MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

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9:53 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[9:53 a.m.]

DR. CROSSON: Okay, maybe we can assemble and begin. I'd like to welcome our guests to the beginning of 2017-2018 MedPAC season.

For those of you following MedPAC, or don't, it's traditional to begin our discussion, and also to begin the March report to Congress, with a presentation of the context for Medicare payment policy. This is fundamentally a statement of the impact of Medicare on the economy, the impact of the economy on the American people, and sets the stage then for a discussion, first of all, of what this Commission has recommended in the past, and then subsequently for the rest of the year, sets the stage for our discussion and recommendations on proposed solutions.

So today we have Jennifer and Olivia, and we're going to have a presentation on the context for Medicare payment policy.

MS. PODULKA: Thank you, Jay. And good morning, everyone. Part of the Commission's mandate and law is to consider the budgetary impacts of its recommendations and to understand Medicare in the context of the broader

healthcare system. One of the ways we meet these elements of the mandate is to include in the March report to the Congress an introductory chapter that places the Commission's recommendations for Medicare payment policy within the context of the current and projected federal budget picture and within the broader healthcare delivery landscape.

The chapter is intended to frame the Commission's upcoming discussions regarding payment updates and policy recommendations. While there are no policy recommendations in this chapter, we are seeking your comments today on its scope, substance and tone. Please note that some of the numbers that we'll present today are preliminary and will be updated as data are published over the next several months.

In today's presentation, Olivia and I will discuss the main topics of the chapter, which include healthcare spending growth in the recent slowdown, Medicare spending trends and detail, Medicare spending projections and the program's effect on the federal budget, also, characteristics of future Medicare beneficiaries and burden of Medicare and healthcare spending on households, and

finally, evidence of inefficient spending in the healthcare delivery system and challenges faced by Medicare to increase its efficiency.

For decades, healthcare spending has risen as a share of GDP, but then beginning in 2009, its growth rate had slowed. As shown by this graph, that general trend is true for healthcare spending by private sector payers, as well as by Medicare and Medicaid. As a share of GDP, total healthcare spending, shown in the top line here, more than doubled from 1974 to 2009, increasing from about 8 percent to a little over 17 percent. Over that same time period, private health insurance spending, the middle yellow line, and Medicare spending, the middle green line, both more than tripled.

Then from 2009 to 2013, healthcare spending as a share of GDP remained relatively constant, which is highlighted by the shaded portion of the spending curves. However, government actuaries estimate that starting in 2014, spending began to modestly accelerate, driven in part by health insurance expansions under the ACA and increases in prescription drug spending mainly on new treatments for hepatitis C. The actuaries project that over the next

decade, healthcare spending will continue to gradually increase. Growth rates are projected to fall between the lows of the recent slowdown and the earlier highs.

Now taking a closer look at Medicare during the 2009 to 2013 slowdown period. The year-to-year change in spending per beneficiary slowed in traditional fee-for-service Medicare Advantage, or MA, and Part D. These lines look a bit noisy, but keep in mind that they're showing year-to-year changes. The lower rates were generally due to both -- to decreased use of healthcare services and restrained payment rate increases.

Beginning in 2012, the ACA reduced annual payment rate updates for many types of fee-for-service providers and in 2011, began lowering payments to MA plans to bring payments more in line with fee-for-service spending. Then, beginning in 2014, growth is more mixed. Part D was quite high in both 2014 and 2015 then falling in 2016. Both fee-for-service and MA growth began to increase following the slow-down period.

Taking a closer look at fee-for-service. Even before the slowdown, per beneficiary spending was not uniform across settings. For example, from 2007 to 2009,

outpatient SNF, home health, hospice and labs had high rates of growth. Then the slowdown from 2009 to 2013 affected settings differently. Outpatient remained high while SNF, home health, hospice and labs dropped a lot.

There is also a variation in growth patterns in the period following the slowdown. Inpatient physician, SNF, hospice and DME continued to fall while outpatient and home health rebounded. Note that home health and DME experienced negative change. These are two settings where Medicare had implemented specific policies to improve efficiency. The results demonstrate that it is possible for the program to affect spending trends and yield savings.

