently waiting.

DR. REDBERG: There's been a rich discussion. I just wanted to make a few points You know, it's not just specialty drugs and biosimilars that are expensive, but it's of great concern, I think, to our beneficiaries that the generics are going up in price, too, and drugs that have been around for hundreds of years, like colchicine for gout has gone a 500 percent increase. You know, albuterol inhalers, which are all off-patent generics, have undergone increase. And a lot of generics that used to have multiple sources are now single sources and that has had the -- given the companies an opportunity for price increases.

And, so, there are certainly a lot of pressures on drug costs that all affect the Medicare program and beneficiaries.

On the other part, I guess on Slide 9, we had that nice slide on oncology drugs. Per license year gain has increased -- the price has increased over time. But that also reminds me, and you can see it a little bit in those -- how many have circles, which meant the trial showed overall survival, as opposed to just progression-free survival. JAMA Internal Medicine published a study in June looking at oncology drugs and the increasing use of surrogate markers and that very few of them are actually validated and show an increase in survival.

So, there's a concern that not just are these drugs getting more costly, but the evidentiary standard that they actually improve patient survival is dropping, because there's more and more progression-free survival and modeling studies, and with the increased emphasis on faster approvals, it means that we're not getting data, and oftentimes the overall survival data never comes, or when it comes, it doesn't actually affect provider prescription behavior.

So, from our beneficiary point of view, I think we need to think about what are we spending and what are we getting, and there's a lot of concern we're spending a lot more and we're getting a lot less in terms of improved survival and even improved quality of life.

Also, looking at the research costs and what's driving it, I think there was an op-ed in the Washington Post last week from a former editor of the New England Journal noting a few points that a lot of the research and development costs actually are -- at NIH, they are federal government. A lot of the good drug ideas are started at the NIH funding, and then drug companies buy them at the point when they are, you know, much further down the line and clearly looking more promising. And that companies are spending more on advertising than they are on research and development, and she cited a study from York University.

But, certainly, when I am at the gym and see the ads now for chemotherapy drugs and biosimilars, I just think it doesn't seem appropriate to me that that would be a direct-to-consumer ad. You know, that is really a discussion, it seems to me, that a doctor should have with their patient and not someone should say, oh, I --

So, I wanted to get back to the idea, and someone else already mentioned it, of least costly alternative policy that we talked about a year ago, because it was effective. And the idea that a single payment rate is set for a group of products with similar health effects makes a lot of sense, because when I look at, again, from the beneficiary point of view, the future of the program, I mean, there was an article in the New York Times recently from Robert Pear suggesting a 50 percent increase in premiums. I think we're all concerned about the effect on premiums. And, so, you know, certainly, this huge price pressure on drug costs and question of value seems to be addressed by Medicare paying a similar amount for something with a similar benefit.

And, I have to say, not just for drugs, but I think about for other things, you know, for similar effects. And, I'll just, my personal story. I recently had to have the colorectal cancer screening, and I used our electronic record to message my primary care provider and say, just send me this fecal testing kit, and I never had to lose a minute from work. I'm sure that fecal testing, according to the U.S. Preventive Services Task Force, it's

equally effective, the same health effects as colonoscopy. I mean, not just was it easier for me, but it's a lot less costly for the system.

I'm not a Medicare beneficiary, but for Medicare, I think we need to think about the idea that for similar health effects, Medicare should consider offering the least costly alternative. That's not to say people can't opt to purchase a more costly alternative, but I think we should think about what's the responsibility of the program as opposed to the individual beneficiary, and I think we have to think about the future of the program and the incredible pressures on the program, the trust fund, the federal debt, and in terms of value.

So, I would like us to get back to the discussion of least costly alternative, because it seems to me it's like a win-win.

DR. CROSSON: Okay. Follow-on to Rita's points? Warner.

MR. THOMAS: I would just agree. I think it's something that with our concept that we believe in site neutral, to me, this is a very similar concept to site neutral. I know we addressed this last year. It just

seemed to stop. But, I would really encourage us as a Commission to take this up with a serious conversation.

And, also, evolving into just thinking or understanding what are the pros and cons of evolving long term to a Medicare fee schedule for drugs versus an average price, you know, plus a certain markup. There's very few, if any, other areas in the Medicare payment system that do not have this type of payment methodology, and I think we just need to evaluate that and think about the pros and cons of what that would mean for the security of the program and for the beneficiaries of the Medicare program.

DR. CROSSON: Thank you, Warner. You make a good point. Some have observed, and I think we are acutely aware here at the Commission, that for the most part, particularly when we deal with the updates, we are dealing with Medicare as a price setter, for all the warts and difficulties that come from that.

In the case of pharmaceuticals, for the most part, we're dealing with Medicare as a price taker, and it's different, and it's different for reasons that are historical and based on Congressional intent and all the rest of that. But, your point that it is different is very

valid.

Okay. Jon.

DR. CHRISTIANSON: I just wanted to go back to Scott's comment and say how much I think it's important for us to keep our eye on how all of this affects the beneficiary.

I have a question for Mark, I think. Hello.

DR. MILLER: I wasn't bothering anybody.

[Laughter.]

DR. CHRISTIANSON: No, you weren't. So, when we -- we have our payment update discussion coming up. We have data from -- survey data from beneficiaries about access. Is that a survey that we field ourselves, and do we have questions in there about financial access relative to pharmaceuticals? I just don't remember whether we put that in.

DR. MILLER: Yeah. I'm going to look first. So, here's what we do, and I probably can't do this as well as the person who's in charge of it. We have a contractor administer a telephone survey to beneficiaries, and we've done that because we found on the provider side response rates are really poor and somewhat variable, and so we

found the beneficiary stuff more effective.

Mostly, those questions are fairly consistent from year to year about can you get an appointment in this amount of time for these kinds of things. We sometimes add additional questions to it. There's cost, which not a giant issue for this. But, it has mixed success. Sometimes response rates, or how clear the question is understood.

And this is all leading to another point, which is we also, as a matter of course every year, do focus groups with beneficiaries and with providers, usually in three marketplaces, and there, we do do special interest types of questions. And if there is something here you'd like us to pursue, I'm willing to consider either or both of those vehicles to --

DR. CHRISTIANSON: Well, I think it's worth thinking about, because I think if we really want to find out how this is affecting the beneficiary, we should ask them, and think about how we might ask them. And I think this is, I think we all agree, not an issue that is going to go away anytime soon. It's going to get bigger for Medicare. And, so, even if we haven't done it in the past,

that maybe starting to establish a baseline and move forward.

Now, that's all easy to say and it's all, you know, things that the staff would have to come back to us with in terms of the suggestions and cost of the survey and all that sort of stuff.

DR. MILLER: I want to be very clear here. I think we can start fashioning some questions. I don't think the add-on cost to what I'm talking to prohibit our ability to do that. And, so, you should assume that we're going to look at this, based on what you said.

DR. CROSSON: Okay. Can I see hands for folks who would like to make additional points, other than those they've already made or have been made? Scott, and David.

MR. ARMSTRONG: This is probably building on comments that have already been made and may not have that much, but it just really strikes me that as we go forward, a lot of our discussion today in particular has been focused on the price of drugs and how they get set and how they get inflated and all that kind of thing. And I think that's interesting, and yet I sit here realizing when I take responsibility for the overall cost of pharmaceuticals

to the Medicare program, price is just one component part in this whole thing.

I actually realize I don't have a particularly good handle on how powerful a lever price is relative to some of the other variables.

In listening to Rita, for example, I know we spend too much on a per-unit price basis, but is it overwhelmed by how much utilization that's inappropriate or how much we're using the wrong drug or a more expensive alternative than the drug we should be using?

So I say that I think that would have a real bearing on policy interventions, we might imagine, and so I say that asking, is there some way to know more about that?

Craig's point is a great one, and in other areas of the Medicare program, we will often ask, is there some way of comparing fee-for-service experience with experience in ASOs or in MA plans? So maybe that is an avenue for getting a little more insight into how we would answer that question.

But that also comes back to the point of view of how our beneficiaries' care gets managed. In particular, when I was saying I feel like we're taking a big global

look at how this works and we need to come at it in a more personalized level, it's not just so much the out-of-pocket cost for the beneficiary, but it's again to a point Craig made earlier. It is, what are the variables that influence the clinical decisions that end up actually in a prescription? Because that is how you spend the money. It's a lot more things than just the price per unit of service, and that just may offer some more insight into again where we might intervene.

I wish I could tell you what I thought were more powerful ways of intervening, but honestly, I don't have great insight into that.

DR. CROSSON: Scott, I think that's a great point -- a great set of points actually. Not only does it change the paradigm of our thinking, which I think you're right about, but it also I think changes our conceptualization of what some potential solutions should be because some of -- it's like the notion of if you have a hammer, everything is a nail. We are the Medicare Payment Advisory Commission. So we think about prices.

But in fact, as you say, it's more than cost, it's more than price, and it's more than prices of

individual drugs. But as you start thinking about potential solutions to that problem, it begins to move you away from what I might call centralized solutions to decentralized solutions, one of which is this question that Craig brought up as well.

Thanks. One other brief point I wanted to make, and that is our conversation also just presumes -- I think it's true. We spend too much on drugs, and I think we need to get better control over it.

But there is a real return on our investment in drug costs, and we don't have any mechanism for judging the quality of our drug utilization, to kind of use a phrase we used in other -- we judge the quality of skilled nursing care and the quality of hospital care. It just makes me wonder: Is there some way for us to kind of bring that question in as another variable in judging is the spend the right spend for the Medicare program?

DR. CROSSON: Very good.

On this point, Bill?

MR. GRADISON: Yes.

DR. CROSSON: Yeah.

MR. GRADISON: Briefly, it's a conceptual point,

but I think it picks directly up on what Scott said.

I'm interested from a conceptual point of view in observations we have made earlier that may relate to this. Specifically, we have commented about the increased incidence in the Medicare population of certain conditions like diabetes, obesity, high cholesterol, high blood pressure, and so forth. And I'm really thinking about how that matches up with where these drugs are being used. In other words, the benefits -- to the extent that a lot of this new ammunition for dealing with conditions -- not solving them, but dealing with them so people can survive with diabetes when they couldn't before is an example -- to the extent these are focused on where the greater problems are for the population we're responsible for, to me this question of price, while not unimportant, gets scaled down a little bit. In other words, if we're having some societal success at aiming at the right targets, let's keep that in mind and in context.

DR. CROSSON: Thank you, Bill.

Warner, are you on the same point? All right. So I think David was -- oh, it was Jack? Did I miss it?

DR. HOADLEY: On the same point.

DR. CROSSON: Same point.

DR. HOADLEY: Yeah. I think part of why we've sort of moved a bit more into price is the current pipeline and the emergence of a lot of these expensive drugs, although they again interact with volume because, again, the cholesterol -- the new cholesterol drugs is a great example. If they are used for their narrowest indications, A, that may be the most appropriate use, and that means the total cost won't be such a burden to the program. If they become the replacement for statins for the broad population, despite perhaps the lack of clinical evidence why that's appropriate, then that's big.

The other comment I was going to make is I think when Part D was created, medication therapy management programs was a big part of the focus on how we would address proper use, and we've had reports from the staff repeatedly on those programs. The record has not -- they don't have much to show for results, and I think maybe it's part of the point of going back, and maybe we stop looking at those and say, "That just isn't working. Is there a different way?" And maybe that does get back into the previous conversation about how do we get the Part D plans

better linked with the prescribers and other kinds of ways to think about how to address volume.

DR. CROSSON: We have pretty much exhausted our time. David was next and then Mary, and then I think we're going to move on.

DR. NERENZ: I think this will be quick. I was just going to extend on Craig and Rita's comments both, and this is about the prescriber and some of the decisions.

In two specific domains, CMS has already stepped across a line about measuring efficiency as part of an overall quality measurement program, which then leads to financial incentives. And I wonder if there's territory we could explore here in that general area under some label, say, like prescribing wisely. That if we're thinking about what levers are there, well, there are levers that involve measurement of certain quality parameters or efficiency parameters and then linking those to financial incentives.

Now, I almost cringe when I make this statement myself because there are technical difficulties. There are exceptions. There are changing guidelines. Yes. Yes, all that. But just the point being if we're struggling to know what some of the levers might be, I think this is domain we

could at least look at and perhaps some carefully crafted things might emerge.

DR. CROSSON: Thank you.

Mary, last word.

DR. NAYLOR: Just very briefly, this conversation has also helped me to rethink the role of beneficiary because we have been talking about it in the context of the person that's paying the $30 copay on an $88 cost of drug. And I think paying attention to opportunities around engagement and shared decision-making, the work that we did in terms of high-value cancer care and the recommendation that patients know the risks and the benefits and the costs, they come out with different sets of decisions about use.

So I think this in addition to all of the recommendations around coverage, least costly alternative, all of that, we really should look very substantially at the opportunity we have now with a population that's really ripe to get them fully engaged in the decision.

DR. CROSSON: Thank you, Mary, and thank you to all the Commissioners. This was a very robust discussion, and I think it's going to be very helpful to Mark and the

staff and all the rest of us as we move along.

We've now come to the end of the morning period, and we have an opportunity for public comment. Could I see if there are any individuals who would like to make a comment. Please step to the microphone.

[No response.]

DR. CROSSON: Seeing none, we are adjourned, and we will reconvene at 12:45.

[Whereupon, at 11:33 a.m., the meeting was recessed, to reconvene at 12:45 p.m. this same day.]

AFTERNOON SESSION

[12:46 a.m.]

DR. CROSSON: Okay. I think we're ready to start the afternoon session off. We've got three topics this afternoon, and the first one is going to be on Alternative Payment Models and the Merit-based Incentive Payment System, APMs and MIPS. So, Kate and David, take it away.

MS. BLONIARZ: So we're going to talk about two provisions of the recently enacted SGR repeal bill: APMs and the merit-based incentive payment system.

The Medicare Access and CHIP Reauthorization Act of 2015 -- or MACRA -- repealed the Sustainable Growth Rate formula governing Medicare's payments to physicians and other health professionals. In its place are a set of permanent statutory updates for clinicians.

There are two paths. One is the path for clinicians who are qualifying participants in eligible alternative payment models, or APMs. And the second path is for clinicians who do not qualify as eligible APM participants. There is a separate quality measurement framework for these clinicians as well -- the merit-based incentive payment system. Over the next year or two, we

expect that CMS will issue implementing regulations for all of these policies.

This slide shows the difference in Medicare's payment rate for APM clinicians and non-APM clinicians. It is a stylized example, so you should just think of the provider billing a constant amount of services over time.

From 2015 through 2019, both groups of clinicians receive the same update -- 0.5 percent per year. From 2020 through 2025, there is no update. But clinicians who are qualifying APM participants would receive 5 percent in a lump sum payment each year from 2019 to 2024. And you can see that in the orange bars on the graph.

Starting in 2026, clinicians who are qualifying APM participants would receive a 0.75 percent update per year. Non-APM clinicians would receive updates of 0.25 percent per year. And these updates are in perpetuity.

I mentioned two slides ago that clinicians who are not eligible for the APM incentive payment are subject to a separate payment adjustment that provides increases and decreases based on their performance.

The MIPS has four components: quality, resource use, meaningful use of eHR -- or electronic health records

-- and clinical practice improvement activities. The MIPS consolidates the three separate payment adjustments that clinicians are currently subject to: the physician quality reporting system, meaningful use of electronic health records, and the value-based payment modifier. But the measures used in those programs are retained for use in the MIPS. For example, the MIPS will use the PQRS quality measures.

The maximum adjustment factor for MIPS is set in statute, rising to 9 percent in 2022 and later. A scaling factor can also increase the effective upward adjustment above these limits, and there is an additional appropriation for exceptional performance. Finally, the MIPS is linked to the alternative payment models provision because eligible APMs must have comparable quality measures to MIPS.

I first want to talk about some concerns that arise regarding the MIPS. First is the challenge posed by assessing clinician performance at the individual level. The MIPS, like the current value modifier, is designed to produce an individual-level payment adjustment. But many quality and resource use measures are not reliable at the

individual clinician level, and it is a particular challenge for outcomes measures. Based on CMS' experience to date with individual-level payment adjustments, most clinicians will likely look average, and the Medicare program will only be able to reliably identify persistent outliers.

The structure of the MIPS itself also raises additional concerns. The PQRS reporting system presently has hundreds of measures, some of which assess only processes of care and are poorly linked to outcomes. MIPS would combine PQRS with the value modified, eHR meaningful use, and add additional criteria. The resulting system is likely to be overly complex and further burden both providers and CMS, and because the MIPS directly implicates APMs through the requirement for APMs to have comparable quality measures, it could pose a barrier to APMs' ability to use a more meaningful measurement system.

Now I'm going to talk about the APM path, and we're going to spend the rest of the presentation on this topic.

Clinicians who participate in eligible APMs qualify for the 5 percent incentive payment from 2019 to

2024 and receive a higher update starting in 2026. And they're also excluded from the MIPS. MACRA establishes rules for eligible APMs, as well as the required level of participation in an eligible APM for a clinician to receive the 5 percent incentive payment.

The first question is: What is an APM? The pool of APMs are all models under the Center for Medicare & Medicaid Innovation (except for innovation awards), models tested under the pre-existing Medicare demonstration authority, a demonstration required by law, and the Medicare shared savings program.

Then there is statutory language that further winnows down the number of APMs that can qualify clinicians for the incentive payment. They must meet three criteria on the left side: they must use certified eHR technology; they must have comparable quality measures to MIPS; and they must either bear financial risk above a nominal amount or be a medical home that has been certified for expansion by the Office of the Actuary. And I'll note here that that certification has not occurred.

A key takeaway is that not all APMs will be eligible APMs for which clinicians can receive the

incentive payment. They will need to meet the criteria set out in the law, and presently, very few models are likely to do so.

A clinician will qualify to receive the incentive payment if they have a specified share of their revenue in one of these eligible APMs. So I want to draw your attention to the dates on the screen. They are corrected from your handouts, and those of you in the audience can get a corrected version on our website.

The share is set in statute, and it is a bright line. If the clinician meets it, they receive the incentive payment. CMS also has the discretion to make this calculation based on the number of beneficiaries (versus the amount of revenue). Any revenue from Medicare Advantage is not considered for either the numerator or the denominator in the calculation. And there's also an option for an all-payer calculation, and I can address that on question.

If the clinician meets that threshold that I just discussed, they receive the 5 percent incentive payment. The incentive payment applies to their professional services payment and is made in a lump sum. CMS shall

establish a process for making payments to APM participants that do not receive fee-for-service -- for example, an ACO receiving a capitation payment. The additional payment incentive does not count as spending for APMs that compare actual spending against a spending benchmark. In other words, the additional money would not cause an APM to exceed its financial targets.

So I'm going to turn to David to talk about some of the implications.

MR. GLASS: Thank you, Kate.

Kate has just laid out what the statute says about MIPS and APMs. CMS will now have to implement the law. It will have to go through the rulemaking process and have things specified probably by 2016 in order to allow time for practitioners to form APMs and sign up, because 2018 is the base year for the APM bonuses which start in 2019. So CMS just issued a request for information on MIPS and APMs last week, and rulemaking will follow.

One of the key implementation issues CMS will have to address is what spending is the APM responsible for. Remember, it has to be at risk for something, presumably the difference between expected and actual

spending. But what spending will that be? The spectrum would seem to range from spending only for the services the APM clinicians bill for at one end to total Part A and Part B spending for a beneficiary for the year at the other end. It could also be something in between such as spending in a bundle for some period -- for example, all services around a hip replacement for 30 days post discharge.

Another issue CMS will have to address is rules for attributing clinicians and beneficiaries and, hence, their spending to APMs. Also, as Kate has discussed, CMS will have to decide what quality comparable to MIPS means. And, finally, what is risk above a nominal amount? We are not going to go into this last issue at length but, however defined, at a minimum one would need to be able to measure changes in spending if an APM is at risk.

In the next few slides, we are going to look at the first question and use it as an organizing principle for thinking about the issues that an APM program would face.

Decisions about the scope of an APM's responsibility for spending will have an important influence on how the program works. First, let's look at

an APM that is only responsible for the spending its clinicians bill for. Here are some of the characteristics of the APM that would follow.

First, it is likely the clinician would only be in one APM because the APM is defined around clinician billings. In contrast, a beneficiary is likely to be in several APMs -- for example, one with her cardiologist and one with her primary care provider.

One issue with this model is that an APM is unlikely to have sufficient "n" to reliably measure changes in spending or quality, and by that I mean it will not have enough attributed beneficiaries or cases for CMS to determine if there is a meaningful difference between actual and expected spending. Because APMs have to be at risk, this is a problem.

Because the APM is only responsible for its own billings, it has no incentive to coordinate care or control total spending. Spending on an unneeded hospital admission, for example, would have no impact on the APM's performance, so why control it?

Finally, there would also be no incentive to

improve quality outcomes. There may be many quality measures, but the APM would not likely have responsibility for a defined population so it could not have responsibility for population outcomes or an incentive to change them.

An APM defined as responsible for spending around a bundle of services presents a different picture. In this case, a clinician could be in multiple APMs, each responsible for a different bundle of care. Beneficiaries also could be in multiple bundles, hence, in multiple APMs. In this case, there may be a sufficient number of beneficiaries or cases in an APM to reliably measure change, but that could vary widely among the APMs.

There may be some incentive to coordinate care within the bundle but not necessarily outside of it. There also would be some incentive to control spending within the bundle but not to control the number of bundles or total spending. Finally, the last goal concerns improving quality outcomes. The Commission has emphasized outcomes over process measures. Most outcomes are population outcomes. Only an APM with responsibility for all spending could be measured on population outcomes because it would

have an attributed population. If some sort of intermediate outcomes were defined, then the bundled APM could have some incentive to improve them as well.

Finally, let's look at an APM responsible for all of a beneficiary's spending for Part A and Part B over the course of a year. If the logic of attribution were similar to that used in ACOs, the clinician would be in one APM if that physician's claims were used to attribute beneficiaries to APMs. Some specialties, if they were not used for attribution, could be in multiple APMs.

A beneficiary would be in one APM almost by definition. The APM would likely have sufficient "n" or could be required to. In the Medicare shared savings program, for example, a minimum of 5,000 attributed beneficiaries is required for each ACO. Because the APM would be at risk for total spending, we would expect it to have strong incentives for coordinating care, controlling total cost, and improving outcomes.

So far we have discussed each of the three models separately, and that has been complex enough. However, the legislation leaves open the possibility that these models could all exist at once, and that makes things even more

complex as we will show on the next few slides.

So here we have APM-1 with Clinician A in it and beneficiary B1. So in this case, the spending for Beneficiary 1 comes through APM-1 and goes to Clinician A. So in this case, that seems pretty clear.

But now let's add another APM, APM-2. Clinician A is also a participant in APM-2 as is Clinician B, and they share revenues for beneficiary B2. Sorting out how revenues are shared is important to determine if Clinician A, for example, has enough of his revenue coming through APMs to clear the threshold.

Similarly, having APMs responsible for different scopes of spending will complicate the program. We start out with APM-1 responsible for all A and B spending for beneficiaries B1, B2, and B3 -- not vitamins.

[Laughter.]

MR. GLASS: We now add APM-2 responsible for a payment bundle and B2 and B3 use that bundle, and then let's add one more. Let's add B3 responsible for its own billing, and that has a relationship with B3 as well. If all three APMs have a relationship to the beneficiary -- B3, for example -- how would the share of revenues of each

clinicians be counted? How are savings or losses shared? And what if a clinician is in multiple APMs? These complexities would not only make the administration of the program difficult, they could lead to unintended incentives for the clinicians and other providers. They might also confuse and mystify the beneficiary to the extent that the beneficiary is aware of APMs at all.

In summary, there are now two payment paths going forward for clinicians. There are APMs and the bonuses and higher updates that path includes. And there is the path for clinicians who do not qualify as being APM participants. Those clinicians continue in fee-for-service, but with no APM bonus and lower updates. They are also subject to MIPS, which has the possibility of fairly large payment adjustments depending on performance.

Because of the bonuses and higher updates, there will be strong interest among clinicians to be considered qualified APM participants and, thus, pressure to include many models as eligible APMs. But if APMs are not responsible for total spending, incentives for care coordination will be diluted, and the complexity of the program could increase.

So one way of looking at this is focusing on some key questions.

First, how can MIPS be defined to minimize the burden on providers and CMS and to emphasize outcomes of interest to beneficiaries in the program? There may be many clinicians in MIPS if APMs are defined to have strong incentives. Simply combining all the measures and the three current quality and value measurement systems into one may result in an overbuilt system, placing a lot of burden on providers and with too much emphasis on process measures. Is there a better way to go?

Second, should APMs be required to lower costs and increase quality? This seems like a good idea, but the legislation does not require it. And simply having a low level of risk may not do it. For example, if I get a 5 percent bonus and I have a 1 percent risk, I might not work too hard to control spending. Also, if put at sufficient risk, APMs would have to be large enough to measure their performance and to absorb those.

Third, CMS will have to strike a balance between the scope of spending for APMs and having as many APMs as possible. There will be pressure to expand the number and

variety of APMs, but there should also be a concern that it might be better to have fewer, more robust APMs that can take on risk.

Finally, if you think it's important to get clinicians to participate in APMs, should APMs be given additional tools, such as regulatory relief from things such as the three-day rule or the ability to share savings with beneficiaries? This might make it a stronger model and increase the incentive to be in APMs and out of MIPS fee-for-service.

Another way of looking at this, of thinking about these issues, is to consider a hypothetical model for an APM and how the program would look as a result. We have based this model loosely on ACOs to illustrate some of the issues we have just discussed. In this model, the APM would be at risk for total spending, have sufficient numbers, have ability to share savings with beneficiaries, be given regulatory relief, and have a single entity to assume risk. Under this construct, the beneficiary would be in one APM per year, and the clinician would be in one APM if his claims were used for attribution. So this is not a suggested definition but, rather, an example to

illustrate the issues.

We look forward to your discussion.

DR. CROSSON: Okay. Kate, David, thank you very much.

This opens a new chapter in MedPAC's work. It actually is derivative of two extremes of work that the Commission has been doing for quite a long time. One is in the area of delivery system and payment reform. I think many of you are aware that the accountable care organization idea itself had at least part of its genesis here at the Commission, because I think a longstanding belief that some -- not all, but some of the complexities that we deal with, particularly in fee-for-service Medicare, can be more effectively addressed by more integrated delivery systems and particularly by methods of payment, such as David and Kate have suggested, which combine responsibility for larger areas than just the services delivered by one individual to one patient.

It also follows from the recommendation that I think is almost a decade old that the sustainable growth rate formula with respect to physician payment and Medicare fee-for-service was an ineffective incentive and needed to

be replaced.

So I think it's appropriate for the Commission now to take on this work, and our goal here, first of all, is to understand this better, to understand the intent of the legislation, but also to assist CMS and others, to the extent that we can, in thinking the best pathway through because I think, long term, the Commission as well as many other interests within the health care delivery system and payment system have an interest in this direction being successful. And it's quite complicated as you can just see. How it's implemented, how the rules are created, I think will go a long way to determining whether it sets out on a path of success or not.

So this is a preliminary discussion that we're going to have. I think our purpose here today is to try to understand what's been presented and, to the extent that we can, what lies behind it, and to get some preliminary ideas from the Commission about how we should be thinking about this, so that as we design issues to be brought here over this term, we pick those which are the most likely to be impactful and around which we can reach the greatest level of consensus.

So that's our goal, and we'll start as we usually do with clarifying questions. We will start here with Kathy and go down this way.

MS. BUTO: Kate and David, thank you for this presentation. This is really complicated stuff.

So I had several questions that are just a threshold. One was how much leeway the statute gives. I understand that the updates are all in this, probably in the statute, and they've been scored and everything thing else. But how much leeway does the statute give vis-a-vis the complexity of the MIPS themselves? Because the complexity there leads to the complexity of the APMs. So that was question one: How much leeway?

Question two is it looked to me from slide 9 as if the physician meets the percentage APM participation or involvement required to get the bonus, that that was regardless of whether or not the APM met any quality standards. It's just the APM had to have the quality standards, but there's no quality component to it other than that, right?

MR. GLASS: Yeah. That is correct.

MS. BUTO: Okay.

And then, thirdly, I got confused about an APM that was going to take risk for A and B vis-a-vis the ACO, and I guess I imagine that it was possible to be double paying for shared savings to the physician in the update and then also to the ACO, which would then in turn share some of those savings with the physician. So those are the three questions.

MR. GLASS: I'll just take the last one.

So if an ACO were qualified to be an APM and became an APM, they would get -- they could still be eligible for shared savings, and as you said, the practitioners in it would be getting their 5 percent bonus, assuming they were beyond the threshold.

But the 5 percent bonus doesn't go into the calculation of the shared savings. So, in some sense, they wouldn't be being paid double for that.

MS. BLONIARZ: And I can answer your first question. So what the legislation does with respect to MIPS is it basically removes the kind of three separate payment adjustors, but it does retain all the measures and kind of the processes for PQRS, the value modifier, which uses the PQRS measures, meaningful use.

There is a new category of clinical practice improvement activities and then also the resource use, and I think CMS is reading that very strictly, kind of planning to keep all those mechanisms going and merging them into kind of one adjustment.

It would be up to them to decide how much leeway they have under the statute to depart from that, but it seems to be their intent from the RFI.

DR. SAMITT: So my questions are in the same line, and I would turn to the slide 3 because I could use some help understanding this as well.

I am trying to understand the compare and contrast of an APM versus a MIPS provider. So let's take a hypothetical situation. In 2022, let's assume the APM here is a qualified ACO, and the MIPS is a MIPS provider. But in 2022, there is eligibility for a 9 percent in the best-case-scenario adjustor. So if I am an equally high-performing ACO as an APM versus a MIPS provider, in which scenario will I be rewarded more appropriately for being a highly accountable, high-performing clinician? How does it all add up in those two settings?

MS. BLONIARZ: I think it would depend on the

level of risk that the APM is bearing and then also how the APM entity is kind of transmitting the risk it faces down to the clinician. That's going to be another key piece of it.

I think you have brought up another point, which is that people will be in one or the other.

DR. SAMITT: Right.

MS. BLONIARZ: They can't be in both. So if they are in an eligible APM, they are not in the MIPS and vice versa. What I don't know is whether there will be kind of a lot of switching back and forth year by year based on how advantageous it may be, but I think the statute was written that people would only be in one or the other. But that determination happens every year, so people could go from one to the other and back.

DR. SAMITT: I think it would be helpful to see even average modeling of what it would look like between the two scenarios because even the 9 percent -- so the 9 percent would be supplemental to what's listed in green here, and then it puts in question, if I am a provider, would I prefer to be in MIPS, or would I prefer to be in APM? That's not clear to me from the math right now.

I am assuming we would want people to prefer to be in an APM, but the methodology isn't clear that it would incent that.

MR. GLASS: Yeah. And there would be the uncertainty if you were in MIPS of whether you're going to be getting 9 percent or losing 9 percent, and you'd have to have that in the calculus. And then in the ACO or the APM in this, the question would be you'd get the 5 percent on your professional services, but then you'd also be eligible for shared savings on the entire spend. And how that would work out, hard to know.

DR. MILLER: I just want to say, you used the word "modeling," and I started to break out in a sweat.

[Laughter.]

DR. MILLER: I was actually surprised how cool you two remained.

I don't know that we would -- yeah, okay. What I think we could do, though, is potentially give you sort of hypotheticals like this -- yeah. And if that's what you're talking about, I think we could knock that out, but simulating like what might happen here, I don't think we would have the capability. There's too much uncertainty.

DR. SAMITT: Yeah Just confidence intervals is all that I'd want to see. Modeling isn't necessary.

DR. CROSSON: On this point?

DR. NERENZ: Exactly on this point, just in the text, it says the MIPS applies to clinicians who do not qualify. It doesn't say anything about choice or preference. Is there a feature of choice or preference?

MS. BLONIARZ: That's a good point.

So CMS is going to determine whether the APMs, kind of in that big, broad category at the top here, will determine whether they are eligible APMs. I do not know how they will do that, whether they will ask the APMs to come forward with an application, whether they will say things that look like this model are considered eligible APMs. But once that process happens, all of the clinicians that are a part of that APM, like, for example, for an ACO, all of the physicians that are part of that ACO would then get into the next stage where they would look at how much revenue they had going through the APM.

MR. GLASS: But the physicians or practitioners would have the choice of wanting to be in the ACO or the APM or not, so that they would choose "I am in this APM" or

"I am in five APMs," whatever it is, and then CMS would make its calculation.

DR. NERENZ: I was just going to say, because your question implied that physicians could choose which track they wanted to be in, and I'm just trying to clarify that they don't really have that specific choice.

MR. GLASS: They can choose to try to be in the ACM.

DR. NERENZ: I understand.

DR. CROSSON: Alice.

DR. COOMBS: I was curious. If you're an APM during that period 2019 to 2024, you don't have -- you have the same quality parameters, but you don't have any kind of grade. You don't have a report card. No report card for those, right, in the APMs?

MS. BLONIARZ: There's no kind of quality resource use evaluation, yeah.

DR. COOMBS: And so with the others who are the non-APMs, there are still quality benchmarks that are occurring during that time period, right?