Comparing across the decades. On the left side of this graph the upper yellow portion of the bars indicate that per beneficiary spending growth has fallen from average annual rates of 10 percent in the eighties to 1 percent from 20 -- in the nineties and growing to 3 percent in the last six years.

Looking ahead to the next decade is shown by the right-hand side of the graph. The Medicare trustees and CBO both project that per beneficiary spending growth will

fall between the recent lows and the past highs with an average annual rate of 4 percent. In addition, the aging of the Baby Boom generation is causing an increase in enrollment growth, as shown in the bottom green portion of the bars. Enrollment growth increased from about 1 to 2 percent per year historically to 3 percent over the last six years.

This higher growth is projected to continue throughout the next decade, hence, the trustees and CBO project growth and total spending shown above the bars to average about 7 or 6 percent annually through 2025, which will be faster than growth in GDP. This means that the size of the Medicare program will nearly double over the next 10 years, rising from about $700 billion in total spending in 2017 to more than $1.3 trillion in 2026.

While spending is growing, Medicare's financing is growing more strained. Workers pay for Medicare spending through payroll taxes and taxes that are deposited into the general fund of the Treasury. As Medicare enrollment rises, the number of workers per beneficiary is projected to decline. The number has already declined from around four and a half around the program's inception to

about three today. By 2028, when most Baby Boomers will have aged into Medicare, the trustees project there will just be two and a half workers for every beneficiary. These demographics are creating a financing challenge for the Medicare program.

As you may have heard, the trustees project that the Hospital Insurance Trust Fund will become insolvent by 2029, but that date doesn't tell the whole financial story. The HI Trust Fund covers less than half of Medicare spending. It covers Part A services and is financed by a dedicated payroll tax. It's projected to become insolvent in 12 years as payroll tax revenues are not growing as fast as Part A spending. The Supplementary Medical Insurance trust fund, or SMI, accounts for 57 percent of total Medicare spending. It covers services under Parts B and D and is financed by general tax revenues which cover about three-quarters of spending and premiums paid by beneficiaries which cover the other quarter.

It is financed by general tax revenue transfers, which of course, include deficit spending and premiums, both of which are reset each year to match expected Parts B and D spending. In other words, SMI is considered to be

solvent, but only because by design SMI income grows at the same rate as Parts B and D spending. This doesn't mean that SMI doesn't also face major financing challenges. It does, which the next slide shows.

The line at the top of this graph depicts total Medicare spending as a share of GDP. The layers below the line represent sources of Medicare funding. Working up from the bottom, all the layers up to the skinny red layer represent dedicated funds collected specifically to finance Medicare spending, such as payroll taxes, which fund Part A, and premiums paid by beneficiaries, which help fund Parts B and D.

At the top, the purple area below the total Medicare spending line represents the Part A deficit created when payroll taxes fall short of Part A spending, and the blue layer represents the large and growing share of Medicare spending funded through general -- general revenue. That share is over 40 percent today. And keep in mind here that again, general revenue includes both general tax revenue as well as federal borrowing.

Of course, these same dollars and deficit spending could be used to fund other federal programs, such

as education and infrastructure investment. And, of course, there's great competition for these tax and borrowed dollars. The black line at the top of this graph represents total federal spending as a percentage of GDP and the layers below the top line here depict federal spending by program. The aqua-dashed line represents total federal revenues.

Working up from the bottom layers, Medicare spending is projected to rise from about 3 percent of our economy today to about 6 percent by 2046. In fact, by 2039, shown by the vertical line on the graph, spending on Medicare, Medicaid, other major federal health programs, Social Security and net interest will reach about 20 percent of our economy and by themselves exceed total federal revenues.

Final note, the projection shown here is optimistic in assuming that federal revenues will increase above 19 percent eventually, which is greater than their historical share of GDP of about 17 percent of GDP. If on the other hand federal revenues continue closer to their historical average, spending on major programs and net interest could exceed total federal revenues even sooner

than 2039.

And now I'll pass to Olivia with a more detailed look to the future.