MS. BLONIARZ: There are. Yeah, I should just clarify that.

The eligible APM will have to have some criteria, so they'll have to have some kind of -- their payments will have to be based on some kind of quality measures comparable to MIPs, so there's something there.

DR. COOMBS: Right.

MS. BLONIARZ: But the Medicare program is not evaluating that group of APM clinicians.

DR. COOMBS: Right. So you get a waive with a 5 percent bonus and no grade, whereas the other group that's the parallel group, the non-APM, is it being evaluated with the 0.5 -- no update, zero update, right? So it's like a two-tier system that is occurring simultaneously with the APMs on one side receiving the 5 percent bonus. The evaluation of the quality parameters are there, but you don't get a grade. And then you get a zero percent update on the other side, and that's just it, right?

MS. BLONIARZ: Yeah. But there's also that upward and downward adjustment on the non-APM side.

DR. COOMBS: Okay.

MS. BLONIARZ: Right.

And I think I would just say that on the APM side, there is some kind of quality assessment going on.

It's just the Medicare program is not defining what that is.

DR. COOMBS: Right.

MR. GLASS: Also, it's at the APM level, not the individual patient.

DR. COOMBS: Right. So it is reliance on the APM to be the governance of that process.

And then --

DR. MILLER: I think there is some clarification.

DR. CROSSON: Well, I may be making a different point.

So, Kate, am I right that the APM would develop a quality measurement and improvement process, and that that would get certified somehow? CMS would say that's comparable to the MIPS criteria? But then after that, it's all internal; is that right?

MS. BLONIARZ: Something like that.

[Laughter.]

MS. BLONIARZ: So what I'll say is I don't know that CMS has said how they're going to determine whether something is comparable to the MIPS quality or not. I don't know at what level of detail they are going to be

looking at that.

MR. GLASS: And beyond that, the APM in order to get, say, that it was a shared savings sort of arrangement, there could be quality --

DR. CROSSON: Additional.

MR. GLASS: Yeah.

DR. MILLER: The thing I wanted to -- I wasn't quite sure whether we came away with this, that in a sense, you can have a conversation about how the performance of the APM is judged. Did it save money? Did improve quality? And then if there's some shared saving action there, that's one thought.

Then there's another thought, which is does a person who is in the APM get the 5 percent, and I think the conversation about quality's role there is the conversation you were having.

DR. COOMBS: Right, right.

DR. MILLER: Okay. I just want to be sure you were squared away there.

DR. COOMBS: I understand that.

DR. MILLER: Okay.

DR. COOMBS: So the next piece of the puzzle, is

there any way that you could get an automatic acceptance letter into college, the college of APM that receives the 5 percent bonus, when you get funneled through this funnel? Would you say that if you're part of the CMMI, are you guaranteed it? What I really want to know is, what percentage of all of those robust CMMI programs would qualify for the 5 percent bonus? Do we have any knowledge of that?

MS. BLONIARZ: I think right now, there's probably very few.

In the paper, we talked a little bit about the number of models currently under CMMI that have shared savings and losses. There's not that many. There's --

DR. COOMBS: Well, the reason why I say that, we have the Pioneer, and we know that there was some attrition with that, and so it makes a big difference if you have a really, really small -- when you say few, really small number, and during that period, between 2019 and 2024, you just have so few providers that are qualified. That begins problematic in terms of whether or not there is a disincentive to take on a higher risk, even with the MIPS in terms of behavior response to being rejected from

college.

MR. GLASS: Right. That's why the definition of risk above a nominal amount because --

DR. COOMBS: Right.

MR. GLASS: It's very important because there are very few right now.

DR. MILLER: And I'll just say there's a Round 1 thing that we're still in here, and I want to make sure that the -- and then we can get to what do you want to do. Do you want to make it rigorous? Do you want to make it less rigorous?

I also want to make sure that the public understands what Kate just said. There's three requirements for APMs -- to be ineligible APM. Sorry. We're still waiting to see how that's all going to play out. So the answer of how many is really unknown, but the second part of her question is, if you take a layman's look at what's out there, it doesn't look like a lot qualified right at the moment. And I'd just like to make sure that the public follows all of that.

Sorry. Back to whoever is up.

DR. CROSSON: And having said that, I think there is the realization here, I think, behind this approach that it's not designed to essentially work well with what exists right now because what exists right now isn't getting us necessarily to where you want to be, that part of this, the incentives here in this APM creation, is to start providers moving forward to realize that they are going to have to change some of their organizational structural and other relationships in order to get to where they need to be.

MS. UCCELLO: So we keep talking about this APM like it's an ACO type of arrangement, but it seems like that's not the only way to do it. And it seems like from this chart, you could just be part of a bundled payment program. How could you not be in more than one of these kinds of things if that kind of program or whatever is included in this? And you could see a particular clinician getting a share of his or her income from that particular program, but then also being involved in some other kind of program, and you've got to add all that stuff up.

So I don't know how this works, or is that the issue?

DR. CROSSON: Kate is going to emphasize that

there are -- having said that, there are these three criteria that need to be met, and some payment models right now, I don't know that they would meet those three criteria that are on slide number 8, right?

MS. BLONIARZ: That's right.

And the other point I would make is the second step of the evaluation, which is does the clinician have enough revenue in these types of models. So for a bundle, a clinician may only have a small share of their revenue in that model.

[Pause.]

DR. CROSSON: David.

DR. NERENZ: Can you put Slide 15 up, please? I just want to make sure I'm clear what point you want us to take away from this, and I'm not sure I yet understand the problem.

MR. GLASS: This is very much going to Cori's question.

DR. NERENZ: Okay. Well, let me try to paraphrase and then explain why I don't yet see the problem. Let's assume that the two APMs are approved, valid, they're okay APMs. Clinician A -- and the arrows

are dollar streams, right? Dollar flows?

MR. GLASS: Correct

DR. NERENZ: Okay. Clinician A gets two dollar flows, and presumably they are going through APMs, so they count. They're good dollars. Then that total amount is compared against some larger revenue pool to see if you meet the 25 or 50 or 75 percent.

MR. GLASS: Correct.

Dr. NERENZ: Okay. We're good so far. Clinician B gets one dollar flow, and that's compared against some larger total. So what's the problem?

MR. GLASS: Well, the problem will be in figuring out how to share the revenues coming from Beneficiary 2, for example, and --

DR. NERENZ: But why do you have to do that? If each one of those dollar flows counts as legit, the unit of counting is the clinician, not the beneficiary.

MR. GLASS: Right.

DR. NERENZ: I just want --

MR. GLASS: Except that somehow the beneficiary has to be attributed to one of these APMs in order for the dollars to flow through the APM.

DR. NERENZ: Well --

MR. GLASS: So there's this matter of attribution, is the first complication.

DR. NERENZ: Beneficiaries aren't attributed to bundled payment, for example. They're just -- they're in it or they're --

MR. GLASS: Right, they're defined to be in it.

DR. NERENZ: Okay. So it seems to me the key issue is just -- does any dollar flow through? But I'm not sure why we worry about whether a beneficiary has dollars running in different directions. I don't understand why that's a problem.

DR. MILLER: Is it possible that you're talking about two different things? Are you talking about whether they qualify for the 5 percent or whether how --

DR. NERENZ: Yes.

DR. MILLER: -- split savings -- yeah, so across the 5 percent, David, just stay with me.

DR. NERENZ: Yeah.

DR. MILLER: I hate to do this live. I think you may have a point. You know, it's like I'm in enough APMs and my percentage of revenue qualify to get the 5 percent.

DR. NERENZ: Right.

DR. MILLER: But what I think David is answering, possibly, is, all right, a second question is: If these APMs were successful or unsuccessful, how would you hierarchically decide how to allocate the savings?

DR. NERENZ: Well, and I realize -- I don't want to get into Phase 2, but at least as it's currently written, it doesn't matter if they're successful or not.

DR. MILLER: Agreed. But I think David is raising this point of, like, you're still going to want to evaluate how APMs perform and how savings get shared as a separate statement from the 5 percent.

MR. GLASS: Right.

DR. MILLER: Are we in the same place, David?

MR. GLASS: Yes. But, also, I think it's a perfectly valid point, yeah, if you can define which beneficiaries you're sharing revenue -- you know, the revenues are coming from and how they're going through APMs and who's billing for them and all that and keep all that straight, then, yes, you can then figure out for Clinician A whether he has enough revenue coming through APMs compared to his total to meet the 25 percent or 50 percent

--

DR. NERENZ: Right.

MR. GLASS: We're just showing that that can get -- you know, you'd have to keep track of a lot of things going on.

DR. NERENZ: Okay, fine. I just wanted to make sure I wasn't missing something else.

MR. GLASS: No, no. That's fine.

DR. NERENZ: Okay.

DR. CROSSON: Clarifying questions?

DR. HOADLEY: So I'm still wrestling with the question that I guess Craig started on this notion of how the clinician joins or is attributed to, and it sounds like as you've gone on to talk about more of these, that a lot of these, they're just in because they're doing these things, and some -- but in some of these, it may be more of a I have to actually sign up to be part of it. And I --

MR. GLASS: I think they have to sign up to be --

DR. HOADLEY: For any of these, back on that other slide --

MR. GLASS: Yeah, I think the clinician has to say, "I am in this APM." So they have to--

DR. HOADLEY: And any of the subunits --

MR. GLASS: They're going to have to do it on, you know, taxpayer identifier numbers and the whole --

DR. HOADLEY: So whether we're on a bundled payment thing or a demonstration or an ACO, those are all things where the physician would have to have actively opted; they're just not in it because it's something maybe their larger practice is just part of?

MR. GLASS: Well, if their practice is in it --

DR. HOADLEY: It might be done at that level

MR. GLASS: Yeah, and it's done at the taxpayer identification number level, then that would be sufficient probably

DR. CROSSON: So now I'm getting a little confused.

[Laughter.]

DR. HOADLEY: That's why we're clarifying.

DR. CROSSON: We're talking about the money to the physician flowing through the APM. Is that right? Is --

MR. GLASS: That's the way the statute is written. I mean, it says --

DR. CROSSON: So the APM --

MR. GLASS: -- it has to go through the --

DR. CROSSON: -- is not just a payment model. It's an entity. Is that the implication of that?

MR. GLASS: Right, yes. I think that's correct. I mean, the way it's written, it says the revenue has to go through the APM to be counted in order for them to qualify as a participant in APMs. Do you see what I'm saying?

DR. CROSSON: I do.

[Laughter.]

DR. CROSSON: I think it changes things. Okay.

MR. GLASS: Okay.

DR. MILLER: I mean, it can be a passive transaction. So once again --

MR. GLASS: The APM is not paying the physician.

DR. MILLER: Is that clear?

[Laughter.]

DR. CROSSON: Then I think we need to parse the word "through." Have we got a definition of the word "through"?

MR. GLASS: So think about how an ACO works now. I can sign up to be in this ACO as, you know, a

practitioner, a clinician. I can sign up to be part of this ACO, and I'm under the taxpayer identifier number that the MSSP ACOs --

[Laughter.]

MR. GLASS: At any rate -- but the checks come from CMS directly to me in payment. My fee-for-service revenue comes directly from CMS.

DR. CROSSON: Right.

MR. GLASS: In the current ACO, MSSP ACOs. So think of it as that. The check is coming from -- the fee-for-service revenue check comes directly to the clinician, but in the sense that the clinician is part of the ACO, and in this case the patient is attributed to the ACO, then the money is coming through the ACO. And that's -- I'm reasoning by analogy, given that that's the case in ACOs, I assume it's something like that.

DR. MILLER: So half of my -- I'm in -- actually, let's keep it real simple. The reason we keep going through an ACO, Cori, is because --

DR. CROSSON: We know where it is.

DR. MILLER: Let's say all of my patients are attributed to an ACO, just to keep it simple. But CMS is

paying me on a fee-for-service basis. But because each of those beneficiaries, all of my business, was in an ACO, all of it would have flowed through an ACO and qualify, I would be 100 percent by that definition, and I would qualify as being in an APM and getting a 5 percent on that, you know, total book of business.

DR. CROSSON: The actual flow of money or the credit for the flow of money?

DR. MILLER: I would say credit in that sense.

DR. CROSSON: Right, okay. All right.

MS. BLONIARZ: Let me just clarify. So in the statute, it says "through an eligible APM entity," and it's, like, What does that mean? And I think that that will be subject to rulemaking. I think that we have a relatively good sense of what that could mean in the ACO context because money is coming from the fee-for-service Medicare stream, but it's kind of part of an ACO arrangement between the Medicare program and the provider. But beyond that, I would say we will have to see how CMS defines it.

DR. CROSSON: Right.

DR. SAMITT: Can I take on one --

DR. CROSSON: Can you save us here?

DR. SAMITT: No, that's impossible at this point.

[Laughter.]

DR. SAMITT: So what if not 100 percent but 60 percent of my services qualify as an APM? Do I get the 5 percent bonus on 100 percent of the services that I provide or only the 60 percent that is linked to APM?

MS. BLONIARZ: You would get it on 100 percent of your professional services. You would get it in 2019 and 2020, 2021 and 2022. You would not get a payment in 2023 based on this slide, because at that point it's a 75 percent threshold.

DR. SAMITT: I understand. Okay.

DR. CROSSON: Where are we? Jack?

DR. HOADLEY: I have two others that I think are simpler. On Slide 8, you talked very briefly about the medical home that meets the expansion criteria as this other path and said that that hasn't happened yet. Do we know anything more about that? Is it that nobody has tried to make it happen? Is it standards that are hard to meet?

MS. BLONIARZ: So the criteria that I'm talking about is the one that was established in PPACA when the

Center for Medicare & Medicaid Innovation was established that basically says any model under CMMI can be expanded nationally if it is shown to improve outcomes without increasing cost or lower cost without hurting outcomes. Only one CMMI project has gotten that certification. It's the Pioneer ACOs.

So CMMI has a whole bunch of other medical home demos. They haven't reached that criteria yet.

DR. HOADLEY: So it's the whole demo that's going to get certified or not get certified.

MS. BLONIARZ: I think that's probably right, yeah.

DR. HOADLEY: And my other question was on 9 where you talk about MA revenue not being part of the calculation, and I guess that's logical in the sense that this isn't directing MA payments. But I'm trying to think about how that plays out for -- obviously, if a particular clinician is completely in the HMO, doesn't matter. But some clinician who might have 75 percent of their work, this would be out of the numerator and the denominator?

[Ms. Bloniarz and Mr. Glass nodding.]

DR. HOADLEY: And so all of these judgments would

be made on, say, that 25 percent of their business, and then whether 75 percent of that meets the criteria and so forth. Okay.

DR. CROSSON: Okay. I want to make sure we have some time to actually discuss directions, so let's move ahead with the clarifying questions, and I ask for, despite the complexity, as much brevity in questions and answers as is humanly possible.

MS. THOMPSON: A simple question. I thought you did a great job, Kate and David. Thank you for this.

Back to page 8, if we would define the universe of eligible candidates to be considered to become an APM, does it only include those that you've identified in those four bubbles going into -- so what is --

MS. BLONIARZ: That's right.

MS. THOMPSON: I think that's an important point. So what's the line in the sand in terms of date that I or an organization as a physician I'm a part of, do I have to be in a model or in an ACO or bundled payment project? I think that is important. So can you talk a little bit about that?

MS. BLONIARZ: Yeah, so it is only these four

pathways, and the first one, Medicare demonstration authority, that actually has been superseded by the CMMI process. And, you know, demonstrations are required by law. There have been some, you know, through the years, like one-off demonstrations. But I would say that currently the way to get new models in is likely going to be through CMMI.

DR. CROSSON: Very good question, and so the derivative question is, Do we anticipate that CMMI or CMS has the capacity to put enough models out, assuming we got a robust response to this by physicians across the country? Or are there going to be physicians who want to do this but can't?

MS. BLONIARZ: Yeah, I think that's an open question. I should also mention there's another kind of input into this process, which is a physician-focused payment models, technical advisory committee. That is a committee that is just now standing up, and appointed by GAO and staffed by ASPE. They will also come up with models, but the models that they come up with would then also have to go through the CMMI process to get into the bucket of potentially eligible APMs.

DR. CROSSON: Got it. Thank you.

MS. THOMPSON: The second part to my question, because in your criteria that you list, the risk above a nominal amount or a medical home --

MR. GLASS: That meets the expansion criteria.

MS. THOMPSON: I'm sorry.

MR. GLASS: The medical home that meets the expansion criteria, not just any medical home.

MS. THOMPSON: Not just a stand-alone medical home that meets -- okay. That's important, too. Thank you.

DR. MILLER: And the only thing I was going to say about Jay's question, I mean, a question that when we discuss this in the second round and move on over time is how expansive, how many models, versus focus, and I think that's something that the Commission could say that could help the environment sort of define what it's actually looking at here.

DR. REDBERG: Two quick questions. On the mailing material, on page 8, when you're talking about how MA is not part of the determination, it says that CMS is doing a study to look at the feasibility of alternative

payment models and it will be out next year. Do we have any information or timing?

MS. BLONIARZ: No, we haven't heard anything more about it.

MR. GLASS: Well, the legislation requires that it be done by some specific date. Do you remember?

DR. MILLER: We can look that up and get back [off microphone].

DR. REDBERG: Sure. On maybe page 9 of the presentation, clinicians can qualify for the APM if 25 percent of spending, say, in 2018 and 2019 is part of the -- are in an eligible APM. But the 5 percent bonus would be applied to all of your Medicare payment, not just the 25 percent that was in the APM.

MS. BLONIARZ: It says -- "professional services revenue" is the term in the statute. But, yeah, all of it.

DR. REDBERG: That's interesting. Okay.

DR. CROSSON: I'm sorry. I missed Jon coming around this way.

DR. CHRISTIANSON: On Slide 9, that slide, the bullet point about MA revenue not part -- what was the thinking, what's your understanding of the thinking behind

that?

MR. GLASS: Well, it's a fee-for-service program, I think is the thinking. So they're interested in your fee-for-service revenue, and that's where you're getting -- the bonus is a percent of fee-for-service revenue, and I guess that's the thinking, is that they're interested in how much of your fee-for-service revenue is under one of these arrangements, not of your --

DR. CHRISTIANSON: Okay. I was thinking they would be interested in how much of your total revenue as a provider would be subject --

MR. GLASS: Well, that goes to the all-payer calculation option would include MA as well as commercial payers.

DR. MILLER: It would include MA or it's possible that it does that? Is that defined?

MR. GLASS: Possible? Well, I haven't read the rules yet, yeah.

DR. MILLER: Right.

MR. KUHN: Yeah, kind of going on with this issue of the narrowing of the narrowing of the number of APMs out there. So, in addition, maybe a smaller number, but it

could leave large geographic areas in the country without even that option available to clinicians. Is that contemplated in the statute? And is there any backup for that should that occur?

MS. BLONIARZ: There are a couple of provisions that are, you know, directing CMS and the committee to look, you know, more closely at models that would work for smaller areas, HPSA areas, underserved areas, and then there's also, I think, technical assistance money for them as well.

MR. KUHN: Thank you.

DR. NAYLOR: Thanks. I got to read this two or three times before I began to know that this conversation was important. So I --

[Laughter.]

DR. CROSSON: Oh, sorry.

DR. NAYLOR: This starts with all models in CMMI so basics. Not all models are equally successful in the demo, and so was there any qualifier in -- I didn't see it. The language says "all." So if bundled payments -- all of them are in regardless, and then applying those three criteria.

MS. BLONIARZ: Yeah, there's one exclusion, and that's for the innovation advisers. Those are not really models. Those are payments to individuals. So that's out. But everything else -

DR. NAYLOR: Everything else is in.

And, secondly, given the interest in the Commission's emphasis on primary care and clinicians who provide primary care, anything in the MACRA legislation related to MIPS or APMs -- what do you call them? -- that pays attention to primary care clinicians?

MS. BLONIARZ: Let me get back to you. Let me look.

DR. NAYLOR: Thank you.

MR. ARMSTRONG: Jay, you can decide this may, you know, verge on a Round 2 question, but at the risk -- I'm trying to avoid getting lost in a lot of the specificity on what the heck is an APM and so forth and trying to remind myself what was actually the policy goal here other than just replacing SGR -- which is not a bad thing. But it looks like -- so here's my question: Am I reading this right, that there seemed to be strong incentives created

for being part of an APM through which some payment would be made? But there's nothing specific about what the real goal is, like lower costs or better quality or better health outcomes or whatever else you might be looking for. Is that correct? And is that really a part of the work that we would expect to unfold going forward?

DR. MILLER: [off microphone].

[Laughter.]

MR. GLASS: I think that's a very reasonable question, and there isn't a requirement that they save money or improve quality or anything like that, so it does raise -- I think it raises that very question.

DR. MILLER: In fairness to the process, I think -- and my most direct answer is I don't know. You know, I'm not in the room in the end in all of that, but, you know, my sense is some of their intent was to take a look at MIPS. What they're saying is in a sense I'm going to start to fix this dollar, and you're going to have to, you know, compete with one another in order to get it. And it can go down or up, which in theory from an incentive point of view might get a clinician to start to say, well, maybe I want to be in one of these APMs.

And you move over to the APM, but there's a push/pull in the sense, you know, maybe 9 percent, you know, says it dampens the incentive. But if we are one of the people it's not getting at, then maybe the incentive's there. So there's a pull with the 5 percent.

Now, the APM itself, that's where it just didn't seem as rigorous as you might have thought, although there is this real key sentence and definition which hasn't been defined. And I don't even know what the term of art is, but substantially about nominal --

DR. CROSSON: Nominal amount.

DR. MILLER: Yeah, or -- I should have read this before I came into the room. But that -- and I think there was some sense that these models would create some kind of incentives along these lines in the sense of there are quality linkages between MIPS and this and some sense of risk. But exactly how rigorously that gets defined is the complexity.

MR. ARMSTRONG: Yeah, so that's kind of how --

DR. MILLER: I think they were trying to move people, you know --

MR. ARMSTRONG: You know, it's almost like we're

starting to -- this contemplates creating a structure through which at some point, once it gets going, you can begin to really pay much more attention to, well, what are the real outcomes that we're trying to drive toward? So I guess I [off microphone].

DR. CROSSON: Bill, go ahead.

MR. GRADISON: Is my understanding correct that this would cover PAs and advanced practice nurses?

MS. BLONIARZ: It would, yeah.

MR. GRADISON: And how would it apply in broad principle? Let's say an advanced practice nurse who in the course of a year may work for moving around the country for 10 different organizations.

MS. BLONIARZ: So if they are billing directly, it would be like -- if they were billing the Medicare program directly, it would be like any other.

MR. GRADISON: No, but if they're paid for, let's say, by hospitals, they are going where there's a -- they may be travelers. They may go in where there's -- cover vacations or a strike or health care emergency or something. They move around the country.

Conceptually, they have multiple employers.

That's all, paid by the hospital.

MS. BLONIARZ: Yeah. I'm not sure I could speak to how --

MR. GRADISON: Well, it may be too small a question. I've been trying to figure out particularly how this applies to non-physicians, and we'll talk more about that later, I guess.

DR. CROSSON: Warner.

MR. THOMAS: As I was reading this -- and maybe I missed it -- do we have an idea in these different payment models what percentage of the Medicare population is covered in these models today? And if we kind of broke it down and looked at how many folks or how much of revenue is in a bundle, how much are in the Medicare shared savings or ACO program, do we --

MS. BLONIARZ: Definitely get something like that.

MR. THOMAS: I'm just curious as to whether -- is it 10 percent today? Is it already at 25? I mean, I think if you -- you generally think about this as probably -- I don't know. Are there maybe 25 to 30 percent of organizations or systems that are kind of moving down this

road? I'm just trying to get an idea of how big a modification this would be. It looks pretty material from where they are today. I'm just curious.

DR. CROSSON: Okay. So here's what I think we might want to do with the half hour or so we have remaining. We've had a nice discussion, very nice presentation, and I think we've surfaced a lot of the -- either apparent problems or contradictions or just simply lack of understanding about either the intent or where things are going to go, which is fine, and that's the situation that often takes place when there's legislation and the statute and before the rules are written.

This is our first run at this. It seems to me that one thing we might do here is, having heard all this, begin a discussion of what characteristics we would like to see in APMs, particularly, but in MIPS implementation, if you want, but I think particularly in APMs.

David started this. David and Kate started this with the slide they had showing one suggested model. Mark suggested that one issue we take a look at is capacity. What do we think? Where should we be going? Should this be a small number of robust entities who can prove the

point for X number of years, or do we really think that somehow we need to make this opportunity available broadly across the country? That's one question, but there are others.

So let's talk about what should be. Kate and David and Mark might want to comment as we make these suggestions, whether the suggestion fits within the existing language of the statute or not, and that might be helpful.

So who would like to lead off on this one? I see Craig, David, Mary, and Herb -- and Jon. Oh, and Kathy as well. Okay. All right. Enough of that. We've gone this way too many times, so, Jon, I'm going to start with you, and then we're going to go this way.

DR. CHRISTIANSON: All right. So I think we've all -- the Commission has always taken a stance that we should encourage people to be enrolled in MA plans and providers to be participating in MA plans. Is there anything in this that you see that would discourage clinicians from choosing to be part of an MA plan instead of one of these APMs?

MR. GLASS: I thought we were kind of neutral

between an MA or not, but anyway, I don't think there would be any reason for them not to want to also participate in MA plans. But I haven't thought it through, but I haven't -- I can't think of anything.

DR. MILLER: I have to say I hadn't thought about the problem that way. I keep thinking of the -- and perhaps incorrectly, Jon -- as the MA, you end up following the patient. If the patient chooses their way into MA, then as a provider -- it's not quite like that. I get that.

I think I'd have to think about this a little bit.

DR. CROSSON: On this point, Kathy?

MS. BUTO: My question was almost the same as Jon's, only I wondered whether this program was actually going to slow the physicians that find this attractive as an alternative to Medicare Advantage.

It is speculation at this point because it depends on how they define it and scope it. It could also, because it's so complex, that physician will say, "Hey, Medicare Advantage, much better approach to managing care. It is looking simpler, and I like what that looks like."

So it could go either way, but I don't think they are unrelated. I think this program could become more attractive and skew where physicians choose to go.

DR. CROSSON: And I've seen that, at least anecdotally, in medical groups who have tried some of the existing ACO models and have moved away towards MA. So I think you're right. So let's proceed this way. Who wants to go? Sue?

MS. THOMPSON: You're looking for principles too?

DR. CROSSON: Principles, principles.

MS. THOMPSON: Well, on page 14, I think you have outlined principles, and that is, however, we should work to coordinate care and reduce total spend while improving quality, which the triple aim. And my thought would be, coming at the top of the funnel again, any of those projects, whether it's MSSP or Pioneer, those are the metrics that we have been held to in those projects. So it would strike me that those would be operating principles to think about as recommendations are formed.

DR. MILLER: You used the word "total" there, which I took to mean for A/B, but the entire patient's -- almost a population-based concept.

MS. THOMPSON: Absolutely.

DR. MILLER: I mean, people's reactions to that, I think would be very helpful, and it begins to draw some lines around there.

DR. SAMITT: And D.

DR. CROSSON: It is similar to the model on page 19 as well.

MS. THOMPSON: And the only other piece is attention to the regulatory relief and the waivers that have been available to -- particularly in the Pioneer to help make this happen and make it possible to do the work that's required to be done.

DR. REDBERG: So just to build on what Sue said and I think what Scott said earlier, I think of the options you outlined, Option 3 certain encompasses what we think of, I think, as the goals of the program to improve quality and coordinate care and reduce total spending. And I think it's important, you know, as these rules are being written to keep these goals in mind and to write pretty specific and rigorous rules because, hopefully, we have learned from SGR, this is what we're trying to replace and improve. I think SGR, of course, had good intentions too, but I think

it suffered from a lack of rigorous definitions and maybe not looking at the big picture.

That's why I look looking at beneficiaries' A and B spending. To me, SGR was trying to control spending but only looked at updates and didn't look at volume. So it missed a whole -- and why we had 20 years of negative updates -- or however many years it was. And so I think it's important that we be very rigorous going forward and really learn from the past and keep our goals in mind when rules are being written.

DR. CROSSON: Herb?

MR. KUHN: So for me, I kind of laid it out in three buckets. So the first one is program vulnerabilities, as we look at this, to make sure that we're looking at the incentives to avoid poor care, underservice, fraud and gaming, different things like that, so just the overall program vulnerabilities that we would normally look at when you stand up any kind of program.

The second is really kind of the big bucket and what many folks have talked about already here, is the workability of this system. I mean, we've seen a lot a lot of Medicare systems, and this is the single most complex

one I've ever seen as we go into this thing.

But for me, the key here is that data inputs are available to providers in CMS and as close to real time as possible that can facilitate both not only billing, but assessment of the program and maintenance of the program as we go forward.

And then I think even beyond that, we've talked a little bit about it here, but this whole set of quality measures. And I think one of you said it when you were talking about the overview. We all know that the quality system is overbuilt that's out there. How do we take this as a chance to kind of take a mulligan and kind of do it over and get the real measures that are out there that are focused probably on outcomes and quality measures that are aligned with resource use measures as well and get that alignment and get it right as we move forward, so kind of just the overall workability?

And then the final bucket I'd put it in is the end game, and the end game to me is to make sure that we maintain access and we maintain high quality. And then I would add a third part of that, and that is equity and really equity for clinicians because we've got to make sure

that this is going to work for them.

DR. CROSSON: Herb, in terms of workability, where does that take you on scale?

MR. KUHN: That's a good question. I don't know yet. I want to think that one through a little bit more because if you look at these -- and the one example where you have multiple ones, might in a geographic area -- people might be in things that are out there. I think a little bit back to like the old days when CMS used to do demonstrations, and they used to look at parts of the country where there was not something there already because, one, they wanted to maintain the integrity of the program, so that they could have an honest intervention group versus the control group that are out there. And I think about the ACE dem, the Acute Care Episode demo. They searched and searched around the country and said, "Okay. Finally, we can put this in Oklahoma and Texas where we don't have overlap of different areas that are out there."

So in scale, I am really thinking about this overlap as where we go forward, so I want to think through that scale thing a little bit more because it's going to be a tough one.

DR. CROSSON: Thanks.

Mary?

DR. NAYLOR: So these are building on others, but I think that there is a real need for clarity of goals. I mean transparency and clarity of goals. This was to be SGR's replacement for payment to really advance and assure that clinicians deliver all of the things that Herb is talking about, and it seems to me to be a path to -- this is my interpretation -- to create entities and encourage people to move into those entities, and I'm not sure that those are aligned.

I think the idea of simplicity, in any way that we can, to enable the implementation of this to be really a simple path.

Equity, I also think is important for the clinicians and across fee-for-service and MA.

Value, I think that putting into funnel programs or models that have not yet been proven or, in some cases, have been proven not to be working doesn't make sense to me to get ultimately to high-value care.

And certainly placing a real priority on the quality of the goals, why we exist, for the beneficiaries'

outcomes, and so really a payment model that drives towards that.

And accountability, I mean the accountability here is individuals. It's teams. It's systems, and I'm unclear about how this payment model is getting us to that shared accountability of the individual, the team, and the clinician.

DR. CROSSON: Well said and quickly said.

Scott?

MR. ARMSTRONG: So three quick points. First, I agree with Mary.

[Laughter.]

MR. ARMSTRONG: Second, if I were to answer your question directly, I'd pretty much answer it the way the slide up there answers it.

But third, I feel like what I'd want to do is -- particularly since this is through a lens of payment policy for the Medicare program -- is kind of lay out the continuum from fee-for-service to MA and all the different things in between. You've got ACOs, and you've got bundles, and you've got DRGs, and ask how do you want -- what's the goal you want to design this to relative to all

the other payment policy that you have out there? What's kind of the place you want it to be, given the broader goals that we -- and accountability we have for the Medicare program? And I feel like, to Mary's point, I'm just not sure what that is and how it would fit in that context.

Thanks.

DR. CROSSON: Bill.

MR. GRADISON: Herb used the program "program vulnerabilities." My way of thinking about this is very similar, using the term "possible unintended consequences." I've jotted down just two or three that came immediately to my mind.

One is the risk of regulatory capture where specialist groups propose and get accepted as standards, whatever the current standard of care is, which doesn't really change anything, but it might get them the 5 percent.

The second is the possible effect of this new venture in accelerating retirements, especially of older physicians and particularly of primary care physicians. I could see some people looking at this and saying it's time

to move on at a time when we might like them to continue in practice.

And another example -- and I'm just not trying to be too long. I always try to make my point that there are a lot of possibilities here, and this has already been cited by MedPAC in a comment to CMS earlier. And that is the possibility that costs would increase because of the emphasis in the criteria on inputs, inputs unrelated to outcomes.

DR. CROSSON: Right.

MR. GRADISON: So you do more inputs and you get credit for it, but you move your costs up and move the needle on quality. I'm not saying these things would happen, but I think sometimes with something like this, it's not a bad idea to look at the worst-case possibilities and use that as one test.

DR. CROSSON: Thank you, Bill.

Kate?

DR. BAICKER: So building briefly on both what Scott and Bill and Herb were saying, it seems like the goal is to create a system that moves more care into models that are rewarding higher quality, better value, and away from

models that are just fee-for-service without any incentive to modulate quantity and maintain quality.