MS. BERCI: Shifting from projections of spending, we will now summarize the characteristics of future Medicare beneficiaries. Indicators of the health of future beneficiaries are mixed. A study by the United Health Foundation compares the health status of middle-aged adults 50 to 64 years old in 2014 to the same age cohort in 1999, who are now current Medicare beneficiaries. Compared to their predecessors, middle-aged adults about to age into Medicare smoke 50 percent less, have a 55 percent higher prevalence of diabetes, have a 25 percent higher prevalence of obesity, and 9 percent fewer reported very good or excellent health status.

Additional studies indicate that new and incoming beneficiaries have higher rates of some diseases and chronic conditions, but their chronic conditions are much more likely to be managed and well controlled. During the Great Recession, which began in 2007, real median household income declined for all age groups. Since many Baby Boomers, who largely make up the new and incoming Medicare

beneficiaries, may have been near retirement during the economic slowdown, they may be less financially secure than previous generations in retirement, and therefore, less able to bear the burden of increasing out-of-pocket costs.

In 2014, the real median household income for 55 to 64 year olds had fallen 4 percent over the decade. In contrast, real median household income for members of this age group had increased by 13 percent a decade earlier. During the great recession, family net worth also declined. During the six-year period between 2007 and 2013, the median net worth of families with heads of households ages 55 to 64 fell 42 percent in real terms. In contrast, the same age group's real median family net worth had increased by 70 percent over the six-year period ending in 2004. In addition, out-of-pocket costs for Medicare beneficiaries have grown faster than Social Security benefits, which make up a significant or even complete share of many beneficiaries' income.

In 2017, Medicare out-of-pocket costs consume 24 percent of the average Social Security benefit. Medicare out-of-pockets costs will consume 30 percent of the average Social Security benefit by 2039. The burden of out-of-

pocket costs falls on those with private insurance too. In the last decade, per capital healthcare spending and premiums have grown much more rapidly than median household incomes. From 2005 to 2015, premiums for individuals and families grew 55 and 61 percent, respectively. Per capita, personal healthcare spending grew 47 percent while the median household income grew just 22 percent.

Note that these are in current year unadjusted dollars. Only premiums and healthcare expenditures grew in real dollar terms over the decade. This means that a family earning the median household income in 2005 spent 23 percent of their income to pay for the premium for family coverage. In 2015, they spent 31 percent of their income on insurance premiums.

On average, since 2007, the cost of commercial insurance -- we looked at HMO and PPO premiums -- has grown twice as fast as Medicare costs. One key driver of the private sector's higher prices was provider market power. Hospitals and physician groups have increasingly consolidated, in part to gain leverage over insurers in negotiating higher payment rates. Medicare's slower growth is partly attributable to restrained increases and

Medicare's payment rates.

While commercial insurers usually negotiate prices with providers, in Medicare, the prices paid to providers are set by law. In fee-for-service Medicare -- if fee-for-service Medicare had followed growth in commercial pricing, Medicare costs would have grown substantially more. Despite Medicare's lower price trend, there are opportunities for further savings in the Medicare program. There is strong evidence that a sizeable share of current healthcare spending in Medicare and overall is inefficient, providing an opportunity for policymakers to reduce spending, extend the life of the program and reduce pressure on the federal budget. For example, research on Medicare spending shows that areas with higher spending or more intense service utilization do not have higher quality of care or improved patient outcomes.

Services that have been widely recognized as low value or even harmful continue to be provided. Also, the U.S. spends significantly more in healthcare, both per capita and as a share of GDP, than any other country in the world. There is ample evidence that this difference is driven not by utilization, which is similar to other

countries, but by higher prices. As a result, Americans pay more for prescription drugs, hospital and physician services and other medical goods and services.

Despite higher prices and resulting additional spending, studies consistently show that the U.S. ranks poorly on indicators of efficiency and outcomes. Notably, Medicare beneficiaries' gains in longevity are outpaced by their peers in other industrialized countries. Note that not all Medicare beneficiaries are experiencing gains in life expectancy. The paper goes into much more detail about this trend. For example, between 2014 and 2015, white women and Hispanics of both sexes lost ground in life expectancy at age 65.