And there are so many moving parts that I imagine it is impossible to hang any real numbers on the implications of turning those dials, but I am trying to think through, and I think it would be helpful to have some broad breast-stroke, qualitative framework about here are the dials that are most likely to move physicians from one model to the other; here are the dials that are most likely to change behavior within those models.

And I can imagine if you pick one set of options for all of these, you end up in a model where everybody gets 5 percent, and nothing changes. And on the other end of the spectrum, you could make choices such that people are aggressively taking on more risk and delivering higher value, more focused care, and thinking about which of these is pushing in which direction, how powerful a lever it is, both to move people between models and to change behavior within the models. It would help me think through how they play out together.

What you have produced already is incredibly helpful in getting our arms around what the levers are, and

now I want to think through, in a broad brush-stroke way, which set seems like the right ones to try to focus on deployment.

DR. CROSSON: Warner.

MR. THOMAS: So it appears to me, as I look at this, that a couple of comments. One is it seems we ought to be moving more to global payments and not just focused on bundles, and I would just encourage us to consider that in our comments because if you just look at the bundled payments, it really doesn't look at the impact of utilization or avoidable care.

So I would just really encourage us in our comments to think about this in the model you are talking about in an ACO or an MSSP program versus a bundled program because of the opportunity to have avoidable care.

The other thing that I would comment on is, personally agreeing with my other Commissioners, the idea of having bonus payments that are not tied to some sort of quality initiative or cost reduction to me just seems it would be challenging to agree with. And I would agree with Herb. If we could look at this as an opportunity to simplify and create better alignment in the quality

measures, I think this is a great opportunity to do that.

The comment around the clinicians being in one APM, I would concur, especially from a primary care perspective. That would make sense. I think that that could be problematic in some specialties that are more referral oriented, but they may need to be in multiple APMs for this to work.

I would agree that beneficiaries need to be in one. Primary care need to be in one because of the attribution to one APM versus another, but specialists, specialty referral oriented, that could be an issue.

My last comment would be on Medicare Advantage. I think excluding Medicare Advantage in this calculation is a mistake because, frankly, if you can get systems that are taking risk in Medicare Advantage, that will benefit the traditional Medicare population, anyway, because the programs that are put together in Medicare risk usually are applied to the traditional Medicare population as well. So I would just encourage us to think about, as we think about the calculation of 50 or 75 percent, especially in areas that have tremendous Medicare Advantage penetration. I think that's something that should be a consideration.

MR. GLASS: There's just one issue on that. People have pointed out that, but the Medicare Advantage plan would also have to be paying on something other than straight fee-for-service to be counted.

MR. THOMAS: Right. So my comment would be only include Medicare Advantage if the provider is taking risk, you know, global payment or some type of model like that, or some type of risk arrangement around global payment in Medicare Advantage, not a fee-for-service arrangement through Medicare Advantage. So I would just -- I would think about if they were in a risk or partial risk arrangement with the MA plan.

DR. CROSSON: Okay, thanks.

DR. HALL: So I think I'm starting to get it now. I'd like to just put this into context of what I know of MedPAC and some of our recent and not so recent history.

For the last 15 years or so, a recurrent theme and emphasis in MedPAC among all the other things is that we were trying to do something about SGR. And we finally did it. We finally were able to contribute to finding a way to repeal SGR. But remember, at the time we did that, we put together kind of a manifesto of -- some of it looked

at pay-fors, but the other said what is our dream, and the dream, I think, in that document was that we were not going to be prejudicial per se against fee-for-service, but we thought the only way that we could move forward eventually throughout the country was probably to incentivize people to move from fee-for-service to be more in aggregate groups as much as possible.

And so MedPAC suggested the incentive plan, right? That we were going to -- the pay-for included a reduction over a number of years for specialists and a slight payment update for primary care physicians, with the idea being that we would make the environment much more attractive to physicians to think about being in organized systems.

Now, I don't think the discussion that we're having now was very much different than 15 years ago when people said Medicare Advantage, that sounds like communism, or what's going on here? It was new.

So what we're now doing is continuing this process that maybe we had some role in establishing, and that is to say, it looks good on paper, but the complexities involved are just absolutely enormous and

mind-boggling to change physician behavior by mandate.

So I look upon this as a further step in looking at models -- ACOs were one of those models, and this is in a sense another one -- with the laudable goals of trying to reduce complexity, that look at quality, access to care, all the things that have been mantras for us for a long period of time.

So my feeling is that we can of most help to CMS and to anyone else who is listening to us -- and this discussion has been rich in that environment, and we look at this as another progression and just an experiment, really, to see how we're going to move to the Holy Grail, which is a unified payment system that meets a lot of the goals that are important to our beneficiaries.

So we might be able to be of most help to CMS if the distillate of the conversation we've had today and at future meetings would really point out what have we possibly learned from our own experience in looking at how you implement models that alter the payment systems for physicians, and out of that we might be able to distill, you know, 12 or 20 or whatever number of principles that CMS should take into account before we launch into

something else and find out that we were doomed to failure by virtue of not thinking about our ultimate goal.

So I think we're on the right path. I just don't know where it's heading right now.

DR. CROSSON: Did Yogi Berra say that?

[Laughter.]

[Comments off microphone.]

DR. HOADLEY: So I don't want to repeat some of the kinds of themes that people have already talked about, but I wanted to mention three that I really haven't heard come up so specifically. One is along the same lines of clarity and complexity. One of the things I worry about is we'll get to a point where the clinician is going to look at this and not really know whether they're going to end up being eligible for this or not. And so I can see some paths by which that wouldn't be a problem, so I just think that's something to keep in mind, is to make sure that the people who are affected financially by this can understand -- it goes back to those discussions about can I choose to be in or out and are these things that are kind of passive.

The second point is sort of where the beneficiary fits into all of this, and in some ways, the best outcome

might be if the beneficiary doesn't have to know that any of this is going on except maybe their care is getting better and they're getting better quality or something like that. But I think that -- I'd like to make sure as we talk about things like the Option 3 where the beneficiary would only be in one of these things, are we now talking about same discussion we've had in the past about ACOs? Are we talking about something where the beneficiary now needs to enroll or accept or, you know, something? And that could be very confusing. So we just need to make sure, again, it's going to be clear to -- and whether there's any financial impact to the beneficiary. I assume that they don't pay because these extra payments are just over and above the physician, they're not linked to particular beneficiaries, that that's not going to affect co-insurance. So that part's okay.

MR. GLASS: Until they get to having different updates.

DR. HOADLEY: On the underlying fees, right. So, I mean, just trying -- making sure we're thinking about whatever impact or lack of impact there is on beneficiary.

And, third -- and I know you said somewhere in

the paper that you're going to come back to us with more about whether and how drugs might fit into this, and obviously to link that to this morning's discussion. That's a big part of what we're hoping the clinicians are paying more attention to, is the prescribing. And so I look forward to that future topic.

DR. MILLER: I'm trying to track on a couple of things that are happening in the room. I could take some of your comments as -- and you didn't say this; this is why I'm trying to tease it out of you, you know, particularly if you want to make sure that there's a connection to the beneficiary, and then you threw drugs in at the end. Could I be interpreting that as bigger versus smaller in terms of what the model looks like, that you're looking for more of a population base to this, or not?

DR. HOADLEY: I'm not going that far. I'm just trying to say these are implications that I want to understand to be able to make that judgment at some point in the future.

DR. MILLER: I just wanted to [off microphone].

DR. NERENZ: Let me emphasize a little bit, but let me start with the idea of the policy goal and take it

in a particular direction.

The thing was passed presumably to encourage people into alternative payment models, and my signal for that is this 5 percent feature of that track. That seems to be a reason -- it signals to me that that was the desired track.

Because it's structured as a two-track system -- and at least so far I don't see any choice element to it. If you qualify for APM, you are in APM. That's your -- but that's my --

DR. BAICKER: [off microphone].

DR. NERENZ: Okay. So the way the regs are written is going to strongly determine how many physicians end up in one track or another. In fact, they almost entirely determine it. I can see even within the language in the legislation regulations being written so it's relatively easy to be in the APM track. A lot of doctors in the APM track, 5 percent bonus. But I could also see the regulations being written so it's really hard to be in that track. Very few in that track, everybody in the MIPS track. So it just seems like it's going to make a lot of difference, and that balance as a desired endpoint would be

something it would seem like we would want to talk about.

Now, then the fine point within that -- and, Mark, you mentioned it in your example and, Kate, you mentioned it. The APM characteristics are described here at the level of the entity or the program. They're not described at the level of the way the payment is experienced by the individual clinician.

So we could end up in a situation where a lot of physicians are in the APM track getting the 5 percent bonus, but almost every single dollar they get is an absolutely traditional, utterly unchanged, unvarnished fee-for-service dollar like nothing ever changed. And to me that's not a desirable end result of that, that I would then suggest that as this moves forward, whether it's our opinion, in the regulations, whatnot, to the extent possible, given the language, this should be about alternative payment as experienced by the physician, not necessarily as a characteristic of the program.

Now, how exactly to do that is not so clear, but somehow this ought to be moving in the direction of meaningful, direct-to-the-physician alternative payment if that indeed is the policy goal.

DR. CROSSON: I mean, I -- you may want to comment. I mean, I think the inclusion of the criteria for substantial risk seems like it wouldn't work -- right? -- unless that was somehow translated down to the physicians.

DR. NERENZ: Well, two things. At least the language in our chapter does not say that, but maybe it's hidden. But, also, we have programs right now that are being described as alternative payment, pay for value, with percent up-down in the range of a half percent, 1 percent, 2 percent. And if those count and then you qualify for a 5 percent up, then I think we ought to have a question: Is that a good idea?

DR. CROSSON: Or is that substantial risk?

DR. NERENZ: Or is that what Congress wanted to do?

DR. CROSSON: Right, exactly. Okay. All right. Cori?

DR. MILLER: Do you want --

DR. CROSSON: I'm sorry. Miss somebody?

DR. MILLER: I couldn't tell whether I was getting -- I mean, another way to say this -- and I'm trying to pick up on your point of this dollar could move

through in a way and it could feel just like business as usual, even though I'm in an APM. I mean, if you had defined risk very not aggressively -- I couldn't come up with the right word at that -- very nominal risk, and if the APM was not successful at either containing costs or improving quality or those types of things, but 75 percent of your revenue came through it, quote-unquote, you would be getting the 5 percent. And I think you're saying, wait a second -- and it's been said over here, too, like wasn't the point that there should be some connection between performance and that extra money. And I feel like I'm hearing that in a couple of different places around the table, and I'm just saying it out loud to make sure, and make sure that the rest of the world is hearing it.

I'm sorry, Jay.

MS. UCCELLO: So I wonder if -- I can't even speak. You get 5 percent, you get 5 percent.

[Laughter.]

MS. UCCELLO: I'm wondering about if a concern here of setting the criteria too aggressively and making this APM very much modeled on an ACO where they would be the only ones who would be able to meet the criteria, you

know, what that means in terms of geographic issues. You know, we have had presentations in the past that show, you know, ACOs -- comparing ACOs, MA, and fee-for-service in different areas, and whether this would be disadvantaging providers in particular areas. And I think we would still -- even in low spending fee-for-service areas, I think there's still room for better coordination and that kind of thing, and we would want to encourage providers in those areas to also be moving toward those kinds of models. So I think, you know, we don't want to set these criteria so rigorously that that wouldn't be -- wouldn't happen.

DR. COOMBS: So I think of all the thoughts that I had today, I think Mary's on clarity is really important. And the attempt of MACRA to find a pay-for for the SGR is an important piece of this whole conundrum of whether or not MA plans should be included or not.

For me, I think the most important thing, putting my physician hat on, is transition, and as a part of the Massachusetts Payment Reform Commission, what we found was that if you were able to address the infrastructure changes that were necessary for physicians to go into global payment, then you made a big difference. And physicians'

greatest concern was, Do I have the infrastructure to compete? And when you're in an APM, there are certain things that are going to be required.

This whole notion of being able to flow free in and out of an MA plan as an individual provider is not that simple, and I think we're forgetting that, you know, the physician doesn't -- the clinician doesn't wake up one day and say, "I'm going to be part of the MA plan." It doesn't happen like that. And in many areas, it's actually restrictive, and it may be restricted because there's certain requirements of the MA plan for providers to enter in. So I think it is a fallacy for us to assume that providers can just float in and out of MA plans.

Isn't it true that we want the fee-for-service to be more coordinated care? Isn't it what we want, we want to be able to allow the transition of providers to go into a more robust integrated health care delivery system? So why wouldn't we address the transition?

So I don't think that we can have this conversation without talking about the transition of the workforce. And that being said, I was very concerned -- I mean, Herb said something about the vulnerability in

geographic regions, and it is really true. We have the data from the Pioneer ACOs and how many dropped out. That should be evidence about the risks taken, what providers are willing to take risks. And so there was a lot that stayed in the shared savings, but what about the Pioneer ACOs as an example to us looking at what the workforce will be willing to do in terms of signals?

So I think for us to deal with the transition, to look at not just, you know, the workforce, but also the beneficiary and access in those areas where workforces are challenged for fee-for-service. And I think this whole notion of bullets as to clarity of where we want to go in terms of objectives and then how do you actually transition to a different state is really important for providers.

DR. CROSSON: Alice, let me ask you one question I thought of as you were talking. So you've been through the alternative quality contract process in Massachusetts. Would you suggest that there may be some lessons that we could learn from that, that we should look at that as part of these considerations?

DR. COOMBS: I think there's a whole packet that's on the website on the Payment Reform Commission's

final report, but what we had to actually look at is this whole notion of carrots and sticks and where do you go with that. And to be honest with you, the benchmarks that have been achieved with the transition to global payment have been rather satisfying, and it had a lot to do with being able to have multi-stake involvement and actually work with the providers on this whole notion of infrastructure, because they needed to have really robust eHR systems. And then as a part of the MIPS, don't forget there's resource utilization. I mean, you've got to be able to grab that data from your panel. You've got to be able to say, okay, am I shovel-ready for this? Can I fit into this kind of setup or this model? And I think that was really helpful, just the tool set of being able to provide providers with what they need to say, "I can compete." And I think the transition is really important.

I'm just thinking about, you know, just the physician and the nurse practitioners, their part that they play. And you know what? We could have a consequence whereby we have titration, small changes with access in regional areas where someone says, okay, I got a 0 percent update, I'm in the MIPS class, I got the sequester

affecting me, I also have the low-value service penalties redistribution, and I have a bunch of other things that I have at work, I'm going to make a decision that really will affect a group of small community in terms of access for a small community beneficiaries.

DR. SAMITT: So I think most of the important things that need to be said have been said, but I would add just two comments.

My sense to Bill Hall's comment earlier is the intent of this whole model if we go back is to encourage and reward clinicians to deliver care in models that will most likely deliver on the promise of the Triple Aim. I think that was the intent here, that we believe that Medicare Advantage and perhaps ACO models are more likely to deliver on that promise, and so we want to encourage and reward movement in that direction.

So based upon that concept, I would have two concerns about the APM program. I think that the APM funnel needs to be more selective, that if we're going to award the 5 percent bonus to APM alternatives that don't move us any further in the direction of the Triple Aim, then I would say that those should not count as APMs. You

know, just to give them the reward to sort of get them out of their fee-for-service comfort zone, I don't think that's enough. I think it needs to hold the promise of better care at a lower cost. So I think the funnel should be very selective and that we should be careful about which types of models or organizations meet that criteria.

But, also, I'm a little worried and want to know more about MIPS, because this 9 percent -- you know, if I can achieve the 9 percent in an environment where I also am not furthering the principles of population health, then why would I become part of an APM?

So I think that the whole notion is that there need to be consequences and implications to stay in fee-for-service for those who aren't delivering better care, better outcomes. And so I think we also have to be very careful of the criteria that quantify those that will get bonuses and those that will lose revenue in the MIPS space. That requires very careful consideration.

And then the third quick thing that I would add that I mentioned quickly earlier is that I don't think it should be just A and B. If it is all accountability, it should be D as well for the reasons we described earlier,

that accountability is going to also be including the costs of drugs.

DR. CROSSON: Last word, Kathy.

MS. BUTO: Okay. So really two quick points. One is I guess a feeling that although this is the replacement for SGR, it really does not address the issue that we've all looked at, which is the disparity, if you will, between primary care and specialty care. It does nothing about that. In fact, might make it worse because it takes the attention off of that issue to me and really focuses more on the update factor.

And so the way I looked at this -- and it almost seems more like an alternative update model than an alternative payment model, and maybe I'm missing something, but I think we had talked about having a per beneficiary primary care amount for the add-on for managing primary care, but ultimately, you know, does this model -- I guess it's an open question -- allow for the possibility of really developing an alternative payment system for primary care that focuses on more of a per beneficiary kind of focus, because to me that's more of an alternative payment model, and continuing to pay fee-for-service only under

different rules for how you measure, you know, who has made or hasn't made their payment targets is much more focused on fundamentally trying to change the way we pay.

DR. CROSSON: Thank you. You know, our policy on incenting more equity in payment for primary care is still on the table, but your point here, which is to think through whether or not there's anything in this, in the regulations as they're written, that could help augment a solution to that problem is a good one. Thank you.

Okay. This is an initial look, and sometimes those initial looks are pretty messy. This one was in that category, but extremely helpful, a lot of good ideas, and I think for Mark and the staff now, their job is to take these ideas, to use Bill Hall's term, distill them down to some choices that we can start talking about, do this, do that, do this or do that. And we'll be looking forward to that discussion. Thanks very much.

[Pause.]

DR. CROSSON: Okay. Andy, you're going to talk to us about the health risk assessment and its impact on coding adjustments and make some recommendations, so go ahead.

DR. JOHNSON: All right. Good afternoon. In this session, I will present the results of analyses examining the use of health risk assessments in Medicare Advantage and will discuss options for addressing differences in diagnostic coding intensity between Medicare fee-for-service and MA.

Yes?

DR. MILLER: Andy, pull the microphone just a little bit closer.

DR. JOHNSON: Sure.

In this presentation, we will first review background information about health risk assessments and the Medicare Advantage risk adjustment model. Next, I will discuss our findings about diagnoses identified using health risk assessments and their impact on payments to MA plans. Finally, we will discuss how health risk assessments affect differences in diagnostic coding between Medicare fee-for-service and MA, and will consider options for addressing the impact of overall diagnostic coding differences.

Health risk assessments are a preventative care tool used to identify health risks and evaluate patients

for the presence of disease or disability. Once a patient's health has been assessed, patients may receive counseling about relevant health risks and referrals for follow-up care. This process can improve patient engagement in health decision-making. The Patient Protection and Affordable Care Act required that a health risk assessment be administered as part of Medicare's annual wellness visit, which is available to all Medicare beneficiaries.

In MA, most health risk assessments are administered during a visit to an enrollee's home. These home visits typically last about an hour and may include reviewing a patient's self-reported medical history, measuring vital signs, conducting blood or urine tests, reviewing medications, and assessing the risks present in an enrollee's home.

In-home visits are frequently initiated by MA organizations, either through a third-party vendor or their own home visit program. In recent years, the number of assessments administered in enrollees' homes has been increasing.

In your mailing material, I described several

examples of the increase in the number of home visits and the expansion of related entities. Here I will cite the example of one home visit vendor that over the past 3 years increased the average number of home visits provided per day from over 1,300 to over 1,800. This vendor also cites current capability at up to 2,500 home visits per day.

Next, we will review MA risk adjustment. CMS pays health plans in MA a capitated rate for each enrollee. This rate is adjusted so that MA organizations receive a greater payment for enrollees who are expected to be more costly. These adjustments are made through the CMS hierarchical condition category, or HCC model. This model includes enrollee demographic information and also includes diagnosis codes, which are grouped into HCCs.

In order to support accuracy and integrity, HCCs are selected for inclusion in the model, in part based on their ability to predict medical expenditures, and on their clinical meaningfulness and specificity, so that inappropriate manipulation or discretionary coding is minimized.

For payment purposes, each demographic component and HCC is associated with an expected amount of Medicare

spending. The Medicare payment rate for an enrollee equals the sum of the expected spending amounts for all relevant components relevant for that enrollee.

For example, annual Medicare payment for an 84-year-old male with congestive heart failure would have been about $7,800 in 2013. This total is comprised of about $4,700 for demographic characteristics and about $3,100 for congestive heart failure. If this enrollee was found also to have polyneuropathy, Medicare payment would have increased by about $2,900, for a total of approximately $10,700.

For each of the 70 HCCs in the 2013 risk adjustment model, this figure shows the increase in annual Medicare payment to an MA organization for the first identification of a given HCC during the data collection year, which was 2012. For the example I just presented, annual payment for congestive heart failure and polyneuropathy are highlighted in yellow in the figure. This figure also shows that annual payment for about two-thirds of HCCs was between 1- and $5,000, while payment for other HCCs was several thousand dollars higher.

Next, I will present our analysis of health risk

assessments in MA using encounter data for 2012, the first year encounter data were collected.

First, I identified encounters with a health risk assessment based on three HCPCS codes, two for an annual wellness visit and one specifically for the administration of a health risk assessment. However, we became aware that other HCPCS codes were used for health risk assessment encounters. For example, certain MA contacts known to have a home assessment program in 2012 did not have any encounters with these HCPCS codes. Given that this analysis would have underestimated the use of health risk assessments in MA, we added to the analysis encounters that took place in an enrollees' homes for evaluation and management, or E&M services.

In each analysis, we focused on HCCs that were identified only through a health risk assessment or only through a home E&M visit. In other words, these HCCs were not identified on any other physician or other health professional, inpatient, or outpatient encounter that was used for risk adjustment.

In the first round of analysis, shown in the center column, we found that 1.4 million health risk

assessments were administered to 1.2 million MA enrollees in 2012. From these assessments, we identified nearly 200,000 HCCs that were found only on health risk assessment encounters. These assessment-only HCCs included all 70 HCCs in the risk adjustment model and were associated with Medicare payments of $602 million in payment year 2013.

In the second round of analysis, shown in the right-hand column, we found that 2.3 million health risk assessments and home E&M visits took place in 2012, and 1.7 million MA enrollees received one of these assessments or home visits. In this analysis, nearly 750,000 unique HCCs were identified only on a health risk assessment or home E&M visit encounter. These assessment- or home visit-only HCCs were associated with Medicare payments of $2.3 billion in payment year 2013.

Furthermore, we found significant variation across MA contracts in the number of HCCs identified only through a health risk assessment or home E&M visit. For each HMO and PPO contract, this figure shows the amount of Medicare payment per enrollee generated by assessment- or home visit-only HCCs.

As you can see on the right side of the figure,

the largest increases in Medicare payment from assessment- or home visit-only HCCs was highly concentrated among a small number of MA contracts in 2012.

Eleven contracts, with a combined enrollment of about 385,000 enrollees, generated Medicare payments of $1,000 or more per enrollee from assessment- or home visit-only HCCs.

Please note that this number of contracts and enrollees is a correction from the figures in your mailing material. Although it is hard to see in this figure, 86 percent of contracts generated some Medicare payment from assessment- or home visit-only HCCs. This suggests that many MA contracts have the potential to increase the amount of Medicare payment generated from these sources.

Our review and analysis of health risk assessments in MA generate some concerns about their use in risk adjustment. As mentioned earlier, the accuracy of Medicare payments in covering the cost of treating an MA enrollee's conditions is supported by the HCCs' clinical meaningfulness and their ability to predict medical expenditures.

We noted that health risk assessments often rely

on patients' self-report of medical conditions. Allegations from two whistleblower lawsuits also raised concern about the accuracy of diagnoses identified during some home assessments. These lawsuits cite a reliance on patient recollection, medications, and tests using limited equipment. Concerns are even greater for HCCs identified only through assessments or home visits because these HCCs lack a corroborating medical encounter from which the presence of the HCC could be confirmed.

We learned about other aspects of MA home visits from focus groups we conducted in three cities across the country. Every year, we conduct focus groups with Medicare beneficiaries and primary care physicians addressing access to care, coverage choices, and the organization of care.

This year, MA home assessment visits came up during the first focus group, and we asked subsequent groups about their experience. Although the sample of MA enrollees was small, nearly all had received a phone call offering an in-home visit. Roughly half of these enrollees accepted the offer and most appreciated the hour-long discussion with a nurse about their health. The other half

said they were annoyed by persistent phone calls offering an in-home visit. Some enrollees who declined the home visit offer said they were uncomfortable with the idea of a nurse visiting their home.

Several enrollees said they were offered gift cards for $25 or more as an incentive to receive a home visit. Primary care physicians said they generally received reports from home visits for some of their patients. They found the reports mostly unhelpful because they were too lengthy or contained information that was either already known or lacked context in their patient's current care. Some primary care physicians said they spent time ruling out diagnoses that were incorrectly identified during a home visit and addressing their patient's subsequent concern or confusion.

We are now going to discuss overall differences in diagnostic coding intensity. Compared to Medicare fee-for-service, the risk adjustment model creates is a greater incentive to identify and report diagnoses in MA. As a result, enrollees of equivalent health status have higher risk scores and therefore generate higher Medicare payments when enrolled in MA.

Health risk assessments are only one possible source of diagnostic coding differences between the two programs. As reported earlier this spring, we estimated that 2013 MA risk scores were about 8 percent higher than fee-for-service as a result of faster MA risk score growth. These results are consistent with other research in finding that this faster growth is due to differences in diagnostic coding intensity.

For example, Kronick and Welch estimated that MA risk scores in 2013 were 9 percent higher than fee-for-service as a result of diagnostic coding differences. Their paper also showed that the impact of coding differences varied across MA contracts. Other recent research showed similar variation by plan type.

To adjust for differences in coding intensity, CMS reduces all MA payments by a single factor. Since 2014, a minimum adjustment size has been mandated. For 2016, MA will reduce all MA payments by the statutory minimum, 5.41 percent.

Furthermore, in 2014, CMS began phasing in a version of the risk adjustment model that removed certain diagnosis codes for which different coding rates were found

between fee-for-service and MA.

Researchers have estimated that the removal of these diagnosis codes would reduce differences in risk score growth rates by about 30 percent. For 2016, MA payment will be based fully on the model with some diagnosis codes removed.

Finally, CMS has twice proposed excluding from MA risk adjustment, diagnoses identified through a health risk assessment or a home visit. CMS did not implement either proposal. Instead, CMS required MA organizations to flag diagnoses identified through a home assessment starting in 2014 and is tracking these diagnoses to see if follow-up care is being provided.

For 2016, CMS issued guidance on best practices for providing in-home health risk assessments.

Although CMS's policies help, they do not address the full impact of coding intensity differences. MA risk scores in 2016 will be higher than fee-for-service by the amount estimated for 2013, which was approximately 8 or 9 percent, plus three additional years of accumulated impact. We believe that the total impact on MA risk scores in 2016 will be larger than the combined effect of CMS's

adjustments.

We are now going to discuss two options CMS could implement to address coding intensity differences. In option one, health risk assessments will continue to be provided to MA enrollees when they are valuable as a tool for prevention or care planning, or when provided as part of a Medicare's annual wellness visit. However, diagnoses identified through any health risk assessment would not be used for risk adjustment.

To the extent that new conditions requiring follow-up care are identified through health risk assessments, those diagnoses will be identified and included in risk adjustment calculations when subsequent treatment is provided. This option only affects diagnoses identified through a health risk assessment that are not identified on any other encounter used for risk adjustment.

In order to maintain parity between risk adjustment data sources, this option would exclude health risk assessment-based diagnoses from the risk adjustment model for both Medicare fee-for-service and MA.

Finally, this option would adjust for diagnostic coding differences in a way that is equitable across MA

contracts. In other words, MA contracts with many assessment-only HCCs would have a larger effective adjustment, while MA contracts with no assessment-only HCCs would have no effective adjustment.

A second option for addressing differences in coding intensity is to use two years of fee-for-service diagnostic data to estimate the risk adjustment model and two years of MA diagnostic data to calculate MA risk scores. Currently, only one year of each is used in risk adjustment.

HCCs generally identify chronic conditions. Thus, changes in HCC identification from one year to the next are more likely due to variation in coding than changes in condition status.

In MedPAC's June 2012 report, we showed that some proportion of both MA and fee-for-service beneficiaries who had a chronic condition identified in 2007 did not have the same condition identified in 2008. These year-to-year differences varied significantly across HCCs.

Our preliminary analysis of using two years of data for risk adjustment shows that this option would reduce the impact of diagnostic coding differences between

fee-for-service and MA. Furthermore, this option would naturally target HCCs with inconsistent coding across years or with more difference between fee-for-service and MA coding rates. Therefore, we believe that this option adjusts for coding differences in a way that improves equitability across MA plans.

Options 1 and 2 can be implemented simultaneously, but there is no guarantee that, together, these options would address the full impact of coding differences between fee-for-service and MA. A single adjustment factor may still be needed to address the remaining difference in coding intensity. This remaining difference, however, would be much smaller than the current difference, and overall equity across MA contracts would be improved.

Implementing options 1 and 2, along with a single adjustment factor, has the potential to address the full impact of coding a difference in a way that improves the quality and consistency of diagnostic data used for risk adjustment.

I am now happy to take your questions, and I look forward to hearing your discussion. Thank you.

DR. CROSSON: Thank you very much, Andy.

We will start the discussion of clarifying questions, and I am going to do one. And I hope I don't violate my own standard here.

But with respect to Option number 1, a lot of the build-up had to do with the issue of home visits as a site for the health risk assessment. In the proposal, you have made the choice to exclude diagnoses from health risk assessments entirely, not just those done in the home setting. And could you talk a little bit about that choice and the reasons for that and the pros and cons or whatever?

DR. JOHNSON: Sure. I think there are probably two factors that play heavily, and that is that if a home assessment is provided in the home or provided in a clinic and the same visit takes place in which there's an assessment identifying diagnoses codes and then that's it, no other services are provided, I think that those codes have equal or lack -- they both lack value in the in the risk adjustment model.

The second is that if excluding diagnosis codes only from home health risk assessments was implemented, I think that there would probably be some change in location,

whether it be to retail health clinics or new clinics being set up in order to conduct the same types of visits, just in a different location.

DR. CROSSON: Right. Okay.

Let's take clarifying questions. Cori.

MS. UCCELLO: So I've already asked you this, but I want to ask you again. So on slide 10, it shows kind of this distribution across contracts and shows that it seems to be concentrated in a smaller share of contracts, that the large numbers of the home-only HCCs. So for those who are more on the left-hand side who don't have a lot of home-only HCCs, do they still conduct a lot of home risk assessments and have codes for those, but the codes show somewhere else, so they wouldn't be the home-only, HRA-only HCCs?

DR. JOHNSON: So, I think there are a couple different points there. One is that the majority of all contracts had some risk assessments for some of their enrollees. The variation in the proportion of enrollees who received them was different across the contracts, but most were providing some health risk assessments. In some of the contracts, there were many more HCCs identified in

total, and depending on the contract, some of them were health risk assessment only HCCs and some of them had more HCCs identified on this assessment, but also identified on another encounter.

So, there were sort of three groups, I guess. One that had provided health risk assessments but didn't have many HCCs identified, others that had a lot of HCCs identified and a lot of health risk assessment -- or, excuse me, assessment only HCCs identified, and others that were sort of in the middle and that they were identifying a lot of HCCs, but not many of those were only identified on an assessment.

DR. CROSSON: Clarifying questions. All right. I need to do this -- sorry -- I have got to do it in order. So, Bill, we will start with you.

DR. HALL: I was intrigued by your finding that when you look at home visits in the MA programs, that over half of the people refuse a home visit even when they're being paid. That's very counterintuitive to the human nature. Do you have anything more to add to that?

DR. JOHNSON: From the focus groups -- again, that was a small sample. I think the attitudes toward the

home visits were pretty clear in that some people just didn't like the idea of somebody coming into their home. That was roughly half the group sort of had an opinion along those lines. Others thought it was fine and thought it was nice to spend an hour with somebody, which is longer -- it was noted that that was longer than a typical physician visit in the office.

I don't know that there are any specific numbers about the number of people who are offered a visit who end up getting a visit in total, but from all background sources, it seems to be roughly equal.

DR. HALL: I may want to say something about that in round two. I have some ideas.

DR. MILLER: I just want to make sure, from the public's point of view, again, that number, the half refused, very small focus group, couple of communities, just in terms of the breadth of that data.

DR. HALL: I think it's a pretty accurate number.

DR. CROSSON: Jack.

DR. HOADLEY: So, sort of following up on Cori's question, are there -- so, back on Slide 10, are there other patterns of which organizations were more likely

either to do the HRAs in general or specifically to do the HRA only or the home only HCCs, in terms of types of plans, geography, or anything like that?

DR. JOHNSON: Not that we were able to pull out so far. There was a lot of variation, both across HMO and PPO, across plan size, and we didn't get into any geographic analysis quite yet.

DR. HOADLEY: You know, you kind of wonder if there's funny behavior going on, in which case sometimes we've seen that kind of thing very concentrated in types of organizations or geography or something.

DR. CROSSON: Andy, along the same lines, you don't have any way of knowing whether that right-hand size of the curve are entities that subcontract this out in the way that you described?

DR. JOHNSON: Not that I know of.

DR. HOADLEY: And my other question, on Slide 16, when you talked about the earlier analysis using two years of diagnostic data and lack of overlap, what was the magnitude of the -- sort of, overall, what share of diagnoses don't -- and some clearly shouldn't repeat -- somebody has a very acute condition that then is solved.

But, a lot of other things, maybe it just doesn't get picked up because there's no acute sort of version of it.

DR. JOHNSON: Were you asking about the magnitude of HCCs identified that were identified only in an assessment versus those that were also identified elsewhere?

DR. HOADLEY: I'm thinking really of the previous analysis that said, just generally looking at diagnoses that were in, you said, I think, 2006 or --

DR. JOHNSON: Oh --

DR. HOADLEY: -- versus seven, or seven versus nine, or whatever the pair of years was.

DR. JOHNSON: Related to using two years of data?

DR. HOADLEY: Right.

DR. JOHNSON: There is some information about specific HCCs in the June 2012 report about how many were identified in 2007 and not identified in 2008. I don't know -- we have some preliminary analysis using that data that, I think, suggests that there is an effect happening from using two years of data, but we're working on some updated analysis, I think, that would provide a more specific number using current data.

DR. HOADLEY: It would be interesting to know how much that varied between fee-for-service and MA and other kinds of ways, because it might help us think about option two.

DR. JOHNSON: Right.

DR. CROSSON: Kate, on this point?

DR. BAICKER: Yeah. My clarifying question is very similar to this. Would you -- could you give us a little more information about the frequency with which we expect things to show up, and that affects my understanding -- I was a little confused at points about whether the analysis was focusing on HCCs that showed up only in a home visit HSA, HRA, or whether they first showed up there and then appeared later, because sometimes it said "new HCCs" and sometimes it said "only there," and that made me wonder, like, okay, if somebody has asthma and somebody finds it on the home visit, would it -- if the person really has asthma, would I expect it to show up on subsequent claims or only on subsequent claims that related to care delivered for asthma? And, so, I'm trying to understand what we would expect and, therefore, what is a warning sign about something that's showing up first at the

home visit and then not again for a while.

DR. JOHNSON: So, all of the analysis of HCCs that we did just looked at HCCs identified only on a home visit or a health risk assessment. So, some of those -- well, other HCCs were identified on a home visit and then subsequently identified elsewhere as care may have been given, and those were dropped from the analysis. So, that is a good area for future research, to look at how often that is happening. But --

DR. BAICKER: And I'm interested in knowing what should be happening, in the sense of -- so, in some ways, that could be a conservative thing to do if, then, say you're diagnosed with asthma and I'm making all this medicine up as usual, which is why people don't come to me with their health complaints.

[Laughter.]

DR. BAICKER: Suppose you're identified with asthma. Should, then -- routinely, is somebody going to mark asthma on every time you're there, and, in fact, it's no more real because it's marked the next time. It's just that once it was flagged in your record, the provider sees, oh, and yes, so-and-so has asthma and just checks it off

every single time. So, in some ways, then, excluding those would be too conservative. Or, is it should asthma be showing up then on the subsequent ones if the person really has asthma? Is there information in the fact that it's showing up later, or is it only showing up later if care is being delivered for asthma?

DR. JOHNSON: I think that depends on what the coding practices are of the subsequent providers, and I'm not sure I have a good assessment of what is the expectation between --

DR. REDBERG: A lot of medical records, once the diagnosis is in, it will repeat, whether you add it there or not. It's already in there. I mean, there are a lot of things that show up on my patients I haven't put in there.

DR. BAICKER: So, that's why I'm trying to understand what it means to show up only in the HRA visit. Is that more about the system, where it should be auto-populating and it's not, or is it about -- surely, if somebody goes to the hospital for an asthma attack, it'll show up there. But if somebody's just getting routine care, what does it mean to have asthma showing up subsequently on those records versus not? Is that about

whether the person really has asthma? Is it about the system that's prepopulating or not prepopulating? Is it about intensity of coding practices? I'm just not sure how to interpret the subsequent appearances.

DR. CROSSON: Well, and a corollary question. So, is this not showing up -- you know, so it's recorded in the HRA and then it doesn't show up -- is that showing up within that one claims year or is it any subsequent year?

DR. JOHNSON: This analysis is just for the 2012 calendar year. So, they had one health risk assessment, or a number of health risk assessments that identified an HCC, and any other time during that year, there was no --

DR. CROSSON: So, not showing up means within that calendar year.

DR. JOHNSON: Correct.

DR. CROSSON: Okay. All right. I'm sorry. Others, on this point. Alice?

DR. COOMBS: So, when you did the focus groups -- because I'm just kind of hung up where Bill is, and you get a free gift certificate, you know, and you turn down the gift certificate, did they say anything about having to go to the office for an office visit in close proximity to the

HRA?

DR. JOHNSON: Umm --

DR. COOMBS: Did any of --

DR. JOHNSON: Not in direct connection from the focus groups. Most just said, you know, I got a call. I accepted. They sent a nurse to my house and it was offered a gift card as part of this.

DR. COOMBS: But, they didn't complain about, after they got the gift card, someone says, well, I suggest you go and see this provider?

DR. JOHNSON: Not in the focus groups, no.

DR. COOMBS: Okay.

DR. CROSSON: Okay. We were marching up this aisle here.

DR. CHRISTIANSON: Slide 10. Does that tell me the same thing as knowing by plan what percentage of home visits result in an additional diagnosis? Is that kind of the same thing there?

DR. JOHNSON: You could get that information from this slide in that if that additional diagnosis did not show up anywhere else in the encounter data, then there would be some payment related with that that shows up on

this.

DR. CHRISTIANSON: Yeah. The reason I ask is I'm, as you were in the paper, struck by the concentration of this and the sort of apparently inequitable approach to penalize everybody for what seems to be the aberrant behavior of a few. And, I was wondering if there were other ways that would display that, maybe -- alternative ways to display that from Slide 10, maybe, if you could think about that for the future.

DR. JOHNSON: Yeah. I'll work on that.

DR. CROSSON: Clarifying. Rita.

DR. REDBERG: So, related to the gift cards, on page six of the mailing materials, you have in the footnote the explanation that they were not allowed to offer cash or monetary rebates. So, I'm not clear. Are these gift cards turned in for cash, and then isn't that a monetary rebate?

DR. JOHNSON: Apparently, part of the requirement is that they are gift cards that cannot be redeemable for cash. I'm not in a position to speak more about that.

DR. REDBERG: I just wonder what they would be redeemable for. I mean, I could see a gift, perhaps, of like a fresh --

DR. COOMBS: Starbucks.

[Simultaneous conversation.]

DR. REDBERG: Whatever it is, that's money, right. I mean, give a fresh fruit basket or exercise classes or something that encourages good health, but to me, it seems that we are in direct contradiction of the CMS rules here.

DR. JOHNSON: The only example that came from the focus groups was that one of the people who were offered a gift card said that it was for Walmart.

DR. REDBERG: Oh boy.

DR. CROSSON: Herb.

MR. KUHN: Two quick questions. One is, we're only day eight into the conversion to ICD-10, but is there any speculation whether the I-10 coding structure will narrow the gap between fee-for-service and MA? Will it exacerbate the gap? Or is there any speculation yet what it might mean?

DR. JOHNSON: There isn't any that I know of. I think that's something we'll have to look more into before I speak to that.

MR. KUHN: And, the second question I had is a

little bit about on page 15, but I'm -- on that option one -- but I'm curious, and correct me if I'm wrong here, but I thought I read somewhere where this year when CMS issued their call letter, they had a requirement in there that a clinical issue identified in an HRA must be confirmed by subsequent clinical encounter, but after comments, they dropped it out. Is that correct?

DR. JOHNSON: In the advance notice for 2014, they identified health risk assessments that did not have a subsequent encounter. In 2015, they said that they had spoken to some entities in the industry and said that most of the assessments are happening at home, so they proposed a slightly different policy of dropping diagnoses from home visits. And both times, they dropped the proposal after comments.

MR. KUHN: Thank you.

DR. CROSSON: Mary.

DR. NAYLOR: Very briefly. So, I wanted to -- Slide 15. When a health risk assessment is done as part of the annual wellness visit, so the annual wellness visit is usually comprehensive, and I'm wondering, isn't the physical part and the labs that follow and so on -- I'm

just wondering what is the rationale for excluding something that surfaces on an annual wellness visit for which health risk assessment is a part.

DR. JOHNSON: My understanding is that the annual wellness visit portion includes only the assessment of health risks and that if other services are provided at the same time, they can be identified separately as services provided. So, if we were looking at encounters, I think that would show up as two different HCPCS codes, one for an annual wellness visit and one for whatever services were provided subsequently.

DR. CROSSON: And just on that point, and then the diagnoses would track to those -- would track separately, is that right?

DR. JOHNSON: Correct, yeah.

DR. CROSSON: Scott.

MR. ARMSTRONG: Just, if you could go back to Slide 10, that graph. I know -- I think I'm getting it more, particularly listening to the other questions, but this just presumes to the right is bad and to the left is good, right? So, I'm just wondering, do we know which plans there are, and are there five and four-and-a-half

star plans on the right end of that graph?

DR. JOHNSON: I have not done a comparison with star ratings in place, but that's a good suggestion.

MR. ARMSTRONG: Great. Thanks.

DR. CROSSON: Okay. On this point, or just let me finish down there. Warner.

MR. THOMAS: Just kind of a follow-up to Scott's question. I mean, have we looked at -- I think we're making an assumption here that home visits obviously drives up risk scores, but we don't talk about the impact on other costs. Do we look at, or have we looked at medical trend of plans or members that have these home assessments to see if there's any differential, because my -- I think we've seen that in many of these, you end up catching or identifying issues that, frankly, if they kind of were not caught would lead into more hospitalizations, those types of things. So, I didn't know if there was any data or any assessment that's been done in that area.

DR. MILLER: In that circumstance, Warner, wouldn't you also expect to see some other action -- not hospitalization, but some other action on the diagnosis? I mean, the phenomenon here is it shows -- again, as best as

we can estimate it -- the phenomenon here is that somebody identifies something, and, you know, asthma was one thing that was thrown on the table, and then nothing else happens for the rest of the year. And I think one question is, is that possible? Is there a condition where there wouldn't be a follow-up?

Now, the question, I think, we have to contemplate here is whether anything happens or not, in one example, $2,800 is added to the payment. The second is, if they're identifying a condition and nothing else happens, is that -- it's the reverse of that question. Isn't that odd? And, I think, there's some clinical judgment involved in this that makes it complicated. So, I just wanted to get that out.

MR. THOMAS: And I think that's an absolute fair assumption. I just -- I didn't know if there was, over time, an impact or any sort of analysis on the medical cost or trend of the different populations of patients and if there's a difference.

DR. MILLER: And I think one of the other complexities here, Andrew, in answering that question is, this is the encounter data for which we have one year,

right, and, so, we're a bit stymied in thinking about your, yeah, well, what about the trajectory, kind of question.

MR. THOMAS: And I guess the other question I have, do we know of any -- are there any of the ACOs or folks that are in alternative payment mechanisms -- to bring that back -- that are using this model in those different payment mechanisms and could that be something that could be looked at, as well.

DR. JOHNSON: That's certainly something to look into. I'm not sure what our ability is to do that, but that's a good suggestion.

DR. MILLER: But, Andrew, this does go on in fee-for-service, right?

DR. JOHNSON: In the ACO context, I think, yes.

DR. CROSSON: Okay. Clarifying -- sorry. Still on clarifying?

DR. REDBERG: Just a comment on that.

DR. CROSSON: Yeah.

DR. REDBERG: Just looking, again, in the mailing materials on page 13, Table 1, at the list of the diagnoses that were identified by HRA, it does kind of raise questions, you know.

DR. CROSSON: It seemed a little --

DR. REDBERG: Polyneuropathy was the most common --

DR. CROSSON: -- a little creepy.

DR. REDBERG: That's a little, like, non-specific. You can't really diagnose polyneuropathy, I don't think, on a home visit, and a lot of people will -- various non-specific things that one could say.

DR. CROSSON: I agree.

DR. REDBERG: Vascular disease. They're just kind of waste bucket, sort of.

DR. CROSSON: It's not like broken left arm.

DR. REDBERG: Yes.

[Laughter.]

DR. REDBERG: And they are things I would expect, if they were really there, they would have follow-up.

DR. CROSSON: Okay. You thought that was a good addition here.

[Laughter.]

DR. MILLER: Sorry. I'll be --

[Laughter.]

DR. CROSSON: Listen, I spent a lot of years in

training, you know, to be able to say something like that.

[Laughter.]

DR. CROSSON: Okay. So, let's have a discussion. We've got some options on the table. Let's have a discussion about the options that we've been presented with, and who would like to lead the discussion? I see Cori and Craig -- Cori and Craig. Cori.

MS. UCCELLO: So I think this whole chapter is great, but I just find it very troubling. I think it's hard to argue that these kinds of assessments are done for disease management and care management purposes when you don't see these codes showing up elsewhere. So I support both of these options, notwithstanding kind of Kate's question about how much would we expect it to show up.

And another thing to think about there, too, is if -- and I think this was mentioned in the chapter. If it doesn't show up later, if there wasn't any care specific to that needed, well, then, it's not contributing to higher costs, so it shouldn't be adjusted for in the payments. And I think this highlights how these uniform downward adjustments for coding really aren't appropriate because they over penalize some and underpenalize others. So I

like the way that this better aligns things. If you just -- you know, you can still do the assessments. They can still help you with your care management if you find that, you know, of value. But the codes will show up elsewhere if indeed these were real issues that needed care.

DR. SAMITT: So, you know, I've worked in organizations similar to what Warner described that really have relied heavily on alternative visit locations. You know, I think that we tend to think within our existing paradigm that all care needs to be delivered either in the hospital or in the provider office, when I think the world is evolving to a point where patients have mobility issues and there's a lot of value that can be identified by visiting the patients at home. And I think a lot is missed if we don't focus on care delivered at home.

So I'm concerned that we would make a policy, a blanket policy recommendation that would penalize everyone when what we really want to focus on is where are the bad actors here, where coding perhaps may be happening that is inappropriate. The experience that I've had is these home visits and home risk assessments do identify gaps that the clinical team can then help fill. And the reality is that

the services that are provided to fill these gaps may not result in another encounter, so it is a fall risk assessment or med reconciliation or even phone-based telephonic case management that assures that these patients don't get into trouble.

And so I'm concerned that we're undervaluing sort of the promise and the importance of home visits. So I'm not so sure. I think if I were to really focus our attention, it stems from a lot of -- the difference on Slide 10, I think it is, that identifies the fact that there are some real outliers here, and I'm most interested in studying these outliers. Perhaps what we should do, as opposed to essentially eliminating coding that's associated with HRAs, is to really look at where we see differentials, either between RAPS and encounter data on a global basis at a contract level or other examples of outliers that we really should be studying and auditing but not necessarily making a universal policy that applies to all.

DR. NAYLOR: So I fully concur with Craig in terms of the extraordinary value of the home visit for all of the reasons that you described, and as you suggest, Andy, as a major prevention tool, care planning tool,

opportunity to really understand fully risks that people are experiencing.

That said, I think that this notion of using the National Academy of Medicine report on diagnostic errors, the notion that using it as the opportunity to come to real accuracy and diagnosis and coding I think extends the -- I mean, I think that the home visit creates the communication avenue for risks to the team that can be then involved in actually doing all of that follow-up work. And the fact that it's not happening, there isn't that follow-up, is really of concern.

So, anyway, I support Options 1 and 2 simultaneously. I think that gets us to a playing field where people understand how we can use all contexts, but use them for the ways in which we can communicate, assure continuity, get to accuracy and diagnosis.

DR. MILLER: Can I just inject one thing as we go around. I'm really sorry. Andrew, you raised this concern about any policy that would create a barrier to going into the home. Option 2 I'm not sure does that.

DR. JOHNSON: Option 2 does not. It just uses two years of data.

DR. MILLER: Okay. You don't have to -- I want you to think about --

DR. SAMITT: Of the two options, I'd be more concerned about Option 1. Option 2 I think is very valid because it gives a greater window, that if there is going to be a follow-up encounter, which we ultimately do want to see, to validate some of the risks identified in the home, having a longer period of time makes sense. I'm more concerned about Option 1 with a narrow window.

DR. NAYLOR: So Option 1 doesn't prevent the home visit. It really sees it as part of the whole continuum of care and encourages risk assessment. I think that that's exactly what could and should be going on. Then the communication of the risks that lead to the whole diagnostic process is part of what we want to see. So I don't think that -- I didn't interpret that at all as discouraging home visits or health risk assessments in home visits. I specifically was talking about the coding or diagnostic process that seems to be going on in those visits.

MR. KUHN: So I liked what Craig had to say because, you know, to me, at least the difference now with

MA is their ability to detect disease early and hopefully promote early care. And I think that's what we all should be about as part of this process. And, also, how can we improve the accuracy of predicting health care costs? So I can see how these health risk assessments can help us go there, but I've listened to the other sides of the concern about the not follow-up care that's out there.

So I'm interested in the two proposals out there, but I would like to see, if possible, a refinement per what Craig suggested of looking maybe at the outliers as well. It doesn't preclude us coming back and visiting these, but I think it would be nice to at least look at that either refinement or yet a third option to at least see what that would look like and how meaningful that might be in terms of addressing some of these issues, because, again, we don't want to do anything that doesn't promote this early care and this early detection, but also we want to make sure that, per the earlier conversation, we don't create program vulnerabilities here either.

DR. CROSSON: Okay. I see Warner nodding. Rita?

DR. REDBERG: So I do think home visits can be very valuable as part of the clinical care team, but I also

support Options 1 and 2 because I think we should think about -- I mean, when I think about what a home visit can offer that I can't do in my office, it's to do things to evaluate safety and health at home. So, you know, looking at fall risks for older patients, looking at, you know, what's in the fridge, what are you eating, what's the home environment like, are there health risks identified at home, you know, social situations that seem unhealthy, how are your medications organized and if there's some way we could improve on that. But none of those are going to result in an HRA diagnosis, particularly one that wouldn't be identified in follow-up care in the office. And so that's my concern, is that that's not what it's being used for. It's being used for up-coding and increasing payment, but not really things that are helping our beneficiaries and preventing future problems.

DR. HALL: Well, I support both options as well. And just to highlight the important of these home visits, the practice that I belong to consists of a lot of frailer older adults. In fact, almost all of them are frailer older adults, and about 80 percent of them are in MA plans. We would not be able to run our practice if we did not do

home visits, sometimes for assessment, but sometimes for more than assessment. We're very convinced that this keeps people out of the hospital and keeps them healthier.

In fact, it's significantly enough important to us that every one of our first-year residents who are trained in our programs cannot finish successfully the year unless they have participated in an interdisciplinary home visit that is videotaped, and then they have to present a conference to their peers on this, because there's so much value in these home visits, particularly for the frailer or elderly person.

Where this is evolving I'm not sure, but it has linkages to a couple of our other ongoing themes. One would be bundling. I don't see how you could do successful bundling, whether it's a hip fracture or whatever, without having some mechanism to assess people in the home.

Also, we've talked a lot about getting involved in telemedicine. I think telemedicine is going to totally revolutionize the home visit. It's going to be a very different thing. It will have its own issues about billing and all the rest.

To be sure, there are abuses. There have been physician groups that have overly utilized these services and also were very much involved financially in home health care agencies and pharmacies. There have been some notable examples of that.

But this is really something we didn't want to throw the baby out with the bath water here. I think this is a very important part of the care of older adults, so I think we could make a contribution to this in terms of MedPAC.

DR. CROSSON: But, Bill, just to be clear, you support Option 1 and 2?

DR. HALL: Yes, I do Yes, 1 and 2.

DR. HOADLEY: So I also support the combination of Options 1 and 2. I guess I'm trying to think about Craig's comments, and I guess one question, Andrew, is on the -- when you added that second sort of variant on the coding that says here "HRAs plus home E&M visit," so there's still an indication on that event, that encounter, that there was an HRA included in that, so that a straight home visit, home E&M would or would not be in that category?

DR. JOHNSON: It would be in that category. So there was not another indicator identifying that a health risk assessment was taking place. There was some other background information, and CMS has said that they believe that many of the home visits taking place include a health risk assessment. But our analysis including home E&M visits is attempting to capture some of those that we couldn't identify in the data but may have some additional --

DR. HOADLEY: So if there's a home E&M that was more about follow-up and treatment, that would get lumped in in this case with the codes that you've used?

DR. JOHNSON: Yeah, in this analysis today, yes, it would. If we could conduct this analysis using the 2014 data, we'd be able to -- or the flag that CMS has been collecting that identifies when a home health risk assessment has been used to identify a diagnosis, that would be an improvement in the accuracy of identifying when health risk assessments are used.

DR. HOADLEY: So from the point of view of Option 1, I mean, we wouldn't be -- you know, in the kind of scenario where Craig talked about it, there's a home visit,

to go ahead and respond to the things that were raised in the assessment, with the newer codes you're talking about, that could be distinguished. So that would at least help.

And I guess I'm also wondering if we have -- what understanding we have about the kinds of things that MA plans can do for treatment that maybe aren't allowed under fee-for-service. So, you know, other kinds of encounters that wouldn't be payable separately under fee-for-service, they can still presumably generate these kinds of encounter codings. And so I'm just trying to think through and whether we have information on making sure that Option 1 doesn't go too far in the kinds of things that Craig was raising. I don't know if I'm being clear or not.

DR. MILLER: Well, I'm going to ask, because I -- I'm sorry. I know we've got to be conscious of time, but I need to extract this to make sure that when we come back -- the thing that tripped me up on your two exchanges, Andrew, when they get the new coding in place, the flags, it indicates whether it occurred in the home.

DR. JOHNSON: In the home from an assessment.

DR. MILLER: And it almost sounded like you said in response to his question that it also indicated whether

it was follow-up care or whether it was -- oh, I see. So it would be an indication that it was an assessment in the home.

DR. JOHNSON: Yes.

DR. MILLER: And then anything else that happened in the home, we would under Option 1 count or not count?

DR. JOHNSON: Count, under Option 1.

DR. MILLER: Okay. Now, I think I see the distinction that you guys are making, and I apologize. I didn't follow it.

DR. NERENZ: I would be inclined to like Option 1, but I want to make sure I understand the full implication of Craig's comment, because what I thought I was hearing is that there would be subsequent encounters that would effectively deal with the thing identified, but they would not show up in the billing system under our usual common definition. Is that basically a paraphrase of what you said?

DR. SAMITT: Yes, I guess I'm more interested in knowing the follow-up encounters that would be needed. What counts there? And are there services that MA plans or others or delivery systems could be providing that wouldn't

count that would be follow-up management of complex risk?

DR. JOHNSON: All of the other services included in the risk adjustment model would count, so that's physician and other health professional face-to-face visits. For the encounter data, CMS has proposed using some CPT and HCPCS codes as a filter for physician visits when they are replicating what encounters to use as a source for diagnoses in the risk adjustment model. So there is some mechanism that they are looking closely at that, but if a physician visit would be included in the risk adjustment model now, it would continue to be a source for diagnoses under Option 1.

DR. NERENZ: But I thought, Craig, your point was what about things other than physician office visits. There would be legitimate things that would be appropriate, clinical responses to the thing identified at the home visit that would not currently show up under a narrower definition of an encounter, and that would be a flaw in this approach. Again -- okay.

DR. MILLER: But, again, I thought that's what Jack was dealing out. I thought I understood it. You guys, you've taken advantage of me.

DR. HOADLEY: The point I would say is -- I mean, we don't necessarily have to resolve this in this conversation, but we can create, it seems like, or at least build the knowledge base around Option 1 with the goal of making sure that the scenarios that Craig is talking about don't penalize that organization because they did follow up. Whether they all exist today in the codes, maybe it's a modification of the codes.

DR. MILLER: Agreed. That's kind of what I'm thinking, too, but I'm also trying to keep an eye on him, like, you know, what information will be available to do it. Because the other way to answer that question or this concern here, we're just going to tell you what's going to be ruled out, and anything else that's going on that currently is ruled in and counts we're not going to take on. And I'm just trying to make sure that the coding that they change and is going to start showing up in 14, or whatever you said there, allows us to construct the policy that way. And if we need to have this conversation, we'll take it offline. But I think I'm hearing the principle, which is, you know, this circumstance won't count in your risk order, but everything else that's out there we're not

-- you know, we're not going to interfere with that. That's what I think the philosophical bent is here, and then I'll work with Andrew to figure out whether we have the information to implement that. Is that okay, or are you having --

DR. JOHNSON: No. I'm on board with that.

DR. MILLER: Okay.

DR. COOMBS: So I support Option 1 and 2, and one of the issues that I had -- and I think it's okay to say that the last row could be however you wanted to have a provider come in, whether it's a private physician visit, provider visit, nurse practitioner comes into the house, makes the diagnosis, or the patient gets referred to a clinic. That last is that it's confirmed -- the encounter is confirmed by some health -- some entity in the health care system.

The piece of it that's really kind of hard with the list on page 24 and 25 is you have these diagnoses that are pretty dramatic, and they're only diagnosed with the HRA-only frequency, and as I was trying to tease out from the focus group, what about the follow-up care when something is discovered in terms of actual benchmarks? I

look at schizophrenia, and 1,300 people who were just HRA, and they say, "Okay, you're schizophrenic. Bye."

[Laughter.]

DR. COOMBS: No follow-up. I mean, okay, you're going to stay at home. No meds.

I'm just trying to reconcile that part of it, and so -- and it might have been a check-off list that a vendor came in and said schizophrenic, thought disorder, delusions. I mean, so that piece of it is still kind of -- I guess is ruminating within me.

The rest in terms of the last row, I don't have any problem with that. And I think Kate said it. If you have an asthma attack, someone came in and says you have asthma, and they never, ever had another symptom for two years for the second option, then you'd have to say that didn't increase your risk. At some point you have to say -- there has to be a line drawn about what would increase your risk so that you get a pass on the severity of illness or co-morbid condition.

MS. BUTO: I like Option 2 because I think it will further reinforce the plan's attention to encounter data. And I actually think that if you choose Option 2,

implicitly you also are choosing Option 1 and vice versa, because if you choose Option 1, which is don't count, you know, the visit as -- the HRA visit as a way of achieving risk adjustment or contributing to risk adjustment, then you have to have some way of doing risk adjustment. It strikes me that you would then turn to the data. Whether it's two years or one year or three years, I don't know. But I like the idea of strengthening the resolve to submit encounter data and then some ability for the agency to deal with what could be great variation of the use of home visits, as we saw, to contribute to risk adjustment by really turning to the data.

So to me, it solves a real problem, and then on 1, I think a good MA plan is going to do home visits as needed, for all the reasons that people have said.

DR. CROSSON: So you don't think Option 1 would -- you're supporting Option 1 as well? You don't think that would inhibit the --

MS. BUTO: I assume a good plan is going to do Option 1. That's home visits for a variety of purposes, not for risk adjustment, right? And the question then becomes, well, then, how do you do risk adjustment? And I

think you have to either turn to Option 2 or something like Option 2, which is you rely on data to inform that.

DR. MILLER: It's that sentence that just throws me off, but I want to really nail the exchange the two of you just had.

And Mary made this point very strongly, which is you can still do home visits, and if they help you plan care and follow up on care, there's nothing about Option 1 that prevents you from doing that.

But then you said you have to turn to a different -- or to the data to do risk adjustment. I mean, in a sense, what we're saying with Option 1 is you're doing all these types of things with the patient. You're seeing them in an office. You're seeing them in a hospital, and all that feeds into your risk adjustment score. And then there's this sliver of, but if this shows up here in the home and nowhere else, it doesn't count.

And so we expect they're still engaged in all this activity and using that information to get the risk score for the beneficiary. It's just this one sliver where it would say home risk assessment only, and that's the only place that code shows up? Then it doesn't count.

MS. BUTO: And my point was just that Option 2 is using the data. So I don't know why we're choosing between these because I think they are kind of going to go hand in hand.

DR. CROSSON: I'm sorry. It's not clear we have to choose between them. Choose one or the other or both or none.

MS. BUTO: Right.

DR. CROSSON: Jon.

DR. CHRISTIANSON: I like the Option 1 and 2. I think they are cleverly put together.

I would say that there's still a potential to not be equitable to MA plans that are doing risk adjustment -- or doing home visits appropriately, identify a code that's legitimate, and I think about, if I'm saying this right, we're saying before that, the patient shows up in an office and has the code confirmed there, you're not going to get paid at the higher rate.

DR. JOHNSON: No, you will get paid at the higher rate.

DR. CHRISTIANSON: Okay. So you get paid at whatever you submit based on the home visit, and then it

gets taken away from you later or not?

DR. JOHNSON: No, not based on the health risk assessment. But if that beneficiary then goes to the physician's office and the same diagnosis is identified in that setting, it will be included in the --

DR. CHRISTIANSON: So it depends on, doesn't it, how long it takes before the person goes to the physician's office because you'll be paid? No?

DR. JOHNSON: No.

DR. CROSSON: Well, there probably is some issue in the data. If the home visit and the HRA is in November, right, but the patient doesn't get in to see the physician for a confirming thing in January, those are in two different claims years.

DR. JOHNSON: That's correct.

DR. CROSSON: So that would --

DR. JOHNSON: And that's the same timing issues that would occur in the current setup, with or without Option 1, and that the data collection year is strictly the calendar year, and it's used -- data from that year is used to predict spending for the next calendar year, so --

DR. CROSSON: Right. Okay. But that would be

made up -- that problem would be made up in the subsequent year?

DR. JOHNSON: Correct.

DR. CROSSON: Well, yeah. I mean, you can't go back and change the payment for the previous year.

Kate had something, and then Scott.

DR. BAICKER: So I'm supportive of these options. I don't think that they will discourage home visits because it's such a small piece of what should be going on in the home visit. So I'm not worried about that.

I think it would be -- this is -- my understanding of our goal is to try to identify a situation where we really think there is just coding intensity going on that's leading to higher payments. That is not really warranted by the health care needs of the patient, and you've flagged a really salient one of these things that show up only in HRAs at home health visits.

So it's not that HRAs at home health visits are bad; it's that we think it's a particular source of this potential up-coding.

So to understand the degree to which that is a good -- both sensitive and specific, it would be nice to

have a better understanding of those questions about when things show up later, what does it mean? Should they show up later? Shouldn't they show up later? Is there a way to write something down that's slightly more specific where something that shows up in a home health visit that really should show up later and doesn't is more suspicious than something that shows up in a home health visit and you have no reason to think that it should necessarily show up later?

So if we can tweak the -- maybe the broad bucket is about as sensitive and specific as we're going to get and it's fine, or maybe there's a way to slightly refine it to flag more of the problematic cases.

What I want to be careful not to do is inadvertently introduce -- undo our perspective or our risk adjustment that's independent of the care used by saying, "Ah, you get a higher payment if you enroll these patients and send them to the hospital," or something like that. So we want to be sure that the -- we don't want to go so far as to incentivize utilization to justify the diagnosis that otherwise we were going to disallow, and that I would think would be a bigger risk in some kinds of diagnoses than

others. And that would play into trying to write down perhaps a more focused list of diagnoses that are not subject to that, not inducing utilization, and more likely to show up in this kind of behavior.

DR. CROSSON: Scott.

MR. ARMSTRONG: Yeah. I just wanted to repeat a point that Craig had made earlier, and I was worrying it was getting a little bit lost in this, because it reflects my discomfort with Option Number 1, and that is just that we have teams of MDs, nurse practitioners, others going to patients' homes and drawing conclusions, both through a really engaging health risk assessment dialogue and all this kind of stuff. And there could be a really legitimate, effective course of care that doesn't trigger subsequent HCCs, and we just need to make sure we're not discouraging what could actually be exactly the kind of future we want to encourage going forward.

And so I just wanted to restate Craig's point on that one more time as we go forward looking at this policy.

DR. CROSSON: Warner and then Jack, and then I think we -- and Cori. We have five minutes.

MR. THOMAS: I'll be really brief. I would

concur with Scott's point and Craig's point.

If you look at slide 10, you can see on this slide, you've got a small percentage of folks that are out to the right that I think are problematic. And I would encourage us to maybe look at more of the excess or the problematic areas versus having a blanket approach to this, because I think it could have very negative consequences on the type of preventative care we want to have.

DR. CROSSON: I'm sorry. I forgot already. jack and then Cori.

DR. HOADLEY: I just wanted to go back and try to clarify. With these options, are we replacing the across-the-board adjustments that are being used now or replacing the higher across-the-board adjustment that we've called for in the past? How do they interact with what's being done now?

DR. JOHNSON: I think Option 1, 2, and an additional single factor adjustment would replace the current format, but the single factor adjustment that exists now would still exist. But it would need to be adjusted in size to account for the difference in -- of impact and coding differences after implementing Options 1

and 2.

DR. HOADLEY: Okay. Because part of the advantage of this, as you had laid it out, is that instead of being the blunt tool that sort of penalizes all plans for the assumption that somewhere in the system there is this inappropriate coding. It tries to target it better to where that coding exists, and so that would actually -- a plan that would kind of do things by the board would actually benefit off of this.

DR. CROSSON: Cori, the last word.