To sum up, the Medicare program, as well as the healthcare system more generally, face a number of challenges in achieving savings. Medicare has a fragmented payment system across multiple healthcare settings, reducing incentives to provide patient-centered coordinated care. The program has limited tools to restrain fraud and overuse. The Medicare's benefit design consists of multiple parts, each covering different services and requiring different levels of cost sharing. Medicare can

pay different prices for the same service depending on where the service is delivered, and finally, in the process of setting prices for thousands of services, some services are undervalued and others are overvalued, providing incorrect incentives for their use.

The Commission's approach to overcoming these challenges has been to pursue accurate prices that promote the efficient provision of services, to develop policies that encourage high-quality care and the coordination of care across settings, to support policies that improve the information that beneficiaries and providers receive, to advocate for medical education and training that focuses on team-based approaches to care coordination, and finally, to engage beneficiaries in the decision-making about their healthcare.

These approaches are captured in recommendations that the Commission makes. The paper summarizes recommendations made under each of these five approaches over the past several years. Medicare's goal should be to obtain the greatest possible value for the program's expenditures, which means maintaining beneficiaries' access to high-quality services while encouraging their efficient

use.

So with that, I'll conclude. The presentation only covered a portion of the information included in the mailing materials. We welcome your questions and comments on any of the issues discussed in the presentation or mailing materials and look forward to your discussion.

DR. CROSSON: Thank you very much.

Can I see hands for clarifying questions? I see just a few. Jack and Warner so far.

DR. HOADLEY: So on Slide 13, the last bullet on that where you talk about the average SMI out-of-pocket costs, how are you accounting for the costs that are picked up by supplemental coverage and the premiums for that supplemental coverage? Is this based on the actual out-of-pocket or is it based on sort of definitional out-of-pocket without regard to supplemental coverage?

MS. PODULKA: Jack, I'm sorry. I actually don't remember the details well enough on the methodology. I can get back to you on that one.

DR. HOADLEY: Thank you. And in the chapter you had a section -- when you talk about some of the Medicaid issues and particularly the financial impact of the

Medicaid primary care bump, which says in the chapter that the data haven't all played out yet, I wonder if that's one of the areas where there's more information coming, because that's now been quite a few years.

MS. PODULKA: We are missing in the chapter -- slightly more than half of the data points come out during the fall, so we should see updated data on this.

DR. HOADLEY: That's one where it would be useful to see that particular one updated.

DR. CROSSON: Warner and then Jon.

MR. THOMAS: So in Slide 4, the Part D, do we know what's driving the spike and then the big change in '16?

MS. PODULKA: I do have a story to relate. The Part D went up quite a good deal largely because of higher spending for the hepatitis C drugs that came out and that made their way to Medicare beneficiaries. In part, 2016 comes down as that surge settles out. So, in part, Medicare beneficiaries who are diagnosed with a condition that would require hepatitis C treatment, as soon as those drugs came out, within a couple years they get the treatment. That initial surge then calms down somewhat, so

you see a drop. That doesn't mean you're going to continue to see that kind of drop year after year.

Also, there were some other things going on with plans gaining experience with what to expect and changing their expectations for the future. So it might be a one-time downturn. Don't get too attached to it.

DR. CROSSON: Amy, on this?

MS. BRICKER: But, moreover, the price of those drugs also came down dramatically. So I think it's two parts.

MS. PODULKA: Right.

DR. CROSSON: Dana, also on this point?

DR. SAFRAN: Yeah, also on this point. I think, though, it could be helpful to have another display that gets at level versus trend, because, you know, while it's true that, as you said -- and we saw this in commercial insurance, too. We had an enormous spike because of hep C, so trend looks really high. When that spike settles out, the level of spend is still high, though, as Amy said, as the price of the drugs came down, the trend hasn't continued, but the level is still high. So I think it's important to tell that part of the story.

MS. PODULKA: We do include information in the paper -- and then that will appear in the chapter -- about total dollars spent at different points in time. Honestly, we had them on one version of the slide, and there was no more room left for anybody to read it. So they came out. But you will see them in the text.