MS. UCCELLO: Yeah. Just building off of what Kate said, that was the concern about not giving incentives for plans to have an assessment, find a code, and then justify it by encouraging follow-up. That's actually why I had asked Andy about the left side of slide 10, understanding a little more about those plans on the left. Are they just finding more legitimate codes, or are they finding ways to justify the codes that the other plans did not? And so understanding that more would, I think, give us a little more confidence that doing this would not provide kind of perverse incentives.

DR. CROSSON: Okay. And then -- yeah, go ahead.

DR. SAMITT: Mine is just a follow-up request. We have spent most of the time talking about HRAs as it relates to risk adjustment, and I know -- I can't remember whether it was last year or the year before we had a discussion about the general accuracy of risk adjustment. I am wondering if we could have another conversation about it, because I do wonder what's the latest thinking about the accuracy.

We didn't talk about excluded codes. We didn't talk about the single factor adjustment and whether that's fair and equitable within MA. So I don't know whether there's room in our agenda to process this a little bit further, but I wonder if we should.

DR. CROSSON: Okay. So I did a little informal count here, and we didn't spend a lot of time on Option 2. We had one mention of Option 2. We spent most of our time really on Option Number 1 and whether we should do that or not, and I've got something like 7 to 4 and-a-half in terms of let's do it or we have significant reservations.

From my own perspectives, I think looking at the case that's been made here, if you combine the distribution curve on slide 10 with the nature of the diagnoses that are

listed, most of which are rather subject, to put it one way, it sort of suggests that somewhere out there, there is a set of behaviors going on which at least are suspicious if not, frankly, abusive, and that what we need to do, if we can do so, is to craft a solution for that.

So I think we can't -- my guess is with this degree of split, I don't think we're ready to make a decision on this. You've had some suggestions about additional information that I think we could look at. I think anything that we can get, for example, that could help us hone in both in terms of information that you could elaborate -- and I realize the difficulties of what you're dealing with in terms of the data -- in terms of where this behavior is going on, the characteristics of it, the characteristics of the organizations, for example, and see whether or not we can come back the next time with a more targeted option, at least as one of the options we address.

We may have to come back with these options as well, but that's kind of where I think we are.

Are you all right with that, Jon?

DR. CHRISTIANSON: Yeah.

DR. CROSSON: Okay, good.

Andy, thank you so much.

[Pause.]

DR. CROSSON: Thank you. We're right on schedule and we're going to take a look at the MA benchmark process. Scott has two proposals for us to look at which affect MA benchmarks, one moving in one direction, the other moving in the other direction, although presumably in different geographic areas, different plans, et cetera.

So, Scott, do you want to take us through.

MR. HARRISON: Sure. Good afternoon. In the last session, Andy discussed some inequities introduced by plan actions. In this session, I will be talking about inequities introduced by the MA payment system, specifically the setting of the county benchmarks.

Now, usually when we talk about Medicare Advantage benchmarks, the Commission has generally focused on the overall equity of MA payments compared with payments to the Medicare fee-for-service system, and we will revisit that comparison in our December meeting. This session, however, focuses on issues of equity across counties.

The use of county benchmarks and plan bids to determine payments to MA plans began in 2006. The original

MA benchmarks were based on the county-level payment rates used to pay MA plans before 2006. The Patient Protection and Affordable Care Act of 2010 changed the way benchmarks are set. We are currently transitioning to new benchmarks, and staff expects that in 2017, when all MA benchmarks have fully transitioned under the Act, benchmarks will average just slightly above average fee-for-service spending. So, we believe there will be rough equity between MA and fee-for-service Medicare. However, equity issues surrounding the distribution of benchmarks and payments across counties will remain.

We will first go over the basic benchmark setting process and then look at some policy issues surrounding three special provisions of the system. First, benchmarks are capped at county historical rates. Also, certain counties are eligible to receive double quality bonuses, again, based on historical factors. And, finally, we will look at how CMS calculates county-level fee-for-service spending.

Each county's benchmark, excluding quality bonuses, is determined by organizing the counties into quartiles based on their per capita risk adjusted fee-for-

service spending. Counties are ranked by average fee-for-service spending. The lowest-spending quartile of counties have base benchmarks set at 115 percent of local fee-for-service spending. The next quartile of county benchmarks is set at 107-and-a-half percent of fee-for-service spending, followed by a quartile set at 100 percent of fee-for-service spending, and the highest-spending quartile has benchmarks set at 95 percent of local fee-for-service spending.

Conceptually, low fee-for-service spending counties have benchmarks higher than fee-for-service in order to help attract plans, and high fee-for-service spending counties have benchmarks lower than fee-for-service to generate Medicare savings.

High-quality county benchmarks are calculated as the base benchmarks plus a quality bonus of five percent of the county's fee-for-service spending. These benchmarks are the benchmarks that apply to four-star or higher plans.

And, as I mentioned, we are currently transitioning to these benchmarks, and for 2016, 68 percent of the MA enrollees live in counties that have fully transitioned.

Now, let's talk about equity concerns. The first equity concern is that the payment formulations include a cap on each county's benchmark. The cap is set at the higher of the county's expected fee-for-service spending and the county's 2010 benchmark increased by a national measure of growth. So, a county's cap is calculated and then compared with the benchmarks I described on the last slide.

The concern is that local fee-for-service growth will naturally vary around the national growth rate, and there is no reason to think that the distribution of relative spending in 2010 should be perpetuated forever.

If the cap is below the base benchmark, the benchmark is base capped, and because the cap is also compared with the higher quality bonus benchmarks, the caps can more frequently be bonus capped, resulting in the denial or limitation of quality bonuses.

For 2016, benchmark caps will apply if a county's 2016 benchmark is projected to be more than approximately six-and-a-half percent above its 2010 benchmark, and if the benchmark is above the estimated 2016 fee-for-service spending in the county. Counties are most likely to be

affected by the caps if their relative spending has grown faster than the national average.

Nineteen percent of MA enrollment is affected by the caps on the quality benchmarks. They are enrolled in high-quality MA plans in bonus capped counties and the plans they are in are losing some or all of the quality bonuses.

Six percent of MA enrollment lives in base cap counties where the benchmarks are capped below the base rate. All of the MA enrollment in these counties is affected by the caps.

Now, if you look at the zero percent in the middle of the right-hand column, you will notice that no base benchmarks are capped in the highest-spending quartile, and that's because the base benchmarks for these counties are already set below fee-for-service spending.

The bottom row shows the average benchmark reduction caused by the cap. It estimates that at $40 per member per month, although some counties have reductions over $100. The lower-spending counties see larger reductions than the higher-spending counties.

The benchmark caps create inequities across

counties. Some counties have lower benchmarks than similar spending counties because of the outdated fee-for-service spending patterns perpetuated by the caps. Mostly, the caps cut the quality bonuses available in some counties, and one option for addressing the inequity would be to eliminate or limit the effect of the cap.

Another source of inequity is the double quality bonus. PPACA allows certain counties to receive double quality bonuses. There are three criteria to be one of these counties. First, the county must have been paid urban floor rates in 2004. Okay. Urban floor counties must have been in metropolitan areas with a population of about 250,000 -- of at least 250,000 people and had fee-for-service spending below the floor level.

Second, at least 25 percent of Medicaid beneficiaries in the county had to have been enrolled in a private plan in 2009.

And, the county's projected fee-for-service spending must be lower than the national average.

For 2016, the 236 double bonus counties are dispersed around the country, but the process is inequitable across counties because the double bonus is

tied to old geographic spending patterns rather than additional quality performance.

Looking at the effects for 2016, 19 percent of MA enrollees live in the 236 double bonus counties and were enrolled in an MA plan with four or more stars in 2015. Because all the counties in the 95 percent quartile have fee-for-service spending above the national average, there are no double bonus counties in the 95 percent quartile. Also, there are fewer double bonus counties in the 100 percent quartile than in the two lower-spending quartiles.

Assuming the county benchmarks are not capped, the double bonuses will add an additional five percent of fee-for-service to the county high quality benchmarks. The maximum double bonus in 2016 would add $40 to the county benchmark for high quality plans.

Again, the double bonus policy is not separately linked to additional quality performance and perpetuates old payment distribution policies. The policy is inequitable because it pays some plans twice as much to reach the same levels of quality performance.

So, we have one policy, the benchmark cap, that inequitably lowers benchmarks and quality bonuses for some

counties, and another policy, the double quality bonus, that inequitably raises quality bonuses in some counties.

One option to address the inequities would be to eliminate both the benchmark caps and the double bonuses. This option would simplify the MA payment system while improving equity across counties.

This chart shows that the caps, weighted by MA enrollment, currently lower benchmarks by a total of $821 million in 2016. The bulk of the reductions are for enrollees in the lower-spending counties. At the same time, the double bonuses raise benchmarks by over $1 billion, with the increases also occurring across the three lowest fee-for-service quartiles.

We estimate the elimination of both the benchmark caps and the double quality bonuses would result in a net reduction of benchmarks of $197 million for 2016, although it would be possible to make adjustments to have the changes be budget neutral.

Note that, for the most part, the cap reductions in the double bonus, the increases are distributed similarly across quartiles. Through eliminating these two sources of inequity across counties, we could simplify the

MA payment system, keep aggregate payments roughly constant, and keep the distribution of payments across quartiles from changing a great deal.

Now, let's consider the measurement of fee-for-service spending. The starting point for calculating a county benchmark is the estimate of the county's Medicare fee-for-service per capita spending. CMS has been calculating county level fee-for-service spending by adding up all the fee-for-service spending for the county residents and dividing by the total number of fee-for-service residents. When CMS does this, it includes all Medicare beneficiaries who have either Part A or Part B or both. The main problem with this approach is that MA enrollees must be enrolled in both Part A and Part B, and we have found that beneficiaries who are in both Part A and Part B have higher spending for Part A than those beneficiaries who were enrolled in Part A only, meaning they were not also in Part B.

We found that in 2012, nine percent of beneficiaries enrolled in Medicare fee-for-service and Part A were not enrolled in Part B. The percentage of Part A only beneficiaries ranged across counties from about one

percent to 22 percent.

Given that we found that beneficiaries with both Parts A and B have higher Part A spending than those beneficiaries without Part B, we are concerned that the uneven distribution of Part A only beneficiaries could lead to inequitable fee-for-service calculations across counties. Simply put, in counties where a relatively large share, say 20 percent, of fee-for-service beneficiaries are Part A only, fee-for-service will likely be underestimated. And in counties where a relatively small share, say three percent, of fee-for-service beneficiaries are in Part A only, fee-for-service will likely be overestimated.

I did a quick look and confirmed those likelihoods, but more work would be needed as a comprehensive solution would need to examine the relative spending and relative risk of different groups of beneficiaries, including those with both Part A and B, those with Part A only, and those with Part B only. If you would like, we could invest some more time on this issue and report back.

In summary, we have identified three sources of inequity across counties in the current benchmark setting

system. Benchmark caps reduce some county benchmarks based on old fee-for-service spending patterns. The double quality bonuses increase some county benchmarks based on old spending patterns. And the measurement of fee-for-service spending based on the spending of beneficiaries with Part A or Part B can lower the benchmarks for counties with relatively high shares of Part A only beneficiaries.

The caps and double bonuses could be eliminated together to improve equity and simplify the system. We are not ready with a fleshed-out option on the fee-for-service spending measurement, but we can continue to examine the potential of using only data from beneficiaries with both Part A and Part B to measure fee-for-service spending.

Thank you. I look forward to your questions, comments, and guidance on these issues.

DR. CROSSON: Thank you, Scott.

We are up for clarifying questions. Craig will start off, and then we'll go that way.

DR. SAMITT: So, on Slide 3, but also referencing some of the material sent in advance, I'm having trouble with the math. So, we talk about benchmarks being set in the four quartiles that have the weightings as described

here, but then the average benchmark is 101.5 percent of fee-for-service spending. So, if you think about the allocation in these four quartiles, this does not average to 101.5 percent. So, I'm having trouble with the discrepancies.

MR. HARRISON: The 101.5 would be enrollee weighted. Each quartile has the same number of counties, so --

DR. SAMITT: Right. So it's not enrollee-based.

MR. HARRISON: Right.

DR. SAMITT: I've got it. And then my second clarifying question, do we have available information that shows the trends of the per capita costs in each of the quartiles over time? So, I'm just curious that the 115 percent for the lowest cost quartile has been in existence for a while, but what's been happening to the PMPM cost in that quartile over time? Would it be valuable -- or I would find it valuable to look at that trend over the years.

MR. HARRISON: I mean, I save the worksheets from every year, so we can certainly go back a few years and come up with something for you.

DR. SAMITT: It would be interesting to see what's happening there. I mean, it's a different topic that we should discuss about whether the 115 percent is still right. But as the trend begins to rise in the lower-cost counties, how applicable does this weighting -- is this weighting still relevant to, essentially, what's been happening with the baseline costs.

DR. CROSSON: Okay. It's a little on the margin of a clarifying question versus position, but for the moment, we'll accept it.

DR. SAMITT: Thank you.

[Laughter.]

DR. CROSSON: Clarifying questions. David.

DR. NERENZ: This is arithmetic, also. It really is clarifying. If we can start with Slide 3, this is going to be like Craig, go a little different direction. The counties that have the 115 percent, these are the low-spending counties.

MR. HARRISON: Correct.

DR. NERENZ: Okay. So, the benchmark is set in those counties by multiplying per capita fee-for-service by 115 percent, okay. That's three.

MR. HARRISON: Correct.

DR. NERENZ: Okay, now let's flip to four. It says, benchmarks are capped at the greater of the counties' fee-for-service spending. So, let's just pause there, okay. So, we've taken a low-spending county. We've gone up 115, and then we cap -- we come right back down again, it sounds like.

MR. HARRISON: The higher of, so --

DR. NERENZ: Yeah, but 115 is higher than 100 --

MR. HARRISON: It is, but -- no, it's the higher of their old benchmark aged forward --

DR. NERENZ: Well, and -- okay. That's what I want you to walk through.

MR. HARRISON: Yeah.

DR. NERENZ: Okay. So, it's the 2010 aged forward. Do you have an example? I mean, I think --

MR. HARRISON: Yeah.

DR. NERENZ: I just wanted to clarify the concept, but I just was trying to figure out how this cap doesn't immediately just contradict the effect of the 115 percent, but I guess it does --

MR. HARRISON: Okay. So, you do find that there

are more capped counties in the 115. That's true. But, what happened is -- so, in 2010, all the benchmarks were at least 100 percent of fee-for-service, but some of them were quite a bit higher, I mean, like up to 140 percent.

DR. NERENZ: All right. Didn't know that. Okay. Okay.

MR. HARRISON: All right, and so that's what gets aged forward, the old benchmark, not the old fee-for-service spending.

DR. NERENZ: And that's what can be greater -- thank you. Okay.

MR. HARRISON: Yeah.

DR. NERENZ: That's the missing piece. Thank you.

DR. CROSSON: Jack.

DR. HOADLEY: Is there any sense that the particular issues of either the double quality bonus or the benchmark caps is getting worse or better over time, or looking forward to the extent that you have a crystal ball to do that, or is this something that seems like it should be fairly stable from year to year?

MR. HARRISON: I guess the caps could get worse

each year, because, you know --

DR. HOADLEY: By the kind of logic you were just talking about.

MR. HARRISON: Right. If a county is growing faster, then they could bump up --

DR. HOADLEY: I was just trying to get a sense of --

MR. HARRISON: Yeah.

DR. HOADLEY: -- of scaling the problem. I mean --

MR. HARRISON: Yeah.

DR. HOADLEY: -- if this is something that was going to go away on its own, we might have less interest. If it's going to get worse, we might have more interest.

MR. HARRISON: In a sense, there's a limited population of counties that you can be double bonus. It'll only change from year to year based on whether or not they are over 100 percent of local fee-for-service.

DR. HOADLEY: Okay.

MR. HARRISON: I'm sorry, whether their fee-for-service is above the national average. But, all the other factors are historical.

DR. HOADLEY: Okay. My other question, on the A versus -- the Part A, Part B baseline measure, people who are -- one of the reasons people are in A and not B is because they're still working and their Medicare is the secondary payer. Are they still included in this calculation, because they would have, presumably, a lot less Medicare spending.

MR. HARRISON: They are included. Medicare secondary payer is a factor in the risk system, so -- although it's a little different. Plans get an adjustment based on how many MSP people they have, but, yes, I believe there are --

DR. HOADLEY: In terms of contributing to the baseline. I just wonder if that's a -- what that would do, if that's another piece that could be put into that way of --

MR. HARRISON: Yeah, and there is a sense that the A only population is growing as a share, also.

DR. HOADLEY: Right. Okay.

DR. CROSSON: Because of financial issues --

MR. HARRISON: People continuing to work, the high-income premium.

DR. HOADLEY: Also, a lot of federal retirees, presumably, who choose not to --

MR. HARRISON: I know some of them, yes.

[Laughter.]

DR. HOADLEY: They have double sources of coverage.

DR. CROSSON: Clarifying questions. Scott.

MR. ARMSTRONG: Yeah. This is maybe a little bit of a question about the history about how we got here, and these are -- so, I'm particularly talking about the cap that eliminates the quality payments, because these are two really different payment policy ideas. One, to reconcile Medicare Advantage with the regional fee for county-specific fee-for-service payment rates, and so you have these quartiles and we've been phasing them in over time and we're about to get there.

A totally different goal was to incentivize high-quality MA plans with this quality bonus. And, I just -- how did we get to the place where the quality bonus actually is part of the calculation that gets capped? It just seems like those were developed separately, or separate payment policies, and it just -- and now it

creates an issue that we're looking for a solution to.

MR. HARRISON: That's the way the legislation was written. I can't tell you what the intent was.

MR. ARMSTRONG: Okay. All right. Okay.

DR. CROSSON: Other clarifying questions. I'm not seeing any. I'm looking at Jon -- no, Jon? Okay.

So, Scott, we've got -- Scott has put three things on the table. One has to do with the capping in counties that has the effect that in some counties of essentially making part or all of the quality bonus disappear. The second one has to do with the fact that, for historical reasons, based on something called urban floor counties, which was always an interesting term, I thought, some counties receive double quality bonuses.

And those two things can and do, in certain parts of the country, create inequities between one county and the other. And so the question is -- there are two, or two-and-a-half questions here. One is, do we want to recommend changing those, and Scott has then linked them, I think in part because it happens that, at least from the perspective of the cost to Medicare, they kind of cancel each other out. And, in fact, we would be -- I think would

be resulting in a net savings to Medicare, not a net cost. But, they're roughly equivalent.

And then the third question is, or fourth, really, because one is do we want to do A and B, do we want to link them, and then the third one is, do we want more work done on the question of how to solve the potential inequity created by using -- if I've got this right -- only A and B for Medicare Advantage, but in fee-for-service, it would include people of only A or, in some cases, only B. Is that right?

MR. HARRISON: That's the current situation --

DR. CROSSON: Right.

MR. HARRISON: -- and the idea would be to make the populations similar --

DR. CROSSON: And what you're asking is --

MR. HARRISON: -- both A and B.

DR. CROSSON: -- is do we want to see you do more work and come back with a recommendation to resolve that issue, right?

So, those are the three questions on the table. We'll start with Kathy.

MS. BUTO: Just -- do they all require a change

in legislation, Scott? In other words, the A population being included, is that a choice by the agency, because --

MR. HARRISON: I think the agency has some discretion on the A and B issue.

DR. CROSSON: So, one would be a recommendation -- potentially, the first two or combined would be a recommendation to this Congress. This could be a recommendation to the Secretary, right?

DR. MILLER: And the only thing I would say is we kind of conceived of the two together because it was almost an equity issue of quality. So, you know, there's Scott's point of how is it that this ended up taking the bonus away, or part of it or whatever the case may be, and in the second case, I might be on the other side of the county line doing exactly what, you know, the same population, everything is exactly the same, you get paid twice, I get paid once. And, so, it's sort of --

DR. CROSSON: Right. So, it's not just a financial coincidence.

DR. MILLER: In fact, the financial thing was a little bit of a surprise, and we made Scott go back and check the numbers a couple of times.

[Laughter.]

DR. CROSSON: Thank you. That makes more sense.

MR. ARMSTRONG: You just made a point I wanted to --

DR. CROSSON: On this point?

MR. ARMSTRONG: You said the first couple of issues would require legislation and the last might not, and I just wanted to make sure. That's not necessarily my understanding, and are we really sure about that?

DR. CROSSON: Well, I mean --

MR. ARMSTRONG: I'm not sure that's really that important for us, but --

DR. CROSSON: Kathy asked the question. That's the answer we got, so --

MR. ARMSTRONG: Okay.

DR. MILLER: [Off microphone.] I mean, I wouldn't -- I'd be happy to go and --

[Laughter.]

DR. MILLER: I'd be happy to go back and check it. That was my instinct, too, and when he gave his answer, but we'll go back and check this, and particularly if you're not comfortable, we'll definitely look at it.

MR. ARMSTRONG: Okay.

DR. CROSSON: Craig.

DR. SAMITT: So, I think that these -- the recommendations make sense to me, the first two, in terms of removing cap and the double bonus counties. And I do think it's worth exploring alternative methodologies to develop an apples-to-apples comparison for benchmarking purposes regarding A and B.

My only caveat is what I'm not clear regarding the removal of the caps is why are we seeking to do that? Are we seeking to do that to appropriately award plans for achieving the quality bonus? Well, the other way to do that would be preserve the cap but allow the quality bonus to not count toward that cap. So, is there still a need to suppress something, quality aside, that would warrant preservation of the cap plus quality payment on top? So, I don't quite understand the distinction there. We certainly should remove the cap if folks are not getting recognized for quality. But if there's also some additional concern beyond that, maybe the alternative would be preserve the cap and pay quality separate.

DR. CROSSON: That would be an additional choice,

an additional option.

MR. ARMSTRONG: I'm not sure I know the difference. Could you --

DR. CROSSON: He's saying -- I think what you're saying is, leave the caps in place, but not apply the cap to counties who -- or to plans in counties that receive the quality bonus.

MR. ARMSTRONG: So, the quality bonus, you don't calculate toward hitting the cap?

DR. CROSSON: Hitting the cap.

MR. ARMSTRONG: So, how is that different than what's proposed?

DR. MILLER: It would -- Scott, I think what it would mean is there may be still -- it's not a lot, but there are still some counties that their base rate would be restrained a bit by this cap, and so instead of their base benchmark being here, it would be here, but then they get their full --

MS. BUTO: [Off microphone.] Quality bonus.

DR. MILLER: Right, quality bonus, and much smaller financial impact, would be my guess there.

MR. HARRISON: Most of the impact of the cap is

the quality.

DR. MILLER: Oh, no, actually, it wouldn't be a small --

MR. HARRISON: Yeah. Most of the cap --

DR. MILLER: You're right --

MR. HARRISON: Most of the impact of the cap is the quality.

DR. MILLER: That's right. So, it's still roughly the same cost associated.

MR. HARRISON: Roughly.

DR. CROSSON: But, as you said before, that's the observation now. That might not be the observation three years, four years, or five years from now, right?

MR. HARRISON: Could be. Could be.

DR. CROSSON: David.

DR. NERENZ: Just in support of that idea, I thought that's what your comment almost automatically implied, that they just ought to be run as separate things. Keep the cap on if there's a reason for the cap, but then let the payment float up above through the quality measure. Two separate things, not one thing.

DR. CROSSON: That was -- on this point, Kathy?

MS. BUTO: This point, yes. Can you just explain again how we get a lot of savings from eliminating the double quality bonus, but yet -- I think we're all talking as if the quality bonus is going to increase costs. Am I not following this?

MR. HARRISON: So, there's two separate things going on. One is there's this double quality bonus, and it adds --

MS. BUTO: It has three factors or three criteria.

MR. HARRISON: To get in there.

MS. BUTO: Yeah.

MR. HARRISON: And, basically, the counties that qualify for the double bonus are going to be pretty large counties. They're from urban areas. And, so, you have a lot of -- actually, the people turned out to be about the same. About 19 percent of people are in double capped -- sorry, in bonus capped counties, and about 19 percent -- not the same, but some overlap -- are in double bonus counties.

DR. MILLER: [Off microphone.] Was that your question, though? Was it about the populations, or I

thought your question was --

MS. BUTO: Well, I thought that the spirit of what Craig was saying was, hey, why don't we keep the constraint on trying to, in a sense, reduce the variation in the cap, the benchmark caps, which is what those benchmark caps are, is to reduce the variation around the country and try to move the low fee-for-service areas up in their caps, or allow greater growth, if you will. But, let's let the quality bonus float free, right? And, so, I was just trying to figure out, looking at the table, why the double quality bonus eliminate -- yeah, eliminating the double quality bonus gets you the big savings.

DR. MILLER: [Off microphone.] Because you're --

MS. BUTO: It's really the urban area issue, it sounds like, in part, anyway.

DR. MILLER: [Off microphone.] Well, I mean, there is this basic point, which is whatever you would qualify -- so, let's say a plan that has -- so, let's say you had a plan that qualified because it had the correct number of stars, four-and-a-half, five stars, and it qualified for a five percent bonus. In County A, it would get five percent. In County B, it would get ten. And this

would say, no, in both of those counties, they get five, and so that second county, it would bring it down to five. That's your savings.

Was that what you were asking?

MS. BUTO: Yeah, I'm just going to keep thinking about this --

DR. MILLER: Okay.

MS. BUTO: -- and make sure I follow the difference between the double quality bonus and, I think, the spirit of what Craig was talking about, which is let's free the quality bonus from these caps.

DR. MILLER: [Off microphone.] And then that's a different idea, which is in a different set of counties, the benchmark comes up against this cap, and this is what Scott and Craig, I think, are discussing, such that if I had qualified for the five percent, because I did all the right things, it would say, oh, no, there's no headroom. I can't give that to you. And, so, here, if we eliminate that, then the five percent goes in place and that's a cost.

MS. BUTO: Okay. All right. They offset each other.

DR. MILLER: [Off microphone.] Correct. That's the word.

DR. CROSSON: David.

DR. NERENZ: Scott, I wonder if you could state, or restate if I missed it, the rationale or policy goal for the double quality bonus --

[Laughter.]

DR. NERENZ: -- because I really think through the three criteria --

DR. MILLER: [Off microphone.] It was a non-policy reason.

MR. HARRISON: You didn't miss anything.

DR. NERENZ: Good.

[Laughter.]

MR. HARRISON: There were not discernible policy reasons for naming the counties that were named, or doing it the way they did it.

DR. NERENZ: Well, that's a clear answer. Thank you.

[Laughter.]

DR. CROSSON: Other points? Jack, are you looking at me?

DR. HOADLEY: [Off microphone.] I'm trying to decide.

[Laughter.]

DR. HOADLEY: I mean, the problem -- I think the thing we're struggling with is this is really down in the weeds compared to even some of the down in the weeds things we often do. I think it's just hard to grasp some of the pieces. It does sound like these are reasonable directions, with or without the modification that's been suggested, and there is a logic to sort of rethinking about the baseline, the A/B baseline, as well, although I do think maybe thinking about whether secondary payer belongs in there somehow or they should just be thrown out would be another way to -- I don't know what they would do to the numbers. Maybe it wouldn't matter, but -- so, I mean, I generally think this is a reasonable way to go.

DR. CROSSON: Going this way. Scott, and then Herb.

MR. ARMSTRONG: Yeah. I just very briefly would echo Craig's comments and say that, consistent with a question that I asked earlier, I think these are two different payment policies, and I'm really talking about

the problem we have with capping and, therefore, eliminating the quality bonuses in some markets.

You should have the four different quartiles and the caps and all that kind of stuff that's for good reason and so forth, but we really hurt what's an important policy objective of ours, and that is to pay for results, pay for quality, pay for performance, when, in fact, four-and-a-half and five-star plans are actually not able to get any incremental payment because they happen to be in a county that's bumped up against that cap. I just believe they should be separated the way we've been talking about it. Thanks.

DR. CROSSON: herb.

MR. KUHN: So, just one question about the quality bonus, and I think you're all onto something here about freeing -- I think it's, in Scott's term, freeing the bonus from the other, as well as Craig. But, I'm just trying to recall on the quality bonus, I want to think three or four years ago, at least in a comment letter, MedPAC was concerned about some of the functionality of the quality bonus or how it was put together, administered. Do I remember that correctly? And I just want to make sure

that if we're saying we want to keep this thing free, is it something we're saying that still needs further structure or change?

DR. MILLER: Carlos, do you want to --

DR. CROSSON: Funny thing. You're going to be here tomorrow, aren't you?

[Laughter.]

MR. ZARABOZO: So, this comment will substitute for my presentation tomorrow, is that correct?

[Laughter.]

DR. MILLER: It will not. We'll wait and see what it is.

MR. ZARABOZO: Yeah. The issue that was of concern to us was the weight given to measures other than outcome measures, that a lot of the measures were administrative measures, and so now that the method of determining the stars is different, there's more weight given -- you know, they have different weights, more weight to outcome measures, less weight to process measures, and medium weight to patient experience measures. So, our concern, then, was too many administrative measures went into the star system.

DR. CROSSON: Okay. I'm not seeing any more hands, and even a lot of people are avoiding my eyes.

[Laughter.]

DR. CROSSON: But, I seem to remember that from being in school.

[Laughter.]

DR. CROSSON: So, it has been a long day, but, I think, a very good one, very productive one, wonderful presentations and great discussion.

So, we will be coming back to this issue. Scott, I think you have some suggestions. Maybe we have a third option to put on the table. And, I think what we're hearing, or we didn't have a lot of discussion, was about it, was encouragement to go ahead with the A/B issue with respect to the benchmark creation.

Okay. Thank you so much, Scott.

Now, we have arrived at the end of our session and time for the public comment. So, if there are individuals in the audience who would like to make a public comment, I'd ask you to come up to the microphone so we can see who you are, or see that you're there.

[No response.]

DR. CROSSON: That was a bit of a head shake.

[Laughter.]

DR. CROSSON: So, seeing none, then we are adjourned to 9:00 tomorrow morning. Thanks very much.

[Whereupon, at 4:26 p.m., the proceedings were adjourned, to reconvene at 9:00 a.m. on Friday, October 9, 2015.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

Friday, October 9, 2015
9:00 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
KATHERINE BAICKER, PhD
KATHY BUTO, MPA
ALICE COOMBS, MD
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
HERB B. KUHN
MARY NAYLOR, PhD, FAAN, RN
DAVID NERENZ, PhD
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
CORI UCCELLO, FSA, MAAA, MPP

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P R O C E E D I N G S

[9:44 a.m.]

DR. CROSSON: Okay. Good morning. We're going to open up our Friday session.

As you may remember, Scott Armstrong had to leave last night. He was involved in an important work endeavor that he could not change. And Craig has let us know that he's going to be a little late, so he'll be here in 15 or 20 minutes. So we'll go ahead.

We have two presentations and discussions this morning. The first one is going to be part of our continuing work on assuring access to health care services for Medicare beneficiaries who reside in rural areas. Despite the fact that we have add-on payments to sole community hospitals, Medicare-dependent hospitals, and cost-based payment to critical access hospitals -- all vitally important programs, by the way -- some facilities serving rural beneficiaries still struggle financially, in part due to declining admissions. And in those cases, admissions are the basis for their payments.

So this morning we are going to explore some additional options to provide Medicare services to

beneficiaries residing in those rural communities, and we're going to hear from Jeff Stensland and Zach Gaumer, and it's over to you.

DR. STENSLAND: Thanks, Jay.

So we'll talk about new models to preserve access to care in rural areas, as Jay said, and specifically, we'll talk about two ways to move beyond the inpatient-centric models we currently have, including models where you focus on providing the payments toward outpatient emergency services. And before we start, I want to thank Anna Harty for her work on this project

Over the past couple years, there has been a concern over certain rural hospital closures. As we discussed in our March report to Congress last year, inpatient admissions have been declining for several years. As admissions decline, closures increase. For the past couple of years, the share of rural and urban hospitals that have closed has been similar. In rural areas, 30 hospitals have closed. And if we expand the definition of rural to include the rural portions of counties that are in MSAs, the number increases to 41 rural closures since January 2013.

Now, some closures are expected due to declining patient volumes and may be appropriate if alternative hospitals are located nearby. However, in some cases, hospitals have closed without nearby alternatives for emergency care. And it's precisely these situations that motivate today's discussion.

Since the start of the Prospective Payment System in 1983, there has been a series of programs designed to preserve access to care in rural areas. However, the current programs have historically focused on inpatient services, and the largest program uses cost-based payments. Despite these programs, we have seen this slight uptick in closures in the last couple years, including some hospitals that are 20 miles away or more from the nearest alternative source of emergency care.

So this raises the two key questions for today: First, what are the limitations of the current payment models? And, second, what can Medicare do to help preserve emergency access in these difficult situations?

The first limitation of the existing payment models is that they are inpatient centric. The sole community hospital program and the Medicare-dependent

hospital program both provide add-on payments to the inpatient rates. The low-volume adjustment is another inpatient special add-on that goes to 650 hospitals, some of which also get the SCH and MDH add-ons. So the money hospitals receive under these special programs is dependent on maintaining their inpatient services. The most common program, the critical access hospital program, provides added inpatient and outpatient payments. But to qualify for the CAH program, hospitals still must maintain inpatient capacity.