DR. MILLER: I'm sorry. I know we have people on deck. We go back and forth on this one. Jennifer, we went back and forth on this, right? So you're zeroing right in. You know, the other way to do this is you can look at cumulative, which, you know, because sometimes people look at things like that and they go, oh, crisis averted, or, you know, look -- we definitely follow your point. So we'll figure it out either in words or pictures, because we went back and forth on this one ourselves.

DR. CROSSON: Jon -- oh, I'm sorry

MR. THOMAS: I have a couple other questions. So on Slide 5, do we have more insight on the inpatient hospital decrease? And do we have any idea the impact of the readmission penalty? Do we think that's one of the drivers there? Do you have any insight on that?

DR. MILLER: I'll recruit anyone else into it.

What I would say is that we have seen a slowdown in admission rates, and we think that that's got something to do with it. Certainly, the readmissions are in there, and I am looking at Jeff just to get a confirmation. I wouldn't say that's necessarily the biggest component of it, tho.

DR. ZABINSKI: [off microphone] reduction [inaudible].

DR. MILLER: Yeah, so admissions fall, yes, readmissions fell as well, probably in that order to explain the number.

MR. THOMAS: Okay. And then on the outpatient hospital lab services, do you understand kind of the main drivers there? Is it high-end imaging? Or is it kind of across the board, is it all areas?

DR. MILLER: I know we have seen volume growth in the outpatient department pretty consistently year over year. Dan?

DR. ZABINSKI: [off microphone] volunteer information.

DR. MILLER: Which is rare for Dan. We can talk about this offline.

DR. ZABINSKI: [off microphone] drug, particular oncology drugs, you know, a particular shift from the freestanding offices of those practices in the OPD setting. To a lesser extent, you know, tying in with the two-midnight rule [off microphone] here as well in response to all that. But it's primarily, I think, the drug [off microphone].

DR. MILLER: Okay. So anybody who missed that, oncology drugs and observation care are certainly factors in that.

MR. THOMAS: So in the oncology drugs, would that be a shift from the physician fee schedule bucket?

DR. ZABINSKI: To some extent, yeah.

MR. THOMAS: Okay. I mean, I think it may be helpful to just note if there's any major shifts like that. I mean, the observation growth, which is, you know, contributing some to the inpatient hospital decline, also kind of shows up in the outpatient increase. So I don't know if there's material changes like that or the shift of oncology drugs and outpatient. Obviously, in the physician fee schedule you have a decline of the trend. So it may be helpful just to make some comments about that.

My last question is about Medicare beneficiaries under age 65. I may have missed it. Obviously, a lot of information in the chapter. Is there any comment about the growth in beneficiaries under age 65, the disabled, and the impact on overall costs there?

MS. PODULKA: We do include information on beneficiaries under age 65 where it's available. They're sadly lacking some data sources. And you are correct, it's a growing group. It would be more noticeable that they're growing if there wasn't the demographic shift of baby boomers aging in. We don't explicitly break out costs by aged and disabled. It's something that we could reflect in the chapter if you're interested.

MR. THOMAS: I mean, I think if it's material -- I mean, I just don't know the materiality to the overall expense. But I think if it's material, it would be helpful to make a comment about that given that -- and whether there's a comment about, you know, once someone's disabled, they're on Medicare, you know, essentially through their lifetime. And should that be something that's thought about going forward? And if it's material. I just don't know how large an issue that is.

DR. GINSBURG: If I could follow up, I think the disability trend, which I don't know what it is, is very important. It's completely separate. It's really reflecting trends in the overall economy and people qualifying for disability, Social Security Disability benefits, and then becoming eligible for Medicare. So I think it'll be extremely distinct from the over-65 trend, which I think we do understand very well.

MR. THOMAS: And I think getting back -- I'm sorry. Just real quickly, getting back to the worker per beneficiary ratio that we look, I mean, obviously it has a dual impact there potentially. And so I just think it may be something to think about and/or consider.

MS. BERCI: So I can give a little bit of context on the DI portion. We did some work a couple years ago and have updated it subsequently. DI entitlement, individuals in Medicare, the spending is comparable to the aged, but in different categories. So much more ED, inpatient hospital, and physician visits, very high Part D, much lower PAC, but the spending is comparable.