Now, the inpatient focus of these programs reflects the inpatient dominance of hospital inpatient services in the 1980s, and that's when these programs or their predecessors were started. However, this inpatient focus is problematic as we see fewer and fewer patients using rural hospitals for inpatient services.

Over the ten-year period from 2003 to 2013, rural hospitals saw a 12 percent decline in discharges on average. Critical access hospitals saw a 27 percent decline over the same ten-year period. Part of this reflects declining populations in rural areas. Some of it also reflects more specialized services being shifted to

larger hospitals with higher volumes, more practice, and more capabilities.

The trend of declining admissions has been strongest in recent years with a 4 percent drop in CAH discharges from 2012 to 2013 alone. By 2013, the volumes at critical access hospitals had reached fairly low levels for the lowest 10 percent. There were 130 CAHs that had an average of two or fewer discharges per week in 2013. This raises the question of whether the staff have enough practice to provide high-quality care. There are also economies-of-scale concerns. The fundamental question is: Should all of these hospitals continue to be inpatient facilities?

The second limitation of current models is that they often use cost-based reimbursement. Most rural hospitals today are critical access hospitals, and so they receive cost-based payments for their inpatient, outpatient, and post-acute-care services and swing beds. And these cost-based payment cause three problems.

First, cost-based payments favor higher-cost hospitals which tend to be hospitals in better financial condition. For example, some of the poorest hospitals that

we visited on some of our site visits had decided to remain PPS hospitals and take the PPS rate rather than the cost-based rate because their cost structure was so low, their costs were below PPS rates. In contrast, as we illustrate in your mailing materials, some of the higher-cost hospitals that we have seen are in wealthier communities, and the general idea here is when a hospital has more money, it tends to spend more money; when it doesn't have money, it doesn't spend the money.

Second, cost-based payments could favor services that have high Medicare or privately insured shares. For example, CAHs have expanded their post-acute-care swing bed services to some extent because they tend to have high Medicare shares. CAHs have also expanded MRI services which have high shares of private and Medicare patients. In contrast, the Medicare share in the emergency room at CAHs is relatively low, only about 30 percent. What that means is that a CAH will get a bigger increase in its Medicare payments when it increases its post-acute costs or imaging department costs than it will when it spends money on its emergency room.

Finally, cost-based payments reduce the incentive

for cost control. And as you can see from your mailing materials, CAH costs -- in particular, capital costs -- have risen faster than at PPS hospitals over the past decade.

Now, in the early years of the CAH program, rural hospital closures almost ceased. However, over that time, CAH admissions have continued to decline, and in recent years we have seen 13 CAH closures in 2013 and 2014. This tells us that while cost-based reimbursement has increased payments to many providers, it does not always result in the hospital doors staying open. As we show in your mailing materials, we examined the seven CAHs that closed in 2014. What we find is that they did receive payments above PPS rates. The payments for post-acute-care swing beds alone were $550,000 higher than PPS rates at the median closed CAH.

However, the extra dollars provided to these hospitals were consumed by the costs of maintaining these inpatient services. And this raises the question: Is there a way to continue paying the hospitals similar levels of supplemental payments, but to redirect those existing subsidies toward emergency services and away from inpatient

services? In other words, could we offer rural hospitals the option of being a financially viable outpatient-only facility that provides emergency services?

At last month's meeting, several of you brought up the idea of allowing rural facilities to become freestanding emergency rooms. Warner suggested that it may make sense to allow CAHs with a census of ten or fewer to convert to freestanding emergency departments when their inpatient operations were minimal and no other hospital was nearby to provide emergency department services.

However, as Bill Gradison noted, Georgia had three rural closures and had discussed converting those hospitals to freestanding EDs. However, given the volume of cases and the case mix in those communities, freestanding EDs did not appear viable, and the facilities remain closed. The viability of freestanding EDs appears to depend on having either having a strong payer mix -- as Zach talked about last month in some urban areas -- or receiving some type of public assistance to compensate for the poor payer mix and low volumes.

So the question arises: What is needed to make these outpatient-only facilities financially viable? As

Dave said last month, there could be a fixed payment to help cover standby costs and then a per unit payment to cover marginal costs. And we'll explore that idea of a fixed grant to help cover fixed costs.

While special payments may be needed to keep the hospitals open, we made it clear in our 2012 report on rural health care that the special payments should be targeted to hospitals that are most needed for access.

We specifically said that Medicare should target isolated providers. And the idea here is that if you have two hospitals that are five miles from each other and they're both struggling with low volumes, they both are struggling to have enough practitioners to cover the emergency department, in those situations it does not make sense to split the emergency volume between two facilities and make providers have double on-call burdens. To avoid supporting duplicative services, the special payments we'll talk about today would only be available to isolated emergency departments.

What this means in practice is that freestanding emergency departments would need to be some distance away from full-service hospitals to get extra financial support.

For example, the extra payments could be limited to EDs that were 20 or 25 miles from other hospitals. The specific distance criteria could be discussed by you and it could be different for the two models we'll discuss in a moment.

So the first outpatient-only model we will discuss is a freestanding emergency department model. In this case the facility would maintain an emergency department that is open 24/7. Medicare would pay the facility outpatient PPS rates just like it was a hospital-based ED. This would level the payment rates between the freestanding EDs and any full-service hospitals. However, as we discussed, that may not be enough given the low volumes and the payer mix in many rural communities. Therefore, there would be a fixed grant to help with standby capacity costs.

In order to receive the fixed standby payment, the hospital would have to give up acute inpatient services and give up cost-based reimbursement of its post-acute-care services. The hospital could still continue to lease hospital beds to a SNF that would then receive SNF rates, and this conversion of hospital beds in rural areas to SNFs

is not uncommon. So the bottom line is that skilled nursing care could continue in the community, but cost-based payments would not.

Finally, this new option, this Model 1, would be seen as a choice for hospitals and not a requirement. So many hospitals will decide to continue to be a CAH or a PPS hospital. But this would provide a clear option and a clear path for those that are struggling to survive due to declining inpatient volumes.

The second option is for smaller communities that cannot support a 24/7 emergency department. In these communities, there may not be enough patients, or even more likely, there may not be enough clinicians -- physicians, PAs, and NPs -- to really staff an ER 24/7.

In this case there could be primary care clinic which is also affiliated with an ambulance service. The clinic could be open 8 or 12 hours a day; the ambulance would be available 24/7. Currently this model is being evaluated by the Kansas Hospital Association.

The clinic would get two types of payment. One is a PPS rate per unit of service. The second is a fixed grant to help cover the standby costs of the ambulance

service. For example, it may cover the cost of hiring a paramedic to coordinate the volunteer ambulance EMTs.

It could also help cover the uncompensated care costs at the clinic and the uncompensated care of the ambulance service. This combination of a fixed grant and a payment per unit of service is similar to the FQHC model. And some people think of this as the FQHC+ model.

So this is the first of several discussions on rural access issues. If you decide that this topic we have talked about today is worth pursuing, there are several other issues we need to discuss in the future. For example, what size would the grants need to be or what size should they be? And as we discuss in your mailing materials, we'll also have to address beneficiary cost sharing and minimum levels of emergency department staffing at these 24/7 EDs.

Finally, there could be a requirement for some type of a matching grant from the local community. The program we're talking about could be better targeted if it was limited to EDs where the local community believes the facility provides enough value so that they are willing to contribute local tax dollars. In the end, both Medicare

and the local community could provide support for these facilities' emergency standby capacity.

So this brings us to some discussion issues, and you all could talk about whether we should allow hospitals to move away from the inpatient models in some rural areas. We could talk about the PPS plus grant approach and whether that is reasonable for the outpatient-only model with the 24/7 ED we talked about and/or for the clinic with ambulance model we talked about that doesn't have a 24/7 ED. And, of course, we'll be available for any other questions or comments on the presentation or your mailing materials. I look forward to your discussion.

DR. CROSSON: Thank you, Jeff and Zach.

We'll start off with questions, clarifications.

MR. GRADISON: Most of the -- I guess all the current plans in effect are based upon mileage between hospitals, and I understand that. I doubt if that will change. But I am concerned about whether there is some way that might be explored also to take into account driving times, and I particularly would, if you have not already done so, encourage you to take a look at the questions that are being raised about the VA's policies in this regard. I

know and maybe all of us know of situations in which people may literally be only a couple of miles from a hospital with a mountain in between and where the mileage does not mean very much. The VA experience is different in the sense that they're basically, I think, trying to get people to stay in network, and some people feel that they're making it much harder than necessary to go out of network. That's not our situation. So I think that might be illuminating, and I would encourage you to take a look at it.

I appreciate your response on the Georgia experience. To me, what that -- well, I'll come back to that in Round 2.

With regard to closing that have occurred so far, have you done a breakdown or could you do a breakdown of those into whether they are Medicaid expansion states under the ACA or non-expansion states under the ACA? Some people feel that that is -- some people are actually pointing -- some people in authority are actually pointing to that as an explanation for some of the things that are happening, like in Kansas.

MR. GAUMER: We've heard talk of that as well,

and that's something that we will be looking at when we evaluate closures, and we will bring that up in front of you, I guess it's in December this time around.

DR. HALL: And, finally, with regard to getting matching grants from local governments, my understanding is that in some states, maybe many states, local governments' authority is limited with regard to which kinds of institutions they can support with their grants. As a general proposition -- and I'm not saying I've got this entirely correctly, but as a general proposition, it's not surprising they probably can't make grants to for-profit hospitals. But I think some of them are also limited in their ability to make grants to nonprofit nongovernmental hospitals, community hospitals that aren't owned by the government agency. In other words, many of them, I think, can only make grants if it's a public hospital. And any light you could shed on this I think would be useful, since the suggestion, and a good one, of course, of some arrangement with matching grants has some appeal.

Thank you.

DR. MILLER: Can I ask one thing? Were we thinking state grants or community grants?

DR. STENSLAND: We were thinking community grants, so this is the idea that you have -- a lot of hospitals already have hospital district funding, so they might get $300,000 or $400,000 from their local hospital district, and they have their own taxing authority to do that. And the idea of -- they would just take that $400,000 which is going to the XYZ Hospital, and they could still go -- and they could even still call it the XYZ Hospital probably. It just wouldn't have inpatient capacity anymore.

DR. MILLER: Yeah, and, Bill, your point may still stand. We'd have to -- it's what level to look at it.

MR. GRADISON: Of course. Thank you [off microphone].

DR. HALL: So the premise that you've presented to us is the dilemma these hospitals face, that if they close the hospital, they're not going to be able to support the ambulatory services. Is that right? Have I got that right?

DR. STENSLAND: If they close the hospital, there won't be any more emergency services in the community.

DR. HALL: So does the data support that supposition in terms of -- I mean, we have a lot of experience nationally. In fact, are these communities where these hospitals closed, are they destitute of emergency services? Is there any evidence that this has really affected health care overall?

DR. STENSLAND: So I think there's a real wide diversity of these closures, and I think two key points are not all critical access hospitals are the same and not all closures are the same. I can think of -- you know, in the extreme, you'll talk about a closure where something is 60 miles away from the nearest hospital, and they don't think they can financially support their emergency department. And the other extreme, you might have a critical access hospital closing, but it was in visual range of another hospital, so there's no real decline in the emergency access.

DR. HALL: Okay.

DR. STENSLAND: There's also some situations in some of these closures where they have closed the hospital, but they said, "We're going to keep the emergency department open." And there is a real question that I

think is for further research for us to say how often is that viable.

DR. HALL: Exactly.

DR. STENSLAND: And in some cases, it has -- they open it, and later they closed it. And there are some cases it stays open, but some of those freestanding ERs in rural areas that are viable, it looks generally like they have a pretty good payer mix in the -- you know, there's one that's close to the Walmart headquarters and people have private insurance and this is going to work. In some of the other poorer communities without such a good payer mix, it will be very different. So it's a wide spectrum, and we could probably -- in the next round, we could talk maybe a little bit more about the diversity of these closures.

DR. HALL: Thank you.

DR. CROSSON: Jack.

DR. HOADLEY: So, somewhat related to Bill's question about Medicaid expansion, have you taken any kind of look at the impact of changes in DSH dollars and what role that might be playing? I mean, all the details of how the dollars relate to some of these particular hospital

categories.

DR. STENSLAND: We could look at that. I think it's probably not a big issue in most of the closures --

DR. HOADLEY: Okay.

DR. STENSLAND: -- because the DSH dollars are only going to the PPS hospitals, not the CAH hospitals --

DR. HOADLEY: Okay.

DR. STENSLAND: -- and a lot of the PPS hospitals are close to other hospitals. In some cases, it may have an effect, and we can look at that. But, the CAHs don't get DSH --

DR. HOADLEY: CAHs don't get DSH, okay.

DR. STENSLAND: -- and so there, it wouldn't be --

DR. HOADLEY: And then my other question is, any -- to what extent have you looked at the pattern of other providers in some of these affected communities, you know, thinking about the isolated sort of definition relative to other hospitals, but what about the existence of an FQHC or a rural health center in one of these communities or the existence of home health or other PAC providers and whether that's either a factor in terms of their viability or

something that we might take into account in terms of thinking about that vector of isolation.

DR. STENSLAND: We can look into that more.

DR. HOADLEY: Okay. Thank you.

DR. CROSSON: David.

DR. NERENZ: Slide 10, please. If you could just clarify a little bit the third bullet point about no acute. It seemed like the main premise here is that the hospital was going to close, and then the options were how do you preserve ED capacity. So, the no inpatient bed is essentially a pre-set decision. But, your phrasing when you mentioned the slide was sort of the other way, that if a hospital accepted a grant for freestanding, they would have to close the inpatient beds. Now, some of that's just semantic. That's what freestanding means. But, can you talk a little -- is there some other logic point there about why the beds would have to close if they -- or is that -- is it just a phrasing issue?

DR. STENSLAND: I think the idea is to really target this just to facilities that are going to be inpatient or outpatient only and not allow this just to be an extra add-on to some hospital saying, well, I just want

to continue doing everything the way I just have in the past. I just want this extra grant. So, we're saying they wouldn't qualify. That's all it --

DR. NERENZ: So, in our later discussion, we could discuss that -- okay.

DR. CROSSON: Sue, Kathy, Cori, and Alice.

MS. THOMPSON: Thank you. This was an excellent overview.

I have a question related to those hospitals that have closed. We frame it in terms of lack of inpatient costs, but how many of them have closed because they simply don't have a physician anymore? I mean, obviously, the physician drives the utilization of inpatient, but I think there's a fundamental issue here about recruiting physicians and access to primary care in communities as you have described. So, do we have any information that speaks to the availability of the physician in this setting that might be something to do with why we're having these difficulties?

DR. STENSLAND: No, we can look into that, and when I've looked at the closures so far, I'm not aware of any that didn't have any physicians in the community.

Certainly, recruitment is a real difficult problem for all of these communities, and one of the ideas here is that actually having a closure might actually help some recruitment in some situations, because there is this situation where the people coming out of residency aren't that interested in being on call all the time, and if you're in one of these communities and there's only two doctors in town, you're kind of on call almost all of the time.

And if you have two of these things next to each other -- these communities, in general, the supply of people who want to be on call that much in practice like that is below the demand for that. So, there's an excess need for these people, and if we have two hospitals next to each other and one of them closes, all of a sudden, the on call duty of those doctors could be cut in half and it might actually make it easier to recruit physicians into that community.

DR. CROSSON: Kathy.

DR. BAICKER: This is sort of related to Sue's question. I was trying to understand the difference between option one and option two, and option one looks

like it would require a greater staffing by physicians. Option two looks like it could be staffed by nurse practitioners or other primary care providers with an ambulance service. Am I reading that correctly? One is more of an emergency department service with the idea of stabilizing the patient. The other one could be more of a primary care clinic with that capability to transfer patients to an emergency department. So, I'm just trying to understand the differences between these two models.

DR. STENSLAND: So, in the first one, the 24/7 ED department, the way most people talk about that is you have a physician, a nurse practitioner, or a PA at least on call. So -- and you could all talk about, at some point, what the minimum level of staffing should be for these things. But for a Critical Access Hospital, you don't have to have a -- the existing Critical Access Hospitals don't have to have a physician in the hospital. They don't have to have a PA or a NP in the hospital. They could just have a nurse practitioner in the hospital and the PA that's on call 20 minutes away who drives in after somebody shows up at the Ed. So, that's kind of the level that they're talking about, the Critical Access Hospital now, and it

could be a discussion point of whether that's the right level or it should be a different level in a 24/7 freestanding ED.

For the other service, I think the idea there is -- it kind of gets back to what Sue is saying. These communities just might not have enough practitioners that really want to be on call 24/7. If you try to divide up that 24 hours a day and who's on call, it would just be too much burnout for maybe the two practitioners you have in the community, a physician and a nurse practitioner. And, so, the idea there would be they actually wouldn't be on call at night. Maybe you would try to use some of the standby grant capacity to increase the training of your volunteer service from basic life support to advanced life support or maybe higher, a paramedic to coordinate. We have seen that happen in different communities that have lost their hospitals. But in the end, you have a period of the day where there would not be a physician, NP, or PA on call, and it would be those EMS people that would treat them and transport them somewhere else to get their care.

DR. MILLER: And, I almost spoke up when she was asking -- when Sue was asking her question to make this

point, but just to kind of hit this one more time, in the second model, does it have to have a physician on staff?

DR. STENSLAND: I think that could be a discussion point, and it wouldn't necessarily have to, and you actually can run a CAH, in theory, without a physician in the local community.

DR. MILLER: And that was what I -- I thought your answer was very complete, but I do kind of want to draw off her point, which is staffing requirements between these two things could be different and the relief could not just be the 24 hours. It could also be the ability to get the level that a lot of these communities have a hard time with.

DR. CROSSON: On this point, Jon?

DR. CHRISTIANSON: No.

DR. CROSSON: Okay. So, Cori, Alice, Jon --

MS. UCCELLO: My question was already answered.

DR. CROSSON: Oh, okay. All right. So, Alice.

DR. COOMBS: I just wanted to add to that point, it would probably depend on state-based regulations. So, that's the other confounding variable.

My question is related to EMTALA regulations

within the model two. If you had two facilities that were close enough, one decided to convert to a freestanding ED and the other is still in the critical access realm with inpatients, one of the questions would be if you didn't have the distance between the two, an evaluation of how often patient -- the word that's used is dumping -- would occur because the inpatient -- a capacity on the second hospital is close enough to say, we will tier or triage patients from our facility to another facility. That would be one concern with model two, to kind of work through that process, looking at the -- just the medical protocols for patient transfers within a given region. And if you -- I don't know if you -- if you kind of increase the distance between two facilities, it probably would be probably a little bit more protective in that frequency of that occurring with both facilities that are both located within rural areas.

The question I had was, of those 1,300 -- you guys do a great job just describing just the demographics and the distribution, but of the 1,300 rural hospitals, you describe 34 percent as being in areas where there's a radius of 25 miles or greater between the distance. Is

there anything you can say about the proximities and whether or not there's an infiltration of for-profit freestanding facilities within the areas? You might know something about the 1,300. I don't know if you know about the smaller group in terms of for-profit penetration.

DR. STENSLAND: There are almost no for-profit freestanding EDs in the rural areas, and I think it's a payer mix issue.

DR. COOMBS: Okay.

DR. MILLER: But, were you asking that or asking how many of the CAHs are for-profit? The 1,300 is the Critical Access Hospitals. There's additional rural hospitals --

DR. COOMBS: So, actually, of the 1,300, which are for profit.

DR. MILLER: Yeah. If we don't know that offhand, that's certainly knowable.

DR. STENSLAND: There is a few for-profit CAHs, but it's a handful, and there's also a few for-profit PPS hospitals in these rural areas.

DR. COOMBS: Okay. And if, as in model two, clinic with ambulance, then we're saying that they're not

necessarily -- this is a full-fledged clinic, so that if I'm a primary care doctor in a community, I could escalate to this and get some of the opportunities that this would provide, right? Say, I'm not necessarily affiliated and I want to kind of develop my freestanding practice that I have into a model two. Is that a possibility, or am I exempted from that?

DR. STENSLAND: That would be an issue of discussion. I think there is the question of whether -- if it's a for-profit entity, like, let's say, the individual's own personal business --

DR. COOMBS: Right.

DR. STENSLAND: -- that would be a discussion point of do you actually want to give them a grant, and if there was a matching grant requirement, would the county actually give a grant to a physician to run their own practice. So, that's a discussion point.

DR. COOMBS: Okay.

DR. MILLER: And at least the starting point here, Jeff, is the way we had come up to this point was, it's a -- and this goes to an earlier point -- it's a hospital saying, I'm going to let my inpatient go in order

to move to this. That was at least the opening proposition.

DR. COOMBS: So, I was --

DR. MILLER: No, I see what you're saying.

DR. COOMBS: -- the other direction. Okay.

DR. CROSSON: Jon.

DR. CHRISTIANSON: I have, I think, two questions of clarification. There was one part of your written materials, a paragraph that almost seemed counterintuitive, so I want to make sure I understand the logic. So, I think in that paragraph the argument was actually having a higher percentage of patients that were Medicare would be detrimental to the financial viability of the Critical Access Hospitals, which seemed counterintuitive, because usually you'd think, well, the more patients you'd have who you knew you were going to get your costs plus on, the better you'd like it. But, the argument seemed to be that means that there are fewer private pay patients to subsidize uncompensated care. Is that -- do I have that thinking right in that paragraph, or -- and does that imply that the cost-plus based reimbursement for Critical Access Hospitals doesn't include any dollars there that

acknowledge the fact that you're getting uncompensated care?

DR. STENSLAND: I think I'll probably have to go back and see what the wording is on that. But, I think the main two levels to think about are the uncompensated level and the private pay level.

DR. CHRISTIANSON: Mm-hmm.

DR. STENSLAND: And what I was trying to get there is the Medicare is basically paying its cost. So then you're in trouble if you have more uncompensated care than you do private pay patients and private pay profits, because the private pay profits have to cover the uncompensated care because Medicare isn't covering any of that because it's just paying its costs.

DR. CHRISTIANSON: Mm-hmm.

DR. STENSLAND: And that's the point I was trying to get at.

DR. CHRISTIANSON: So, I took it too far by saying that the more Medicare patients you have, the harder it would be, then, for you to cover your uncompensated care, because you have fewer private pay patients.

DR. STENSLAND: Yeah. If I worded it that way, I

probably shouldn't, because in theory, if you had 100 percent Medicare, you'd be okay, because all your costs would be covered.

DR. CHRISTIANSON: Yeah. So, the second question was, has there been any research, or have you guys looked at the question of if you convert to this freestanding emergency department and do away with the inpatient care beds, that the emergency department becomes less attractive? In other words, if people have a choice of traveling ten more minutes to go to an emergency department associated with a hospital, they would now do that, and, therefore, that -- I mean, you kind of alluded to that, because you said some places have tried this and it worked for a couple of years and then not so good. So, is this a transition to no emergency care, because people will just see it as a less attractive -- gee, if I'm going to -- if I have an emergency, I want to go someplace where, if I need to be admitted to a hospital, I can be admitted to the hospital.

DR. STENSLAND: I'm not aware of any research on that, but that is a key question of what will the volume be at these facilities. And what you're saying is the volume

might not be the same as it used to be.

DR. CHRISTIANSON: Right.

DR. STENSLAND: And then the question is, even if it goes down, will it be high enough to maintain. There are a couple freestanding EDs that have lasted a while in rural areas, and we can look at it from that standpoint.

DR. CHRISTIANSON: I think that would be good.

DR. CROSSON: Other clarifying questions? Warner and Mary.

MR. THOMAS: Just a quick question. Has there been any -- have you seen any information about trying to repurpose any of the inpatient capacity in these facilities with any other types of services? For example, I know one area that we see a significant shortage of are just mental health beds. So, I know we've looked at some opportunities in some of these facilities to repurpose the beds in mental health. So, I don't know if you've seen that anywhere else or what you think about that idea.

MR. GAUMER: The only thing I'll add here is that we have seen a couple of closures turn -- inpatient closures turn into SNFs, but just a couple.

DR. CROSSON: Mary.

DR. NAYLOR: So, we've been talking about this in the context of conversions, and wondering if this opportunity presents -- is it only designed for conversions, or does it present the opportunity for new models -- emergency departments, clinic with ambulance -- to develop that have not been formerly inpatient units.

DR. STENSLAND: That just gets an issue -- maybe it's an issue for discussion, of how targeted should this be, and just from a political standpoint, how could you kind of keep a lid on how big the program gets if you did that. If you're just saying, for closed hospitals, we're going to help your community out, it kind of puts a boundary around how big the program would get and how much it would cost. If you just -- if you opened it up, that would be a political science question.

DR. MILLER: And are we in round one or round two?

DR. CROSSON: This would be round one, clarifying questions.

DR. MILLER: Okay, because if it were round two, what I would have said is --

[Laughter.]

DR. MILLER: -- we should focus very much on this, because this has come up a couple of times. You know, you could be building a whole new program and double what is out there, and I think at least we came into this with the discussion of trying to help the community that's struggling with its volume.

I apologize for saying something about round two.

[Laughter.]

DR. CROSSON: Speaking of round two, I think we're ready for round two.

DR. MILLER: Oh, so I was leading off.

DR. CROSSON: Well, wait. What is this? Is that -- I'm sorry. More clarifying questions? Yes.

DR. REDBERG: I think it's clarifying.

[Laughter.]

DR. CROSSON: Okay. Well, you ask it and I'll clarify.

[Laughter.]

DR. REDBERG: Okay. I was just -- you know, I'm always interested in outcomes and impact on outcomes, and I think it's a little hard to measure in areas where there are closures and things. But I'm wondering if we have any

information on sort of case mix and the kind of problems that are seen at CAH hospitals and rural hospitals and hospitals that closed, and does it look different? How does it impact? And, you can get back to me on that.

DR. STENSLAND: First, in terms of the impact of closures, Karen Joynt did a study recently and she looked at hospitals that closed and she didn't see any long-term impacts, or statistically significant long-term impacts on the patients' health. Now, the number of isolated rural hospital closures in her sample was really small, so maybe that's why there was nothing there.

In terms of what the CAHs do, it's really a wide open spectrum of what kind of services they offer. You know, some services are -- just have a very limited inpatient capacity with a general practitioner there as the only physician in the area, maybe even a single one. Other places will have an orthopedic surgeon, a general surgeon. Some places offer dialysis stations, 24/7 ED, emergency trained physicians. So, there's just this big wide spectrum of what a CAH is.

One of the things that we did talk about in the paper and in our rural report is this concern about volume

and outcomes, and you know at least as well as I do the volume outcomes literature. So, if some of these did close, there would be a shift in the volume from that facility to another facility, possibly an urban facility or possibly another small rural facility. So, there could be some potential, though I don't think anybody has ever quantified it, of potential quality improvements at even the neighboring hospital. So, it's not just about this individual community. It's this neighboring hospital, which now it has more volume, now its nurses have more practice, and that actually could be a good thing for the people in the neighboring community.

DR. REDBERG: Thank you. That's helpful.

DR. CROSSON: Pretty good, Rita.

DR. REDBERG: Was that clarifying?

DR. CROSSON: Pretty good, yeah. Pretty good.

DR. REDBERG: Thank you.

[Laughter.]

DR. CROSSON: Clarifying questions? No?

[No response.]

DR. CROSSON: Okay. So, now we're going to enter round two. Throw up Slide 13, please. And, who would like

to lead off? I have Jon. We're getting a lot here. So, all right. So, we're going to start with Jon, and then we're going to move this way.

DR. CHRISTIANSON: So, back to my clarifying question, which I am now going to turn into something else -- so if -- the way you described it, it seems like the problem is if you have Medicare patients, you're okay because they cover your cost. If you have private-pay patients, you're probably covering your cost. So the problem with some of these hospitals that are closing is they had too much uncompensated care. So why are we talking about some new approach to uncompensated care for some of these hospitals instead of a whole new program around emergency care and so forth?

DR. CROSSON: So the notion would be to have an additional add-on payment that varied related to the amount of uncompensated care.

DR. CHRISTIANSON: I don't know -- I don't know what -- it seems like if the problem is being driven by uncompensated care that can't be covered, then maybe there's another approach.

DR. CROSSON: So is that something that could be

modeled, Jeff, Zach?

DR. STENSLAND: There's lots of things you could do. You could just make some of the CHs eligible for the uncompensated care pool. You could see how much, how big this uncompensated care payment would be.

I think one of the issues here is that also the hospital has this inpatient volume, which is really low, and it's a really high cost per unit. So part of the thing is if they maintain the inpatient capacity, then the amount of money you're going to have to give them to cover each uncompensated care day in that inpatient unit is going to be a lot higher, so that is an issue.

And there could be -- there's lots of ways to go with Jon's comment. You could say keep it the same and give them uncompensated care. You could say make them outpatient only and give them an uncompensated care payment.

DR. MILLER: And I think we're saying the same thing.

I mean, at the most extreme, when you have a couple of hospitals that are -- and let's just make the example extreme, five miles apart. They are both competing

to maintain -- and in your context, a question, Jon, would be if we keep the inpatient and the swing-bed payment, they are going to continue to engage in a lot of maintaining that mission in order to pull that subsidy in, and I think there's some real questions -- and the quality question got into this -- about what exactly the role of a hospital -- and the most extreme situation, it's five miles apart from another one -- in these particular lines of business. So it would at least continue to try and think about how to give them incentives to get a more consolidated inpatient situation where hospitals are competing really close to each other, and we're just fueling that competition through the subsidies.

DR. CHRISTIANSON: Well, I think, certainly, the quality question is something that is out there, but I don't know that I could tie it that closely to this, I guess.

I mean, if there's a quality issue right now, we should be dealing with suggestions relative to the quality issue.

DR. MILLER: And I guess the only thing I would ask is, in the situation where you're saying an

uncompensated care addition, which it is definitely something we would -- we can think about, would you keep the inpatient mission, say, in a hospital that has really low volume? Were you thinking that, or was it just a different way to kind of --

DR. CHRISTIANSON: I was just -- I wasn't thinking that far ahead. I was just thinking if the problem is X, there seems to be a straightforward way of dealing with the problem. If the problem was X, Y, Z, and a bunch of other things, then I think the argument for what we're doing here becomes quite a bit more complex.

DR. STENSLAND: Yeah. And at least for me, I'm thinking there's thinking the uncompensated care problem is an issue, and implicitly, what we, I think, were talking about here is you're sort of recognizing that the Medicare dollar in this instance, while it would be reorganized into a flat payment and all of that, is playing this role of subsidizing for uncompensated care. But I also think there's this other problem of sending money out to two hospitals that are in close proximity to one another.

DR. CROSSON: So, theoretically, I think there is two really fundamental, pretty different ways of doing it.

The one that -- the one that we've talked about here is essentially a redistribution model, saying you're already getting all these extra special -- extra subsidies on the inpatient side. Let's take the existing extra subsidies and shift it to the outpatient side, and then we get rid of the inpatient costs. And that's really where the savings for the whole system comes by.

Another way of thinking of it is saying, "Oh, we're worried about the uncompensated care cost, so we'll just come up with new money and put it on the uncompensated care," and that would be a separate model.

DR. CROSSON: So, theoretically, one could be cost-neutral or even cost savings; the other would be an added cost to the program. Is that --

DR. MILLER: Depending on how he's thinking about it. That's the point I was trying to get at.

DR. CHRISTIANSON: Well, I guess I was just wondering if we could do some thinking about it.

DR. MILLER: We can.

DR. CROSSON: Sue.

MS. THOMPSON: Lots of thinking to do.

In the State of Iowa, there's 118 hospitals, 88

of which are critical access. I am very familiar with a number of those hospitals and recognize not only the great economic boost they give to many, many of these communities -- and that's substantial -- but the passion that these communities hold, the pride they hold for these hospitals, but also the challenges that goes with particularly recruiting physicians to many of these communities.

I'm curious to know -- and I'm going to make some more comment, but one of the questions I'm very interested to know is how did we come to have a county where there are 99 counties in Iowa, and in one of the counties, we have 4 critical access hospitals? And there's less than 40,000 people in that county. So what was the intent, and how -- I mean, that goes well beyond, I think, meeting access issues.

So I think there's some underlying questions here that we need to understand, and is there an opportunity in that to better understand not only reducing the competition? And obviously, there's challenges around competency of the staff who are caring for minimal numbers, but where is the opportunity, I think, in much of what Warner was suggesting about converting some of this

capacity to services that would better serve the Medicare population?

With that, the other learning that in our observation in Iowa is that we have had counter-incentive when we've worked towards value-based contracts. I mean, these organizations have been working to increase volume and increase utilization in order to survive, and in many cases, that's not been consistent with what we've wanted to do in terms of not only improving quality, but reducing PMPM on these contracts.

So if there's anything we can do to invite and incent these communities to become a part of what it is we're doing to transform health care for Medicare -- and I think there are opportunities there, but it has to do with what's in those allowable costs, because in that cost report, we assume Medicare costs are covered, to the extent that are defined by allowable costs. And today, that does not include all emergency service costs.

So there's a lot of devil in the detail here, but there's so much opportunity. I'm just really excited, the fact that we're having this conversation, so those would be my comments.

DR. CROSSON: Herb.

MR. KUHN: So I too want to add my thanks for this conversation and put my comments in kind of two levels. Let me make some general comments and then make a few observations about the options that you put forward.

First, I like this idea that it's an alternative for low-volume rural hospitals. It makes a lot of sense.

Also, what I like is the information you shared about what's going on in Kansas, and I know those kind of conversations are going on in other states that are out there. So I think we're kind of moving along with some of the conversations that small communities, but some of these states are trying to grapple with. And so, in that regard, I'm really excited about when we get to the public comment period because I would want to hear what the rural advocates that are in the audience have to say about hits, but also, if not today, hopefully they're engaging the MedPAC staff to help us refine this thinking as we continue to move forward.

But just a couple of other thoughts. One is you have to really put your -- try to put yourself in the minds of these small rural hospitals and particularly the

governance of those small rural hospitals. Many of those boards for those small hospitals are elected in those communities. Some have had good governance education; some have had less. And so they're grappling with these very complex issues trying to make these decisions, and if they see something that comes down the road that they don't think is in the best interest of their community, they won't take it or they would overturn a decision, perhaps, of another board after the next election that's out there.

So the one thing as we think about this, what it augers for me is that we have to have maximum flexibility, if they get this conversion opportunity, to design a system that works best for that community because, again, you've seen one CAH, you've seen one CAH.

Also, I would just raise a cautionary note about these distance requirements. I think Sue raised a good point about four in one county. But you may have a critical access hospital that's 20 miles away from one hospital, but then the next hospital is 50 miles away as well. So the distance stuff, it's difficult. You have to grapple with it, but just kind of bear that in mind.

So let me talk a little bit about the options.

So, obviously, it's to redirect a subsidy, to get us away from an inpatient-centric model to kind of an ambulatory-centric model. I like that. I think it makes a lot of sense.

But I do worry a little bit about the notion of the changes that we're talking about for post-acute care services, particularly swing beds. I see the notion of moving them to a PPS system. I'm not sure if I'm there yet. I still think the transitional care nature of what these entities can be is pretty important, whether it's observation status or whether it's swing-bed status of keeping those folks in the communities for those services, and whether a PPS versus cost-based would work for them as they go forward, something just to think a little bit more about that.

I also worry about how these smaller facilities are going to service their debt in the future. Many of them are old Hill-Burton facilities, but some have rebuilt into new types of facilities, and they have accumulated some debt, and would this work for them to be able to manage that that's out there?

Other issues to think about is telemedicine and

the opportunity. We've talked a little bit about physician recruitment. Could this be a real incentive that these folks that do the conversion maybe get some special opportunities through telemedicine, maybe for ED physician coverage? Or for supervision coverage opportunities they could facilitate that through telemedicine. That way, they're not struggling with the recruitment issues, but they still have the coverage issues out there. It might be a sweetener to add to this to help them think that through.

There's other kind of regulatory things that I think we'll have to look at. Well, just going back to the telemedicine thing is Medicare has always had a bias that they want face-to-face encounters for billing purposes, for program integrity, all those kind of issues that are out there. It's time to face the facts that the technology is there. We're going to have to move in this direction, and maybe there is a way for opportunity.

On other regulatory things that are out there, will these facilities continue to keep their Part A status? And I think that has a lot to do in terms of the rural health clinic opportunity if they don't have a Part A status. So if they lose their inpatient capacity, what has

happened there? It's something to think about.

Also, their ability to go outside the hospital to deliver services -- and it's an example I remember years ago. I don't know whether it's ever been fixed or not, but the hospital lab wanted to go to a skilled nursing facility or to do lab samples, draw blood with phlebotomists from a patient, and Medicare would not allow them to go off site. Everything had to be done in the hospital. So you had to transport that elderly person from the nursing home to the hospital just to do a blood draw and then back. And so there's some regulatory things that I think could make it more seamless for the communities to help them think that stuff through.

I do think there ought to be requirements here that they have to have a formal partnership with a larger facility for both clinical and operational assistance.

I do think there needs to be community skin in the game. The taxing authorities you talked about is something that's out there. The communities have to be invested in these facilities. I think that's an important part of that.

And then, finally, this will probably be a tough

one for some folks, but I think we have to at least have a conversation about it, is that if they make a decision to do this conversion, but they come a few years down the road and said, "This was a mistake. It's not giving us the services we need in the community. Can we convert back?" I think there at least ought to be a one-time opportunity that you get to convert back if it's not meeting the community needs because you don't want to lock them into something that's just not going to serve them as they go forward, so just some random thoughts here.

DR. MILLER: Can I get you to say one more sentence on what you meant by the Part A status?

MR. KUHN: Yeah. So my understanding, Mark, is that with the Part A status -- and I'd have to go back and look at more detail -- it triggers at least rural health clinic ability for payment system through RACs, and so there might be other things that are triggered through Part A status. I just want to make sure that we understand what those are and we don't limit them from other services that they could be providing to the ambulatory side.

DR. STENSLAND: So I think what you're talking about is if you have a hospital and you have a hospital-

based rural health clinic, you can get cost-based reimbursement for those rural health clinic visits without a limit. So you could have, like, a $200 per visit at your rural health clinic if you're a hospital. If it was a freestanding rural health clinic, you wouldn't get that. You would be limited at the limited rate that they give to rural health.

DR. NAYLOR: So, Herb, I don't know that you said it all, but --

MR. KUHN: Sorry.

[Laughter.]

DR. NAYLOR: I know. No, wonderful.

I just wanted to reinforce that I also think this should be a focus on conversion, even though I raised the question about whether or not it opens the door in thinking about alternative systems, care delivery models.

As we think of the models, I also believe that we need to think how models are emerging, so federally qualified health centers, patient-centered medical homes are moving to 24/7. So we need to think about how existing services in these communities are changing in response to new expectations and whether or not that factors in as

we're looking at assessment or of availability of services. So then it might mean that a federally qualified health center now gets extended ambulance capacity to be able to meet the needs. Telehealth, I think is also a central opportunity as we think about alternatives here.

We had a wonderful study on ambulances a long time ago. I don't know to what extent all of that, those recommendations come into play here, but it seems like we spent a year looking at them. And I'm really excited that we're getting a chance to reintegrate that knowledge back into our work.

And then, finally, on workforce, I would really want to make sure that we know fully the evidence about who is providing care in these environments, and nurse practitioners and PAs have played a central role in the delivery of services in these communities, for which there is a robust body of evidence around quality. So I hope that as we think about the workforce and teams that we need to be thinking about that we build on that.

And lastly, to Rita's point, quality is everything. So as we think about these alternative opportunities, however they are constructed, can we make

sure that we link some performance expectations to these sites?

MR. GRADISON: I too congratulate Herb on his home run.

[Laughter.]

MR. GRADISON: My understanding of this situation is that there is not a single problem, that there are multiple ways in which these problems can develop, and that there is unlikely to be a single solution that would fit all these circumstances as well.

Now, having said that, I ask myself is it possible for Medicare -- does Medicare have the flexibility to deal with the variation? And I think that's something that really -- you could call it a broad philosophical issue, but I think it's really kind of fundamental to how we deal with this.

And it suggests to me a couple of things. One of them is it's pretty early in the game to figure out what the needs may be because the -- yes, there have been closings, and even one closing can be very damaging and affect our beneficiaries. I got that.

But considering the potential and the number of uncertainties out there, I think it's relatively early to try to identify the issues and the potential solutions in any kind of a final way.

I also want to suggest a great deal of caution with regard to this matter of uncompensated care. To the extent that the uncompensated care may, in some instances, be the result of underpayments, payments less than cost by Medicaid, which does happen, I would simply remind my colleagues -- not necessary for me to remind everybody, but we faced this same issue with regard to SNFs, which came in and said, "The states are underpaying us in Medicaid; therefore, Medicare has got to pay us a lot more than real costs in order to permit us to keep our doors open," and we have said no. So I think we need to know a little bit more about where this uncompensated -- what occasions this uncompensated care, which is why I earlier asked about the expansion versus the non-expansion states.

From a point of view of next steps, I think it might be beneficial, staff to staff, if you had conversations with our counterparts on the Medicaid side and see how this issue looks to them, if it's even on their

radar. At least that would be very helpful to me in trying to think that through, and maybe you've already done that.

DR. STENSLAND: You mean states or MACPAC?

MR. GRADISON: MACPAC. Yeah, MACPAC.

DR. CROSSON: Kate.

DR. BAICKER: So I want to build on comments by Rita in Round 1 and feel that I don't -- I haven't been thinking of this primarily as an issue of uncompensated care, and I very much agree that we don't want to be in the business of filling buckets that other leave under-filled. Rather, I think of this as a critical mass issue, and that in places with thin populations, cost structures are different, and you need -- we want to ensure that everybody has access to emergency services in a timely way, everybody has access to primary care, and that this is about making sure the payment structure is consistent with places that may have low variable cost and high fixed cost because of their geography. And we have a -- I think we think it's particularly important to have access to emergency care in a closer radius.

Building on Rita's point, which was one of the main takeaways I took from this, I don't think we want

people getting lots of inpatient care at facilities that don't do very much of it. That's not time-sensitive care. We want people going to other hospitals to have higher quality outcomes, not that these hospitals and providers aren't doing the very best that they can in providing vital services, but we know that you need critical mass of different procedures to get them done effectively.

So the models that you've laid out seem like great steps in the direction of preserving access to things that we think are time sensitive for everyone, while not paying to prop up inefficient and not time-sensitive access to services in places where there just isn't critical mass. So I'm very supportive of moving towards alternative models that have that lends of which services do we want to ensure are provided everywhere and devoting the money that's necessary to cover those services for our enrollees, which is going to look different in a low-volume area, and creating incentives to move people for the other kinds of services to places where they can get higher quality and more cost-effective care.

DR. CROSSON: Thank you.

Warner?

MR. THOMAS: I would just concur with a couple of my colleagues that, one, I think creating incentives for folks to transition out of inpatient care that is just not material or has a very low census I think is a benefit to beneficiaries at the end of the day, and I think going to the point made is a benefit to other hospitals that, you know, folks would be transferred to. I think it creates a better experience.

Two comments. I do thinking about an opportunity for these facilities to transition some of their inpatient capacity to something else that is worthwhile, whether it be skilled nursing, as you mentioned, whether it be mental health, is something to contemplate or think about and maybe explore whether that would be a potential.

And then I would concur with Herb's point about the opportunity to have a one-time option to go back, because I think one of the things you're going to run into is boards are really going to avoid doing this because they're going to wonder what's going to happen. And I think if they have an option to have a lookback on this, they're more likely to go down that road and try it. I think once they try it, they'll see it's actually a better

solution. But many will avoid trying it because they're just worried about the consequences of that.

So I would really encourage that type of option because I think that's going to incent more organizations to try this as an option.

DR. CROSSON: Thanks, Warner.

DR. HALL: I think this has been a terrific discussion, a topic we have talked about before, but this is really getting into the weeds.

I wonder if there isn't also a possibility of considering a Model 3, and a Model 3 would be that instead of propping up some of these communities and wondering how we're going to get expensive emergency services in there, what if we incentivized the closest hospital, full-service hospital, to get involved in this and extend their own network in a way that makes sense? It's not going to work in every community, but I've visited a lot of communities over the years where there have been tragedies, hospitals have closed in a community, a lot of hand wringing about this. And sometimes the quality of medical care and the access to services has improved logarithmically once the system was there.

I spend a bit of my year in rural northern Michigan. I'm 45 miles away from a full-service hospital, north, south, east, west. So it's a minimum of a 45-minute drive. Hospitals have closed in three of the little communities around there, but the major hospital has taken this up -- and I don't know how they did that, what the state regulations were, but they basically take responsibility for the delivery of care to this entire area. And it has made a vast difference so that I can get probably better medical care there than in my home state when I live practically a block away from a major academic medical center.

After all, we do want to have systems of care develop, and we always say, well, rural, they're too small, the margins are such that they can't be part of a health care system, but I would challenge that and say that we should look at some of these models that have been very, very successful, and I think every state will have some of them, and see whether -- take the subsidies away from the rural communities and put them in a place, but have some teeth in it in terms of what they have to do to these areas.

When we have these very major hospitals and Medicare is a substantial buyer of services, why is it that one of the requirements can't be to take care of your area? We talk about this all the time, but we don't do it very often. Maybe this is not a problem but an opportunity to consider these kinds of models.

DR. CROSSON: So, Bill, can I just ask you, when you say for that one hospital to expand its network to take care of the surrounding communities that perhaps have lost their hospitals, what would that look like? Would that look like these models we're describing of emergency services, or what?

DR. HALL: Well, I think it would take care of the staffing issues, because the responsibility for staffing would be at the mother ship more or less, so that every emergency service, outpatient clinic, whatever it is, these are employees of the system, not of East Podunk or whatever the community is.

DR. CROSSON: Right. I'm just trying to understand whether you're suggesting that the core entity would function to keep the other hospitals functioning or -

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DR. HALL: No.

DR. CROSSON: No. Okay.

DR. HALL: Not at all. Not at all.

DR. CROSSON: But they very well then could include in their network the kinds of facilities we're talking about here.

DR. HALL: Right, and maybe it's just a question of transferring the subsidies that are already in the system through Medicare and encourage people to think out of the box in terms of these networks. I can give you several examples of communities that have done this.

DR. MILLER: I'm going to ask the same question just one more time, because at first I thought -- I think I heard it this way, and now I think I'm hearing it differently. So the model you might be talking about -- and I'm not trying to get you to say anything you haven't said. You might be talking about there's currently a subsidy going to this hospital, and it's five miles away, and it's a very low volume; and there's another -- and let's just say for sport -- larger and, you know, maybe system, that type of thing. This subsidy goes away. The

money moves over here, and they're --

DR. HALL: Right.

DR. MILLER: Okay. I follow that.

DR. HOADLEY: So I concur with what a lot of others have said, that this, I think, is a very intriguing model. I like a lot of what I hear, and I think the discussion you guys provided for us was great.

You know, I've been hearing -- I can remember examples going back into the 1980s of hearing people talk about, you know, how are we going to address this in one particular state, you know, and really a lot of some of these same ideas, taking a small hospital that can't sustain itself and figuring out what function it should serve. And I think, you know, what you're talking about here provides a mechanism to allow that to happen.

I share with Bill Gradison -- I mean, the issue of whether Medicaid -- you know, the failure to expand Medicaid is one of the explainers on the uncompensated care side I think is something we don't want to sort of fill in a gap for a state that hasn't expanded Medicaid. So, I think, you know, thinking about that side of it.

Beyond that, I think, you know, so on the core --

the two words that came to my mind were "sustainability" and "flexibility," and we heard a lot of discussion about different elements of that flexibility sort of within this notion of transitioning away from critical access hospitals, what are the rules. I think this notion of how the community partnership -- and, like Bill, I've heard examples of places where, you know, some counties have this taxing authority, but it has to be granted by the state, and so other counties would have to go to the state legislature to get it. So we obviously need to be sensitive and flexible to those kinds of arrangements.

And sustainability I think is -- you know, maybe part of it is this idea that Herb put up, that if you have this one chance to go back, that's one of the kinds of ability to sort of address sustainability, is, okay, you know, if I'm worried, and you've heard this in a lot of the other things going on. I'm not sure I want to do this because what if I get on this path and it doesn't work? Maybe that's one of the kinds of ways you try to address the sustainability.

I think, you know, notions of grant funding and community grants and things are always things that can be

on the chopping block the next time around, and I think we also should think about whether creating this sort of grant notion inside what we're doing makes it more vulnerable to staying funded over time as opposed to the funding streams that, you know, are just core parts of the funding system that we have in Medicare. The fact that the politics of rural areas tends to help sustain things may make some of those less of an issue than they might otherwise be. But I do think, you know, sort of thinking about how -- what's our ability to sustain a community of this size to do this, and make sure that they can continue to do it over a period of years once they've sort of taken this big step is just something that -- one of the lenses we should use.

DR. NERENZ: Just a general point, because others have made all sorts of more insightful comments than I have about real care.

The intriguing thing to me in this discussion is this idea of grants for standby capacity, and I say that because it's just a special case of this larger question of how does Medicare pay for something that's not a service, or whether Medicare should pay for something that's not a service. And this thing gets woven actually into other

topics and other discussions we've had around this table, standby capacity, emergency preparedness capacity, that kind of thing. And the way it's typically done is that there is some sort of an add-on to a service payment, but I think about Mike Chernew when he was here as playing out that that kind of sort of side door/back door approach to payment sometimes leads to perverse incentives that then leads to other problems.

So in this case, actually, there's a reasonably straightforward thing to consider with some reasonable boundaries around it that may be sort of an instructive test case of how this might work on a larger scale, and how and whether should Medicare pay for something that is not inherently a billable service.

DR. CROSSON: Thanks, David.

DR. NERENZ: It's a non-service. By definition, it's somebody or something sitting there.

DR. CHRISTIANSON: It's called option value [off microphone].

[Laughter.]

DR. COOMBS: This has been a really exciting time, I think, because it's getting at all aspects of rural

medicine, and I thank you, Susan, for some of the points that you brought up, being from Iowa and understanding the landscape.

The scenario that I was speaking of earlier is exactly what you said, for rural hospitals within -- critical access hospitals within a short distance from each other. I just think that if we do a payment or grant for standby capacity, it should be tied to something. And so I had experience in Ghana where I went to a hospital and talked to the workforce there, and they said, "We just want you to help us to help the people who get in accidents on the roadside, to get them stabilized to get them to the Korle Bu Hospital." And it was really an interesting thing. When I think about EDs, freestanding, whether it's a small critical access hospital, is what kind of tool sets can Medicare actually enhance for the beneficiary who gets stuck by the roadside with some kind of travesty, whether it's an MVA, whether they come in with a cold stroke or MI. And the critical thing is time. I mean, you know, several people have pointed out time-sensitive therapy. I think the distance makes a difference in terms of who we try to really support.

And so I think the distance is going to be a factor. I think telemedicine is going to be a factor. If you get a grant or some kind of special monies, I think this should be tied to some kind of contingency that says telemedicine is a piece of that process. And I'm thinking about, you know, we have the elderly beneficiaries, they're going to have strokes, they're going to have heart attacks. What are we doing to incentivize something that is in the health care delivery system to take care of the true emergencies?

So if there's money for standby capacity, then there should be standby capacity strategies that are woven into a requirement. And I think as I sit here and think about it, I think those are the important things to me as a provider if I was in a freestanding ED.

And then the other piece of this is how we deal with the other clinics or whatever kind of other facilities that are there to try to meet the needs of the community. I think we ought to approach this in the population health perspective. I like what Bill had said, but I don't like it where it forces an entity to have to be under the umbrella of a larger entity totally, because they may be

more dictatorial and not understand the nuances within the grassroots of that community.

So I like what Bill said in terms of utilizing the resources from the integrated delivery system, but I don't know that there has to be a formal contractual agreement there.

DR. CROSSON: Thanks, Alice.

MS. BUTO: I wondered whether we really -- whether we believe that or we're ready to say that all the hospitals that meet our mileage criteria, the CAHs really should be converted. In other words, I guess what troubles me a little bit is putting in place new programs that surely will be taken up and creating whole new categories of providers.

I'll give another example. The FQHC option, which is FQHC plus ambulance, you know, why wouldn't FQHCs that exist now want that option? So I think there is a potential woodwork effect for the second option. I don't know what that would be. And I'm worried about the first option keeping or providing more funding to entities that maybe should, I think as Bill Hall mentioned, affiliate with a larger hospital or do something -- affiliate with

each other. I'm really not sure.

Bill Gradison asked the question of whether there's some ability to provide CMS flexibility to work with different situations, and I think the demo authority that CMS already has, CMMI has, could be that flexibility.

So another thing that I thought was because we don't know the array of entities or problems that they're facing, you sort of want them to come to -- or have CMS go out and say if you want to convert, come talk to us about how you want to do that. How would it best fit your circumstance? And then if that model works, it could be taken nationwide and made available to other entities. I'm just nervous about creating new categories of providers.

And then the issue of the grant troubles me a little bit because I struggled to think of any other circumstance where CMS provides a grant without it being tied to some kind of per member per month or per patient issue. So, yes, we provide Medicare Advantage payments in advance, and we do that on a PM/PM. Usually it's tied to some kind of service or beneficiary involvement. And this one feels like it could go to an entity that never sees a Medicare beneficiary. That would be the extreme case. So

I'm wondering whether -- I liked Alice's idea of actually attaching -- if you're going to do a grant and assuming CMS could get the authority to do that, and PHS wouldn't want to take that over, which is the way I would see it, then the idea of associating that with a series of requirements, if you want this money, it's about converting -- it's a little bit like the eHR thing. If you want additional money to adopt information technology, we'll give you some additional money. So maybe it could be that way.

And then I think several people have asked the question -- I think Herb raised the question of could these entities come back into the program. I don't see that there's a reason why they couldn't as long as they met the criteria for that type of provider, critical access hospital, unless that -- is that program closed now?

MR. KUHN: The necessary provider program closed in '06, and you can tell us how many people came through the necessary provider program. Probably more than half came through that --

MS. BUTO: Yeah, I don't think there would need to be a special provision. I think there are avenues now, and maybe you'd want to put that in there. But, again, my

basic nervousness is about creating new provider types without knowing what the unintended consequences are.

DR. CROSSON: Kathy, could you just clarify one thing? So when you said an option would be to have the hospitals who have these difficulties come to CMS and say, "We would like to convert, could you help us?" convert to what?

MS. BUTO: Well, they'd have to -- as in a demo program, they'd have to -- either CMS would have to go out with a solicitation saying, look, we think there's an issue for rural hospitals, we think the current system really forces you to provide inpatient services or tries to get you to provide inpatient services to be viable, we are looking at alternatives, we'd like to look at, you know, alternatives that would affiliate -- create a greater affiliation with, say, a neighboring inpatient facility or one that's 25 miles away, or whatever.

Again, this is a little bit of Bill Hall's idea of CMS could go out with something, and then entities could come in and say, look, this is our proposal to do it, this is the kind of flexibility we need, we want to try this out in our area, we think this is going to work.

I basically like the idea of letting different circumstances and entities in those circumstances develop their proposals for solving the problem within some general framework and overseen by CMS and then evaluate it. So that's the notion of a demonstration program.

I can't remember who said something about -- I think it was Mark's clarification about, you know, in a Bill Hall situation, would the inpatient hospital be the one that gets the money essentially? Would you shift that? It wouldn't have to be that way. I mean, you could set up a circumstance where the entity gets to keep the money, but in an affiliation agreement that stipulates what it is the relationship is and so on.

So I mean, you could structure it a number of different ways.

DR. MILLER: Yeah, I mean, the way I took the comment -- and you intellectually may have come to it entirely on your own, but it sort of pings from Bill to Bill to Kathy. Bill was saying it may be too early to really form a solution because -- and other people have said this. You've seen one CAH, you've seen one CAH. And Bill proposed this other option. And what I hear Kathy

saying is turning the thought on its head, instead of Medicare saying I'm going to create this new category, set up something through, let's say, CMMI or the demonstration authority, put out a solicitation, have individual hospitals come forward and say this is our solution for our community. Maybe that solicitation includes some models, like here's some stuff to think about, but come in and talk to us, and let the motivation come from the field instead of the opposite direction. That's sort of what I feel like I hear you're saying.

MS. BUTO: That's kind of what I would prefer, recognizing that there may be a need to save certain institutions that are critical. But I'm trying to figure out, okay, this option is going to require legislation. That doesn't happen overnight. Are there some transitional things that could be done through demo authority to keep some of these entities more viable in a more reasonable way? I don't know. You know, it could be just as hard to do a demo.

DR. CROSSON: Thank you, Kathy.

DR. CHRISTIANSON: I think what I have to say is consistent with the discussion here, and as we move

forward, if we could think about framing this a little differently. The first slide sort of frames it as there's closures out there, is there something we should be doing? The discussion really is a much broader discussion than that, I think. And so if we could think about just how to approach this topic in the next round where we don't start out with there have been some CAH closures and, therefore...

And then the other thing I want to just put on the table is I'm not totally conversant with this literature, but my understanding is -- and I think Jeff is into this better than me -- that it's not the case for a wider range of quality measures that community access hospitals are somehow lower quality. I don't get this impression that if we can just get people to larger hospitals in cities somehow they're going to get better care. I don't think the literature necessarily supports that across all the DRGs, and I just want to make sure that we don't have this sort of general feeling that care is always better in bigger hospitals.

DR. CROSSON: Okay. Other comments?

[No response.]

DR. CROSSON: You know, it seems to me that this has been a good discussion. We have had, I think, two options presented, and I think the kind of net takeaway from this discussion is that we would like to see perhaps a larger range of options, you know, brought forward, taking into consideration both some of the implementation details that might follow from the options you've presented as well as, I think, Bill, Bill, and Kathy's idea that perhaps there's a way that this could be done through a more flexible approach.

I think it might be useful to have some more details about the relative ease or difficulty of moving different approaches forward so that we get a sense of what we could do more quickly than perhaps some other approaches and revisit this with a little bit of a broader look at the questions. It seems to be I'm getting some bobblehead consensus going on around that conclusion, so with that, Jeff and Zach, thank you for your presentation, and we'll see you again.

[Pause.]

DR. CROSSON: Okay. And speaking of second acts --

MR. ZARABOZO: So you're the top banana and I'm the --

[Laughter.]

DR. CROSSON: Carlos has come back to visit us. As you may remember in September, we talked about the issue of what to or how to deal with the issue that the Medicare Advantage star program ratings can be influenced negatively by the existence of low-income populations and/or high numbers of under-65, disabled Medicare beneficiaries and what we could do about that, and we had, I think, two points of view on the Commission. One was, well, we understand there's a problem, but we would prefer to not change the measurement process in one way or the other because the measures are what they are, and so perhaps the most direct thing to do would be to deal with the financial implications of the perturbation of the rating system and others, I think, who would prefer seeing CMS change the structure of the measurement process to make up for high populations of low-income beneficiaries or disabled beneficiaries.

So we were not able to reach a consensus, and what we are going to do today is we're going to look at the

issue again. And we're going to hear from Carlos about some potential solutions for that divergence of opinion, and at the end of the discussion, I'd like to see us either decide we want to go one way or the other or one of the additional options, which would perhaps bridge the differences, or come to the conclusion that we just simply have a difference of opinion, with the realization that there are other bodies working on the same problem.

MR. ZARABOZO: Thank you for that introduction.

This is, as Jay said, a follow-up to the September presentation with a little bit of additional information provided.

TO summarize the issue we're considering, the Medicare Advantage program provides bonuses to plans that perform well in the 5-star rating system. Plans with overall ratings of 4 stars or higher are eligible for the bonuses.

A concern has been raised by plans that primarily serve low-income populations, such as special needs plans for Medicare-Medicaid dually eligible beneficiaries. Such plans do not achieve the same level of star rating as other plans, making them ineligible for bonuses. These plans

attribute their relatively poorer performance to their enrollees' more complex care needs and their socioeconomic status.

In research that we have done and that RAND has done for CMS, we do see an association between low star ratings and a plan's share of low-income enrollees, as well as a plan's share of enrollees under the age of 65 who are entitled to Medicare on the basis of disability.

In September, we discussed some of the issues in detail. Today we will review some of the CMS findings that were released a couple days before the September meeting, and we will talk about what the findings mean in terms of their impact on star ratings. We will also talk about the questions and issues you raised at the last meeting, including some alternative approaches to address which you discussed or which are possible.

There are two points to highlight from the CMS findings released in September. One is that CMS found the low-income effect and the disability effects apply to a limited number of measures, and their effect at the measure level is relatively small.

The other important point to highlight is that

after taking low-income status or disability status into account, the addition of socioeconomic status as an explanatory factor does not improve the ability to predict or measure results; that is, low-income status and disability status are sufficient to account for factors such as the level of education and the poverty level of the area where a beneficiary resides.

CMS stated that the effect is a small effect. So what does that mean?

This table summarizes the RAND/CMS findings on the low-income and disability effects. The researchers examined only those measures with no case mix adjustment. Of the 44 star measures, 16 were not case-mix-adjusted for a low-income effect, and 15 did not have a case mix adjustment related to disability status.

The researchers looked at within-contract differences between each category of beneficiaries; that is, for a given contract, how much higher or lower were the results for low-income beneficiaries as compared to non-low-income beneficiaries in the same contract.

What this table shows is what CMS reported as the magnitude of the median difference for 90 percent of the

contracts; that is, excluding contracts with results at the very high end and at the very low end. In the column labeled "large effect," there are, at most, two measures that we were referring to as having a large effect, where the median population difference was about 8 percent.

In the next column, mid-range effect, there were 7 measures for low income and 11 measures for disability status where the median difference was in the 2 to 7 percent range.

The last column shows the measures where the difference was less than 2 percent, or where the median performance level was better for low income or disabled beneficiaries.

Another reason these results suggest a small effect in the overall star ratings, as currently constituted, is that the differences usually apply to a relatively small segment of beneficiaries within a larger contract, given that the stars are assigned at the MA contract level.

For example, in 2012, among MA plans with a star rating, the average share of enrollment of beneficiaries under the age of 65 was 17 percent. As pointed out in the

slide, we could find for a given measure that there is an 8 percent difference between the result for enrollees under 65 compared to enrollees who are aged, but that 8 percent difference translates to a 1.6 percent difference in the measure results at the contract level if only 20 percent of a plan's enrollees to whom the measure applies are under 65.

So the biggest effect of what is a small effect to begin with is to be seen among specialized plans, and it involves a very small share of overall enrollment.

So I'm going to give you some information that is not contained in the slides. As noted in your mailing material from last month, in 2012 there were 37 HMO contracts with star ratings where the contract was 100 percent D-SNP contract, and they represented 3 percent of all HMO enrollment in Medicare Advantage at that time.

For the disabled, of 25 HMO contracts, where 50 percent or more of the enrollment was comprised of beneficiaries under the age of 65, 16 out of those 25 were 100 percent D-SNP contracts, and only 2 of the 25 were not majority D-SNP contracts. Two percent of all HMO enrollment was in the 25 contracts where half or more of

the enrollees were under age 65. So it's a small share of enrollment in those kinds of plans.

So combining these two overlapping categories, in 2012 there would have been 46 contracts that were either exclusively D-SNP or majority disabled, and they represented about 3.5 percent of total enrollment.

If one were to adopt the peer grouping method of evaluating these plans, that is to say, assigning star ratings just within this subgroup for bonus purposes, and if the peer grouping resulted in a distribution of bonus plans that was the same as the program-wide distribution of bonus plans in 2012 across all of MA, then 17 of the 46 plans would be bonus-eligible.

Using the current distribution where about 40 percent of plans are in bonus status, about 18 of the 46 contracts would be bonus-eligible. However, 7 of the contracts already were four stars or above, so the net change is about 10 or 11 contracts if you used this peer grouping methodology to apply to these plans that would move to bonus status.

Turning now to the issues discussed at the September meeting, one question that Kate raised was

whether or not specialized plans show better performance for the populations they serve when compared to non-specialized plans.

Much of the discussion at the September meeting also revolved around the question that can be summarized as "Is it the stars or the dollars?" meaning that if any changes are to be made, we need to consider their purpose and end results. Is the purpose to make changes to the star ratings so that more plans serving particular populations receive star ratings at bonus levels and can have those star levels reported, or is the purpose and desired end result to provide additional funds, outside of the star system, to particular plans?

Another way of looking at the issue is to ask, as Cori did, whether the purpose is to level the playing field for MA contracts in their star ratings, or is the purpose to level the playing field for groups of beneficiaries whose quality of care currently is below the levels of other beneficiary groups.

So I will get around to answering Kate's questions, but before doing so--

[Laughter.]

MR. ZARABOZO: Later tonight.

[Laughter.]

MR. ZARABOZO: I should mention that when we talk about specialized plans, what we are talking about is mainly the special needs plans for dually eligible beneficiaries, or D-SNPs. Although the two populations of concern are low-income beneficiaries and beneficiaries with disability status, in terms of plans with significant enrollment, there are only specialized MA plans for one subset of the low-income population, the dually eligible beneficiaries enrolled in D-SNPs. However, because a large share of the under-65 population are dually eligible, D-SNPs, other than those limited to aged beneficiaries, have larger shares of under-65 enrollees than non-D-SNP plans.

While we do not have plans specializing in the disabled, except for some chronic care special needs plans, we would expect plans with large shares of under-65 enrollees to be able to address the care needs of their enrolled population.

So in order to answer Kate's question, we used the 7 star measures that we analyzed for last month's presentation where we found statistically significant

differences for dually eligible beneficiaries and for beneficiaries under the age of 65.

Controlling for other factors affecting measure results, such as the presence of a diagnosis of dementia, we compared results for the populations in different types of plans. The first set of plans shown in the slide are D-SNPs, where we compared their performance for their primary population, beneficiaries with full Medicare-Medicaid dual eligibility status, with the performance of non-D-SNP plans with full dual eligibles enrolled. What we found is that for the aged population, D-SNPs perform better than non-D-SNPs. This is also true for the under-65 population, though not to the same extent as for the aged population.