On DI entitlement in particular, there was a very sharp increase in the number of people receiving awards

through the Great Recession, through the last couple of years, a more recent slowdown in the number of people applying as the economy has recovered. But you did also say something that's true, which is once people are on DI, a very small share of them ever return to the workforce.

DR. MILLER: And I thought the point on the switch in the economy actually does get mentioned in the chapter someplace, or am I just dreaming that?

MS. PODULKA: Right, and we can add to that section.

DR. MILLER: Yeah, so we'll make sure that that jumps out. And, Kate, I'm sorry. One other thing before you go away. The other thing that I thought -- and I hate to do this when I don't know the answer to the question. The other thing about the DI crew is that the per capitas are very different depending on what their disability status is. Right? So you can find, you know, ESRD, very high spending; you know, physical disability I think lower. So I think among the DI, you know, by category, there are some pretty huge differences.

MS. BLONIARZ: Right. Yeah, so ESRD is a separate entitlement, so that's kind of --

DR. MILLER: Oh, right, I'm sorry.

MS. BLONIARZ: They're very high spending generally, but, yeah, there is some variation. But, again, you know, we've made the point that the primary way that individuals are receiving entitlement to DI right now, about half of them are coming in because of mental impairment and musculoskeletal factors. So there are, you know, groups of beneficiaries who have birth defects and other types of catastrophic physical impairment. But, you know, it's a very diverse eligibility group.

DR. MILLER: I'm sorry. I think I distracted us.

DR. CROSSON: Dana, on this?

DR. SAFRAN: Yeah, on this. Just following up on the slide that's up on the screen and Warner's point, I understand that some of what is accounting for the outpatients, the oncology drugs, and observation, just a question, which is: Is it also a shift of procedures that were happening inpatient and now happening outpatient? Because we for sure see that in the commercial side, and if that's part of it, I think it really does bear mention.

DR. MILLER: Yeah, it is decidedly part of it.

DR. ZABINSKI: [off microphone] long-term trend.

DR. MILLER: Yeah.

DR. CROSSON: Paul.

DR. GINSBURG: I just want to make a general observation on charts like this. They're dangerous. You know, people look at them, and they can -- they don't really understand the distinction. So I think we need to have them. But I guess we need a lot of text space to point out some of the major factors that we understand are behind them.

DR. CROSSON: Okay. Point taken. Jon.

DR. CHRISTIANSON: So on Slides 14 and 15, you use the word "premiums," particularly on 15, and, of course, large -- any self-insured employer doesn't pay premiums, doesn't buy an insurance product from a health plan. So am I correct in assuming that this pretty large hunk of expenditures for health care in the private sector is not represented in this?

MS. PODULKA: The large chunk that the employers are paying.

DR. CHRISTIANSON: Self-insured employers don't buy health insurance.

MS. PODULKA: Right. Yes, that's not reflected

here.

DR. GINSBURG: This is just individual coverage?

DR. CHRISTIANSON: Well, it could be employers, I think, that pay premiums.

DR. GINSBURG: Because I think, you know, there's a term called a "premium equivalent" that's for self-insured, and so a lot of discussions about premiums for employer-based coverage include that.

DR. CHRISTIANSON: So I think it's really important to clarify what's in this and what isn't [off microphone].

DR. CROSSON: Pat.

MS. WANG: Just to pick up on the comment that Paul made about the previous chart which showed percentage changes in spending by sector, I agree it's important to show that. But also it's important to note that, you know, small changes in percentages for something like inpatient could be huge dollars, and a large percentage increase in another category could be very small dollars. So that's another context to keep in mind.

My question was going back to Slide 3 and some of the materials that we're tracking sort of the trends in

total health care spending. Could you say more about how -- so in 2014, a lot of people started gaining more insurance coverage through Medicaid or through the insurance exchanges who had been previously uninsured. Does the total health care spending sort of capture out-of-pocket kind of expenditures on health care that uninsured folks had been spending? I saw definitions of personal health care spending, but it sounded more like cost sharing when you have insurance coverage. I'm just wondering if that is in the total trend, because definitely 20 million people gained insurance in 2014. Is that captured in here?

MS. PODULKA: Yes. So there's definitely individual out-of-pocket both insured and uninsured individuals. That is reflected. The total health care is trying to capture a total, including out-of-pocket. It's not necessarily reflected in the bottom lines at the bottom of the figure.

DR. CROSSON: Okay. Bruce, clarifying questions?

MR. PYENSON: Yeah, thank you very much. On Slide 13, my question is whether the out-of-pocket costs for SMI, if that reflects fee-for-service or does that include the one-third of beneficiaries who are in Medicare

Advantage?

MS. PODULKA: This is for fee-for-service beneficiaries.

MR. PYENSON: I'm wondering if it would be -- if the information for Medicare Advantage would be there since it is such an important part of the Medicare population.

MS. PODULKA: I will need to confer with those colleagues to see if we can come up with an estimate across the different MA plans eventually. I'm not getting a high five, but we'll get somewhere.

MR. THOMAS: Thank you.

DR. CROSSON: Okay. I am seeing no more questions, so we will proceed to the general discussion, and we're going to start with Warner.

MR. THOMAS: So if we could go to Slide 10 and maybe use this as a backdrop. I guess generally I would start with a comment. You know, a lot of information here and good information, but as you look at this as a backdrop, I think the challenge we have is whether we're dealing with the payment issues and dealing with our work with enough urgency, and also putting enough focus in the chapter on the urgency that we would request CMS and

Congress to work with.

I think if you look at these projections, it's clear kind of what's before us. It's been clear the previous years. And I would just encourage us in the chapter to make sure that our wording is strong enough about the seriousness of the issue that we face and the seriousness of the work that needs to be done. So I would use that as kind of a context.

The second comment I would make really relates to the back end of the chapter where we talk about how you're really breaking MedPAC's work into five areas, and a couple of comments on that.

One, in the area of care coordination, my concern there is that we are not talking enough about the payment model reform and transformation and movement and change in the incentive program. So the incentives in our fee-for-service model we know are incorrect. They're not aligned with what we're trying to do with the program. And I would really encourage us to be much more direct about the payment model reform and the delivery system reform.

There's some mention in there on ACOs, and I know that there has been a lot of work done on ACOs. But if you

look at the amount of time that we spend as a Commission and I think CMS spends on fee-for-service reimbursement versus the new models and ACOs, it's disproportionately focused on fee-for-service, and I think that's a fundamental problem of where we spend our time and where the government spends its time going forward.

So I would just encourage us to be much more direct and clear, that we need to create the right incentives, the right guidance to have physicians and delivery systems move into ACOs and move into shared and/or downside risk, which I believe will actually help us move the trend. And going back to the comments we made earlier about movements between the different buckets, inpatient, outpatient, and what-not, we need to look at this as a global total amount of cost of care and to reduce the overall cost of care, not the bucket that it ends up in.

A couple other comments that I would have is I think on the Medicare enrollment, and obviously with the growth in the Medicare program, I think a comment around that we really probably cannot do enough in the payment system to overcome the growth in Medicare. And the reality is that, you know, we're not going -- I don't see us

reducing payments, you know, 15 or 20 percent in order to make the program affordable. So we know that people are going to age into Medicare. The escalation is going to accelerate. So without some fundamental changes in the structure of the overall program, you know, the sustainability obviously is not going to work.

And then two other comments I would make and the last comment's about what MedPAC's going to do. There's really no mention in any specific way about drug cost, which continues to be a major factor, and I think ought to be -- in my opinion, we ought to have six areas that we focus on, and one of those ought to be drug cost specifically, both as it relates to all parts of Medicare, not just Part D, because the escalation in drug pricing affects all the different components of the payment system. Whether it's, you know, in the Part A component that essentially is absorbed in hospital payments or it's absorbed in the patient area, it is escalating cost in the overall delivery system.

And then I would just encourage us getting back to the urgency piece, that we've got to be, you know, bolder with our recommendations. We've got to push the

envelope more. We've got to make more compelling arguments around the focus on the payment structure and the delivery system restructure, away from fee for service, because we've been making recommendations but many of them are not taken up, and I think we've just to be more pointed in what we put forward.