The second comparison set can be thought of as an evaluation of whether plans that you might expect to specialize in care for the under-65 population, which is plans who have a large share of under-65 enrollees, do better for these enrollees than plans with lower shares. We used percent of enrollment under age 65 as an explanatory variable for this analysis. What we found is that for both D-SNPs and non-D-SNPs, having a higher share of under-65 enrollment was not associated with better

performance on measures for the under-65 population.

So our findings that specialization may give D-SNPs an edge over non-D-SNPs in serving their populations, particularly among the aged, along with the finding that plans with higher shares of enrollees under 65 do not show better performance for the under-65, suggests that we should pay more attention to the needs of the disabled. Because our research and that of CMS found that there are disparities in care for beneficiaries with disability status, we want to pay particular attention to this population and attempt to reduce disparities in care for this population.

One way to focus attention on the needs of the disabled is to use the star rating system as a vehicle for improving care for the disabled. We know that MA organizations pay attention to the star ratings because they are tied to bonuses and they are publicly reported. Currently, the measures in the star system pertain mostly to the aged. If there were more measures that applied mainly to the disabled and if such measures were more heavily weighted, that would be a clear signal for focusing on the needs of the disabled.

The lack of measures addressing care for the disabled is not a new issue. In 2010, the Commission recommended that more measures should be developed that apply to people with disabilities.

There are ways to change the star rating system that do not involve major changes to the manner in which stars are determined. This slide lists two approaches that CMS has used, or proposed, which change the relative ranking of some plans in the star rating system.

CMS decides on the weights of each measure in the star rating system. Currently, for example, outcome measures have a weight of 3, while process measures have a weight of 1. In the context of the topic we are discussing, as mentioned in your material, CMS had proposed reducing the weights for some measures where there were population-based differences for low-income individuals, but the proposal was withdrawn.

CMS has increased the weight of the two improvement measures it calculates. They previously had the same weight given to outcome measure of 3, but now the two measures are each weighted 5. One possible modification to the weighting approach which helps to

address the issue of disparities is to give more weight to improvement only for measures in which we find disparities.

At the September meeting, you discussed whether the way to improve care for certain populations is to provide more direct financial assistance to plans with large shares of particular populations. Such an approach would be similar to the Commission's recommendation on providing funds to designated providers through the QIO program to improve their performance. That recommendation called for funding on a budget-neutral basis.

On the question of care for the disabled, something that might help is giving plans greater flexibility to design benefit packages based on specific diseases, which is something the Commission recommended when we examined the issue of the various types of special needs plans.

And for some additional information that is not on this slide, on the question of funds available to MA plans for low-income individuals, I should mention that as mentioned in the mailing material, for example, the risk adjustment system provides a bump up in payment for dually eligible beneficiaries, about 20 percent for the aged and

about 10 percent for the under-65 dual eligibles. Also, all dually eligible beneficiaries received a low-income subsidy for the Part D premium. In addition, because some categories of the dually eligible are full duals, they received Medicaid benefits that the plan might otherwise have to finance, and the Medicaid program is responsible for the Medicare cost-sharing liability. So these other sources of income free up rebate dollars for certain plans.

One final point is that when CMS released its findings on this issue that we are talking about today in late September -- in September, rather, the agency noted that -- the direct quote here -- "Parallel analyses are being conducted to determine if modifications are needed for the payment risk adjustment models." They mentioned this in the context of this issue because some of the payment modifications could result in higher payments for certain categories of beneficiaries.

Here we review why, for the time being, an interim to this issue seems to be most feasible. We have mentioned that the effects found to date would appear to have a relatively small impact. The stars for 2016 have been determined already and will be posted shortly at the

medicare.gov website, and if there are going to be any changes to the star system, there may be a question of whether it is legally permissible under the current statutory authority to have separate stars for bonus determinations and public reporting, if that is the route that CMS would choose to pursue.

CMS and the Department of Health and Human Services are continuing to look at this issue, as required by the IMPACT Act in the case of the Department. Later this year, possibly in November, CMS will issue a request for comments that is a preview of the February call letter, and in that preview document, CMS is likely to discuss what its next steps will be on this particular issue.

As modifications to the star system are being considered, policymakers need to keep in mind the degree of infrastructure change needed, especially if we are talking about a small effect and there are alternatives that are simpler or more streamlined.

So I look forward to comments you may have on the interim solutions and any other issues you would like to discuss, and would remind everyone that we will continue to monitor the ongoing work of CMS and the Department on this

issue. Thank you.

DR. CROSSON: Okay. Thank you, Carlos.

We'll start as usual with clarifying questions.

DR. BAICKER: This was very helpful, and thank you for answering my question, and we can get back to that in Round 2. But just a quick question about the assessment of the small versus large impacts. I want to be sure I -- I think I understood from the mailing materials that the measures that were excluded were case mix adjusted, which is different from risk adjusted. That's about the survey issues. I just want to be sure that the measures that were excluded weren't the very ones in which we would expect there to be a bigger effect. But I took that to be more about the survey methodology than about risk adjustment.

MR. ZARABOZO: They excluded the case mix adjusted measures, which is the CAHPS measures and the measure, for example, of was there improvement of physical or mental health coming from the health outcomes survey, which are pretty heavily weighted.

DR. BAICKER: And the reason to exclude those is?

MR. ZARABOZO: That they already incorporate these factors, such as low income, for example, in the

CAHPS.

DR. REDBERG: Thanks for the helpful presentation. You had mentioned when you showed us Slide 12 that CMS withdrew their proposal to down-weight certain measures. Were there particular reasons or problems? I'm interested in --

MR. ZARABOZO: Yeah, that was mentioned in the mailing material, that for some plans it did not help them very much; other plans said, well, you know, you're not paying attention to measures that are important to measure and, therefore, you shouldn't be down-weighting them. And once you start removing measures, what are you left with in terms of the measures that you're looking at?

DR. MILLER: The other thing I would add to that is I think there's a fairly -- these two statements are not inconsistent with one another. You can say that there's a statistical relationship, but the effect may not be large. And I think there's a perception out there that this is going to move large blocks of money around and a lot more activity. And I think the realization is starting to dawn that it might not be as big as people were thinking. And so I think some of the reaction that CMS got to this was

where is the large action that we thought we were going to see here.

MS. UCCELLO: So this is on the tailored benefit package issue. Did CMS just recently announce a demonstration or something that would allow MA plans, like a VBID type approach?

MR. ZARABOZO: Yes, CMS announced a VBID demonstration.

MS. UCCELLO: I was confused -- I didn't read it in detail, but I was a little confused by it. It made it sound like it was -- that you would still have plans that were particular for certain people, almost like a C-SNP. Or did I read it wrong? Could you just have one plan that covers all these people, and you could vary the benefits based on their condition?

MR. ZARABOZO: My impression was you could vary the benefits. For example, targeting disease, so let's say diabetics, you will provide transportation only for diabetics because you want to see them. So it's similar to our recommendation that we said, you know, rather than having C-SNPs, we would like, within larger plans, the ability to say, yes, we have a different benefit package

based on a person's disease, which is currently not possible.

MS. UCCELLO: Okay. Thank you.

DR. MILLER: And that was the other reason or even the main reason we put it on the list, is we were trying to say -- you know, there's a couple different ways that you can go at this, one of which is giving the plans greater flexibility to tailor their benefit to the disabled population, for example, that they have, even if it's small, it may give them some greater ability to move the quality and scores, et cetera, on them. And we just wanted to make sure to remind you that we have a standing recommendation in that area, and you could think of a statement that says you need to do some things we said before, and, you know, you could mix and match how you responded.

MS. UCCELLO: I just have one more. So the risk adjustment model includes factors for disability and low-income?

MR. ZARABOZO: Yeah, originally entitled based on disability as a factor, for example, and then the demographic factors are age factors, and then low income.

As I mentioned, dual status gives you an increased payment.

MS. UCCELLO: And is there any sense that those bump-ups aren't big enough?

MR. ZARABOZO: Well, on the dual status issue, for example, Dan Zabinski did some work that said, you know, currently the dual status bump-up is any category of dual, which is both the partial duals and the full duals. So if you make a distinction between the two when there's a valid reason for doing so, you may have more payments going on behalf of full duals, for example.

DR. HOADLEY: I think you started to hit on this with Cori's question, but on the point about tailoring the benefit package, can you remind me what were some of the things that we had in mind in that recommendation of a couple of years ago?

MR. ZARABOZO: It was, for example, reducing cost sharing or eliminating cost sharing for physician visits for people with certain diseases. I mentioned transportation limited to -- so, for example, some of the C-SNPs that we talked to said we do this for the purpose of transportation, that's why we have a C-SNP for diabetes because those people need to be seen more often. We cannot

to our entire population provide this level of transportation. It's not economically feasible. So, you know, the benefits and the cost sharing is what we were looking for changes in.

DR. HOADLEY: Thank you.

DR. CROSSON: Okay. No more clarifying questions, so I suggest we enter into a discussion here, and I tried to see if I could catalogue the different potential directions we could go in, and I may not have gotten that completely correct. But one is that we could decide that this problem, although it's real, is small enough that we should just leave it alone and not propose solutions that add complexity based on trying to solve a problem that is real but relatively small.

We could simply reiterate previous positions of the Commission, including that one way to address this would be to allow for plan flexibility to tailor benefits and, therefore, potentially improve the quality of care for these populations and move their star ratings up.

We could suggest one or more set of changes to the measurement process or the process of converting measures into star ratings.

We could, on the other hand, suggest that the star rating methodology and the conversion of the measures to star ratings stay the same, but in recognition of the financial impact of this on a small number of plans suggests an add-on payment for plans that have some percentage of disabled patients or low-income patients or both.

Or we could simply suspend our discussion and wait for the CMS proposed rule and then make comments on that based upon our wisdom and thinking at the time.

I think those are the five options. I may be wrong. So not seeing anything else, I thought we might discuss and see whether there's a central tendency here on the Commission to move in one direction or the other of those -- and I'm very sorry -- five possibilities.

Who would like to lead off this one?

DR. SAMITT: So as I think about what we're trying to accomplish here, I would imagine there are two things. One is to assure that the plans have necessary resources to manage this critical and disabled needy population, and the second is to continue to instigate toward further improvement in quality outcomes. And so of

the five options that you've identified, I don't think there are many that achieve both.

I don't know the degree to which your Option 2, allowing the plans flexibility around benefits, achieves these various outcomes. So I'd love to learn more about whether that allows the redeployment of resources to improve quality that those plans don't currently have.

But the only other one that I also think does both, gives necessary resources and instigates quality improvement, would be to find a simple but elegant way to change the measurement process or to allow like plans to compare with each other from a stars achievement perspective as opposed to being blended in the broader stars pool. But, you know, I would not advocate for just adding on to the plans with a larger percentage of disabled patients because that doesn't necessarily instigate and redirect those resources toward quality improvement. So that would be my vote.

DR. CROSSON: Thank you. And I'm sorry, but Craig actually brought up a sixth possibility.

[Laughter.]

DR. CROSSON: No, legitimate, because we had

thought about this as well, and that would be some process of tiering. So taking plans that had a large percentage of disabled or low-income individuals, beneficiaries, and put them into a separate tier so that they would have their own tier or star ratings separate from the others, and then the regular rules -- but the measurement process would be the same, but they'd be comparing like to like. That's a sixth potential possibility.

DR. BAICKER: Just following up on Craig's point, he mentioned simple but elegant, and I would note that that does not appear to be our specialty.

[Laughter.]

DR. BAICKER: And given the magnitude -- I was very interested to learn about how small a difference this made in most cases to include some of the candidates we thought were the most likely candidates, and that combined with the absence of the simple, elegant improvement to the less than simple and elegant system that we have right now might argue for leaving well enough alone until we get the next round of analysis, which I thought was really helpful to my thinking about this.

DR. CROSSON: I'm sorry, Kate. Analysis from

MedPAC staff or --

DR. BAICKER: Wait for the CMS report.

DR. CROSSON: Yes, I see. Thank you. Okay.

Who else? David, you were the one who said -- yeah, go ahead.

DR. NERENZ: Yeah, just a couple of points, and I think I may end up after this in our set of choices perhaps where Kate was.

A few of the interim things that are discussed here I think are okay, but obviously not perfect, and I think in the long term, rather than down-weight some measures, for example, it would actually be better to keep them but adjust them. And I've made statements in this room in the past why I think that's a good idea. We could get into that again if you want to. So I don't know that it makes sense to do something quick that's imperfect if we could do something -- if it's not a crisis right now.

One of the things about that down-weighting that I just want to point out is it does effectively distinguish between process and outcome measures. The ones that are down-weighted are outcome measures. And I think that distinction really matters in this discussion. It is

crucial in this discussion. The measures in which these social and other effects have their effect and generates all the debate are largely in the outcome domain. They're really not so much in the process domain.

And so one approach to a problem is to say, well, let's just down-weight the measures in which we have the problem and maybe it'll just go away if we sweep it under the rug. But I think in other contexts, we've favored outcome measures. We say outcome measures are important. We want to move in that direction. And then I think consistent with that is to say, yeah, let's move in that direction, let's weight them heavily, but let's get it right.

Now, just very briefly, part of the reason it's in my head about getting it right is that the crucial thing about outcome measures, at least as I would phrase it -- and an article in this week's JAMA said it the same way -- outcomes are determined by quality of care and other things. They are multiply determined, and if you want the measure to reflect quality of care, you have to deal somehow with the other things. And that's a big debatable philosophy point, but at least as I think about it, there's

quality of care and -- and you have to somehow deal with the "and." Down-weighting just kind of pushes it away.

So a couple of points then about like additional dollars for quality improvement or measures for improvement. It sort of spins off the point I just said. In some of the cases, plans will not be able to improve because they can't affect the "and" where it's extremely hard or expensive to affect the "and." So I don't want us to get into this territory and say, well, let's just find other ways to have plans improve and then it will all eventually work out. I think one of the points about adjustment is that some of the factors that are in play here are just not subject, are not amenable to quality improvement. Again, I understand it's debatable, but I think we have to pay attention to that.

And then the last thing, just about what are big or small effects, I just want to perhaps remind a point. Because we're a Payment Advisory Commission, we naturally pay closest attention to the dollars, and we look at which dollars move where and which policy approaches move dollars this way and that way. But the star system is not just about dollars. It's about public reporting. It's about

identifying plans as good plans or bad plans, highest, lowest, and presumably that public reporting exists for a purpose, for people to use the information to choose.

So I don't want us to just pay attention to where the dollars shift, of crossing one particular threshold. I really want us to think about where the star ratings themselves shift, because part of what goes on here is public identification of plans as good or bad. Again, we're doing it for doctors, we're doing it for hospitals. But, you know, here the focus is on plans.

So short term, I think I may end up saying let's -- if the better solution is one that takes a little more time and is hingeing on some CMS action, maybe it would be best to do that. Get it right rather than do something half-baked quickly.

DR. CROSSON: Thank you. But the central tendency, I think, of what you're saying is something in the range of actually altering the measurement process or perhaps -- and/or creating tiers. Would those be --

DR. NERENZ: I favor the former over the latter, but latter does something -- again, the tier thing is usually -- it's like what we did a couple years ago with

readmission. It does do perhaps a good thing with payment. It doesn't speak to the problems of public reporting because you still get flagged as -- now, in Craig's example, you might tweak it that way. But, no, I actually would be okay with changing the underlying measurements, the specs of the measure to include adjustment when justified, when there's a big "and" and a relatively small quality contributor.

DR. CROSSON: So let me be clear what I was saying in terms of tiering, because maybe that's not clear. The notion would be, arguably, to take the plans that qualified by having some percentage of low-income and/or disability. They would then be put into the star rating system, but compared among themselves. So they wouldn't necessarily have the same low star ratings unless they were, in fact, low in comparison to like plans.

DR. NERENZ: And we've essentially done that with readmissions. I think it's not a bad thing to do here. So I'd be generally okay with that. I think you start having trouble when there starts being five, six, seven factors upon which something matters, and then you've got this big grid with 50 cells in it and the plan is in one cell and it

gets tough.

DR. CROSSON: Okay. So let's now start the general discussion. We'll start with Kathy.

MS. BUTO: I was misunderstanding of the tiering. I thought -- and I don't know if this is one of your six options -- that you were talking about sort of a different set of measures, particularly for plans that deal with people with disabilities as opposed to -- because if you look at the measures, the ones where there's great disparity tend to be screening measures. Most of them are process. Most are screening. It seems to me with an under-65 disabled population we're talking about different things that we care about and that the population cares about when they're looking at which plan to choose, how well does this plan actually manage different areas of disability, whether it's mental disease or physical disability or, you know, access to care in other ways.

So I don't know if that's an option, but I don't think the low-income population is in the same bucket as disability. I would actually leave the low-income population in the general population and think about whether CMS ought to dedicate some resources to providing

better resources, educational resources to those plans that have a concentration of low-income to better reach those populations in terms of screening. And when I was at HCFA, one of the things we tried to do with HIV/AIDS testing is we actually worked with different organizations like the Council of Black Churches because you have to get out information in a different way if you're trying to reach certain populations that may not pay any attention to Federal or even managed care plan outreach. So it just seems to me the issues are different for the low-income versus the plans that focus on disability.

I guess having said all that, I'm inclined to wait because I don't see a clear solution. It doesn't seem to me that just using the same measures with the disability population in either downrating them or putting them in a tier with low income really gets at either of those issues very well, at least at the moment.

DR. CROSSON: Thank you, Kathy.

So just to be -- I was going to say "to be clear." This is actually making it more obscure.

[Laughter.]

DR. CROSSON: A lot of the six solutions could

apply to both low-income and disability or to one or the other. If you -- because, yes, I think Carlos has demonstrated that the impact of high numbers of under-65 beneficiaries has more impact than the low-income. So that's good. So let's go down this way.

MS. UCCELLO: So, last month, I think it was Dave and I who sounded like we were probably on the opposite sides of the continuum, and I think if -- but, I think we actually agree more than we disagree. And if I can just kind of engage him here to make sure I understand this, you know, making sure we get the measure right, are you saying that getting measures in there that truly can gauge the quality for a disabled population and have that as part of the whole quality ratings, is that where you're trying to get at with that last part of your comment?

DR. NERENZ: Let me just emphasize again, I focus very heavily on outcome measures, so some of what I'm going to say has nothing to do with most process measures. If you're going to use an outcome measure as a measure of performance or a measure of quality of care, you have to start with this idea that it's determined by quality and. And I think to get the measurement right, if you're

considering quality of performance, you have to somehow deal with the "and." It's just a basic fundamental -- why do you ever adjust anything for anything.

But, that is driven by the idea that -- you have to accept the idea that there's this "and" component. If you look at the measure and say, that's just pure unadulterated quality of care because we declare it so, then you don't adjust. But, I don't view it that way.

MS. UCCELLO: And I think I just -- I try to push that box out as much as we can on taking some of that "and" and bringing it in, to the extent that's possible. But, in general, in -- so, I like -- I personally want to keep the bar as high as we can when we're assessing these plans, along with giving plans the tools and the resources that they need to help achieve what we hope they can achieve. So, reiterating our comments and recommendations in the past regarding fee bid type approaches for this population, I think would be appropriate.

And, in terms of -- instead of thinking about this payment add-on, if we recast that as kind of reiterating our recommendation on the partial versus full dual in the risk adjustment, I think that's where that kind

of add-on comes in and comes in appropriately. So, that would be where I would want to go.

DR. MILLER: The other thing I'll say, and I didn't realize we had sat you two right next to each other --

[Laughter.]

DR. MILLER: -- but in retrospect --

DR. NERENZ: She said we really don't disagree that much. We worked this out last month.

DR. MILLER: I think it was brilliant, actually, doing it that way, whoever.

[Laughter.]

DR. MILLER: The other thing that I felt like I heard in terms of your comments, both last time and to some extent this time, is what public reporting is for, and David, you seem to focus on the fact it's, like, well, it's to say which plans are good and bad, and I think there's some truth to that.

But, I think the reason public reporting was created was to move quality for the population, and sometimes I feel that's what you're saying. And while you seem to be, but the "and" should be out if it's really an

"and," and I think Cori is trying to say, but, shouldn't -- Cori is saying maybe the "and" -- you know, reach to put the "and" in, and that's, sometimes when I hear you two talk, the difference that I hear.

And, now, Jim, could you move them to different seats?

[Laughter.]

DR. BAICKER: But, also, just to --

[Laughter.]

DR. MILLER: Don't do it.

[Laughter.]

DR. BAICKER: Just to clarify my understanding of the choice base, when we say include or exclude, it may actually be the opposite of what people are picturing in the model. When I hear you say you need to take the "and" into account, to me, that means, no, put it in the regression model because we want to hold fixed these other things. And whereas you say including these factors, you actually mean not including them in the regression because you don't think that quality should vary based on those things, so you don't want to control for them. And, then, the --

DR. NERENZ: And there's exactly the distinction, and this runs through this entire big debate every time we have it. Is quality one contributor to outcome, among other things, or is the outcome quality itself? And, I can -- it's harder for me to articulate that second view. Is that just -- is it a dimension of quality itself, and all the contributors, whether it's community factors, crime in the neighborhood, what not, that's just all wrapped into quality. Dealing with it is quality. Maybe that's a way to do the distinction. Is it or isn't it?

DR. BAICKER: But, what I took from what you said is a really helpful distinction to draw is the goal is for the stars to capture quality of care delivered by that entity. For process measures, maybe we think you don't need to control for those things, like giving the patient the right -- giving the patient antibiotics before the surgery should have nothing to do with those other factors. It's a process measure. Cori's -- I'm going to call it Cori's regression -- makes all sorts of sense, because you don't -- those things shouldn't affect that, whereas for the outcome measures, as you were distinguishing, we can't use those as a clean measure of quality because all of

these other things contribute to it.

So, conceptually, it makes more sense to say, if you want to isolate the quality delivered in that entity, you need to control for those other factors because they are directly affecting -- they are confounding your estimates of quality --

DR. NERENZ: Independently affecting.

DR. BAICKER: -- and you do want to control for them. So, with the same principle, you might get different regressions, depending on whether the outcome variable is more or less confounded by those factors.

DR. NERENZ: [Off microphone.] Yes.

DR. CROSSON: As you say.

[Laughter.]

DR. MILLER: Jim, if you could also get Kate into a different --

[Laughter.]

DR. BAICKER: Could I be seated further away? Is that possible?

[Laughter.]

DR. MILLER: That's what I'm asking.

[Laughter.]

DR. CROSSON: Moving on -- I'm sorry.

DR. HOADLEY: I'm not sure what I should say at this point. You know, I'm finding this hard -- struggling with trying to think about these things, and maybe that comes back to that answer that we shouldn't try to take any particular direction until we've heard more or until this issue matures in some way. I think I'm going to leave it at that.

DR. CROSSON: Okay.

DR. HALL: I sort of get into this conundrum and then say, what's in it for the Medicare recipient? So, if I'm the average Medicare recipient and I am in a community that has seven or eight MA plans and I'm choosing, they say, well, just look at the ratings. Well, it sounds like four-and-a-half is better than four. I'm not sure that actually means anything. It's like all ratings, that we rate colleges, we rate medical schools, we rate toothpaste, and the idea is you simplify it down to a point where it's an almost meaningless measurement.

On the other hand, given all the discrepancies in the things, if one plan has a rating of five and the other one has a rating of one, I'm probably going to take that

pretty seriously.

So, I think we expect more from ratings that have a five-star system -- that it's going to answer all of our problems, and I think you're just pointing this out, that it's impossible to do it. And maybe that's almost the point that needs to be conveyed. And if we are really worried that it's reflecting major quality issues, then we need to revise it in a big, major way. But, I think we need to know a lot more about this until we say it.

And, the other thing is, do we know much about how consistent these populations are? When consumers have choice of five or six MA programs, doesn't this change from year to year, depending on sort of the luck of the draw, more or less? You may have less low-income. You may have less disabled. It's not a constant, is it, over time, or is it?

MR. ZARABOZO: Well, the low-income, of course, can change plans on a month-to-month basis.

DR. HALL: Right.

MR. ZARABOZO: But, there isn't really -- you know, we did a little analysis of the movement. There's not that much movement across plans, if that's your

question.

DR. HALL: Okay. So, I think we may be trying to solve problems a little prematurely here.

DR. CROSSON: We'll come back up this way. Warner.

MR. THOMAS: So, I tend to lean more towards Craig's comment, that I think reporting similar plans and comparing them is important. There is a difference here. It may not be material, but there is a difference. And, to me, that does impact the ratings. It impacts the quality measures, and I think we need to take that into consideration.

DR. CROSSON: Thanks. Herb. Oh, I'm sorry, Bill.

MR. GRADISON: I support number five, particularly because the timing of the cycle of the announcements of the stars. I think that letting a few months go by isn't going to substantially affect the influence we might have simply because of the timing situation.

Tiering, I'd like to give a lot more thought to that, because I don't know what other tiers might be

suggested in the future. I haven't examined the data, but what if we were to find, hypothetically, that in MA plans, people over age, say, from 85 and over have substantially different outcomes within the plans than people 65 to 75, which could -- I don't know what the facts would show, but if we were to find that, and if we start down this tiering, I think we'd be hard-pressed to say, well, maybe we should have a separate category for that, as well. So, I appreciate that's purely a hypothetical, but, bottom line, number five would be my choice at this time.

DR. CROSSON: Herb. Herb, and then Rita.

MR. KUHN: So, I appreciate this conversation, because I think we're all trying to seek equity, equity for the plans and equity for the beneficiaries and this issue of outcomes, as David, I think, so artfully said, and the "and" and how you deal with that.

But, I guess I have a question for Mark. Obviously, there will be -- as Carlos said, there's some information maybe come out next month, and then, ultimately, a call letter in November. Do you have all that you need with past positions the Commission has taken in order to respond effectively to these asks for

information or these issues that CMS will be putting out?

DR. MILLER: I mean, the other thing, just before I try and answer your question, is there's also a mandated study that CMS is supposed to do which also comes in behind those.

There is certainly -- as you can see, there's a lot of material from positions the Commission has taken where we could say some constructive things for you to think about, CMS, are these, or bear in mind, Congress, there are some legislative recommendations we have made that we think could potentially help the situation, i.e., let all managed care plans tailor their benefits toward certain populations. So, there are certainly constructive things we can say without having to litigate this specific issue, which the Commission doesn't seem to be completely -- or having to litigate the issues in this room that the Commission doesn't have consensus on. There are still constructive things that we could say. And we could also say it in a way of, these are just ideas that you, CMS, could consider that are consistent with past positions.

So, there is, I think, reasonable responses that could be put on the table without having to resolve the

thing -- the few things -- well, you know, without having to mix up David and Cori, and then however Kate fits into that --

[Laughter.]

DR. CROSSON: Rita.

DR. REDBERG: So, I think it's been a great discussion, and I would favor, I think, leaving option five, that is, until we have the CMS input announcement.

And, tiering is interesting, but I have some concerns with it, because -- I mean, as David alluded to, we sort of want good outcomes for everyone, and when you start saying we're going to make adjustments and suggesting, then we're suggesting less than the same outcomes for some populations.

And I appreciate the reference to the JAMA article, which, you know, was a comment on a JAMA Internal Medicine article which I happen to know very well, which pointed out that patient characteristics that are out of our control, like housing and income and race, really played a big part in sort of readmissions and probably other quality ratings, and clearly that isn't something that Medicare can -- itself can address and adjust for very

much.

But, it does also, I think, beg the important question of what are the outcomes measures, because what we have here listed as outcomes measures are not outcomes measures, I would say. You know, these are -- I think they called them intermediate outcomes, but they're really -- I mean, outcomes are things that patients can feel. I mean, these are -- controlling blood pressure, medication adherence, we hope that they could reflect outcomes, but, unfortunately, they don't actually reflect outcomes, most of them.

For example, again, a paper published last year in JAMA Internal Medicine from the Yale Group analyzing Medicare data showed we have more admissions now for hypoglycemia than we do for hyperglycemia, and some of that, I think, can be attributed to the well-intentioned outcomes measure of controlling HbA1c, and we've now gotten so aggressive on controlling HbA1c that we're putting more people into the hospital because they're too low on their blood sugar, and I have a lot of concern.

I actually was talking to a colleague just a few days ago at work who takes care of a lot of diabetes

patients who told me that another unintended consequence of our outcomes measures is that a lot of doctors are now screening healthy patients for diabetes because it's so much easier to control HbA1c in people who are borderline, not really diabetic, than they are -- and, so -- and the same with the blood pressure measure. You know, a lot of our Medicare beneficiaries suffer from falls because they're on too many hyptertenses.

So, I think before we start tying a lot to our outcomes measures, we need to really have another look at what we're calling outcomes, which I'm saying are not outcomes measures, and look at harm and really kind of make outcomes measures something meaningful that we can really get behind.

The last thing I wanted to point out is that, right now, we don't have any quality measures or process tied to overuse, and there's a lot of overuse that leads to harm in the Medicare population. For example, the diabetes measures are supposed to apply to patients 18 to 75, but I think a lot of our population is over 75 and more likely to suffer. And then outside of these, the cancer screening measures, a lot of them stop at age 75, because after --

you know, the mammography and colorectal cancer screening, because the harm exceeds the benefit past that age group. I think we should have quality measures that look at overuse or inappropriate use in our beneficiaries over 75, because that's where harm starts exceeding benefits.

DR. CROSSON: Thank you, Rita.

Jon.

DR. CHRISTIANSON: I think I agree with Kate, but it's a long time ago, so --

[Laughter.]

DR. CHRISTIANSON: So, it's on a general principle.

[Laughter.]

DR. CHRISTIANSON: No, I think the idea is the dollars aren't that big. CMS has been charged to do work in this area over the next few months and we have some positions that we've taken in the past that are relevant, so I would say that we shouldn't do anything other than reaffirm those positions right now.

DR. CROSSON: Kathy.

MS. BUTO: Just to, I guess, keep my position that I think we should wait for CMS, but I'm wondering,

Mark, whether we could encourage CMS to find out a little bit more from the disability community as to whether the star ratings are helpful. So, if they don't find them helpful, or if they find them -- if they're distressed in some way, it would be good to get that input as they think about the next step in the process.

DR. CROSSON: Okay. Thank you, Kathy, and thank you all.

This has actually been a very good discussion, both this discussion and in September, because I think what we've done here, not just for ourselves but for others who are looking at this, including potentially our colleagues at CMS, is to elaborate the complexity of this issue and all the competing values that go into proposing a solution. And I think that's very valuable work. Sometimes, we can reach a consensus and come up to a conclusion, and that's helpful for people who are our customers. But, sometimes simply elaborating the complexity for people who, in this case at CMS, are trying to wrestle with the same issues is a very valuable service, also, although I would have to say if I were at CMS and working on this and sitting in the audience right now, I think I'd be considering a different

career. Just a joke.

[Laughter.]

DR. CROSSON: So, we will -- I think the consensus here is fairly clear, and that is we will not disengage from this issue, but we'll suspend our deliberations pending at least the most -- the soonest iteration of findings from CMS, and then I think we'll be in a position to react and perhaps help refine that, and we think that may occur sometime in the next few months, is that --

DR. MILLER: [Off microphone.] -- a couple of versions, but one is early and it's the next few months, and then a couple other --

DR. CROSSON: Right. Right. So, any other comments on this?

[No response.]

DR. CROSSON: Okay. Thank you again for the discussion.

We're now at the point in time where we have an opportunity for public comment. If there are any members of the audience who would like to comment to the Commission, please find your way to the microphone so we

can see who you are.

Okay, so we have one individual. Let me just remind you, as well as the rest of the audience, that this is an opportunity, but it's not the only opportunity for input to the Commission, to the staff and their work. They are available to the public and there is also a website that is an opportunity to provide comments before MedPAC deliberations.

So, I'd ask you to identify yourself and your organization, and you have about two minutes to make a comment. When this red light goes back on, that two minutes is up. Thanks very much.

MR. ZAMAN: Good morning, and thank you to the Commission for its insightful discussion today. My name is Shahid Zaman and I'm commenting on behalf of America's Essential Hospitals.

America's Essential Hospitals is a membership association of over 250 hospitals and health systems dedicated to high-quality care for all, including the most vulnerable.

Our comments focus on the Commission's discussion today around quality measurement in MA plans and the

discussion yesterday afternoon around the requirements of the MACRA legislation.

Appropriate risk adjustment of measures, whether in mix or in MA star ratings, is imperative to ensuring providers and plans are not unduly penalized for serving low-income patients. We are particularly encouraged that CMS in its request for information on MACRA is seeking comment on requiring quality measure data to be stratified by demographic characteristics such as race, ethnicity, and gender.

Other factors outside of hospitals' and providers' direct control, such as homelessness, income level, education, and primary language, can influence health care outcomes and skew results in certain quality measures, just such as those for readmissions. Without proper risk adjustment, an essential hospital, other provider, or MA plan serving a disproportionate share of lower-income patients with confounding socio-demographic challenges might be unduly penalized for reasons outside its control.

We would ask that, going forward, the Commission make recommendations that take into account the unique

challenges certain providers face due to their complex and diverse patient populations.

We look forward to following the Commission's work on these issues. Thank you for the opportunity to provide comment.

DR. CROSSON: Thank you for your comments.

Seeing no other individuals at the microphone, we are adjourned until next month. Thank you all again.

[Whereupon, at 11:33 a.m., the meeting was adjourned.]