And a final comment. When I talk to a lot of people generally about this, whether it's employees, board members, people in the community, people don't understand that when Medicare was started the average life expectancy was 65. So if you won the life lottery and lived beyond 65 you got Medicare. And today life expectancy is, you know, depending on where you look at it, is 73 to 75, and many people go on Medicare. So the overall structure of the program doesn't work, and I don't know if that's our role, to make that comment, because I know we focus more on payment policy. But it certainly is a fundamental structural problem in the system that is creating, you know, this pressure and this difficulty for us.

So just a few comments on the chapter.

DR. CROSSON: Thank you, Warner. Can I see hands for further comments? So we have quite a few, so I think

we'll start down at this end with David.

DR. NERENZ: Thanks. I would like to echo and support Warner's comments on urgency, and actually, if you can put up Slide 11, you know, this, to me, is even more the compelling slide. I've even had occasion to use this with neighbors and relatives when we get into discussions of politics and Medicare spending. If I'm reading this chart correctly, it says that the point of the vertical line, which is within many of our lifetimes, there will not be one dollar available for anything other than what's illustrated below the horizontal line. Is that right? No defense. No infrastructure. No education. No nothing, right?

MS. PODULKA: From federal revenues, correct.

DR. NERENZ: From federal revenues, but that's pretty important. And also if I understand correctly, that horizontal line is not just kind of this loose illustration or average. It has the sense of a hard cap, if I understand both history and economics, as an amateur, that this is about the level that governments have been able to extract from their citizens in the form of taxation, across countries and across time. Is that also correct?

MS. PODULKA: No. We definitely did not do a cross-country comparison.

DR. NERENZ: But I'm just saying --

MS. PODULKA: A historically --

DR. NERENZ: -- aside from your analysis, I'm looking at others around the table, that's about what you can get, right?

DR. MILLER: I think, well, at least, we don't know, but this line is what's gone on in the U.S.

DR. NERENZ: All right. Again, I understand completely the context of what you've got. I'm just extending the point to say we can't look 20 years in the future and say, well, everything will be fine. We're just going to raise that horizontal line and it will all work out. Again, my sense is it doesn't work that way.

So again, this is simply to echo and to support Warner's point, that this is a burning platform, I think is the phrase. We have to do something.

DR. MILLER: Yeah, and none of our comments were -- your main point is taken. That is the point of that line, which is, if that's historically what's gone on you're running up against it. That is the point.

DR. CROSSON: Okay. Alice.

DR. COOMBS: First of all, I want to thank you. You did a fantastic job of compiling some very interesting ideas that span across a whole bunch of different issues. And one of the particular things I was interested in is Slide 10, the Mount Everest of our work. I think, you know, looking at this, you know, some of our efforts over the years have been how and what and measuring over-value versus the undervalued services. And I can't help but think about how can we make the biggest impact on this curve? I think that what we're doing is important but I think the nature of how it's done at the microscopic level is really, really important.

And I can't help but look at some of the slides you have for the chronic conditions, the leading causes of mortality, and George T. Boland, an associate, actually did a paper about a week ago in the New England Journal on interprofessional education. And it talked about how they managed case dilemmas and actually could have made a large difference if it was done on a larger scale, in terms of health care spending and spending more time in the patient's office.

And so today, released in the New England Journal, is the Eric Schneider piece on why we are not doing what we should do in terms of this country. And three things they point out -- lack of access, and lack of access in the sense that you may have access but all access isn't the same. And so I think we're afraid to get into that box because it really involves looking at inequities that span, you know, all of the precepts of timely care, efficient care, and all those wonderful things that we talk about.

But in reality, as an internist, many years ago you had a little bit more time. Today I talk to the internists and they have 15 minutes in the box, and then you go on to the next one. No new patients are slide in and, you know, there's this timeliness that is really important. And I see it now in my current practice where I have actually 30-year-old men who come in who are on dialysis because of poorly controlled hypertension. Hypertension and diabetes gives us what is the leading cause of end-stage renal disease, and results in the highest cost of care.

And so those are the things that are important.

And then one of the other key points is the under-investment in primary care. So what does that look like? And I think the interprofessional education is really key, but it looks like the patient getting in the right system, whether it's a nurse practitioner, a PA, or a physician, but actually getting in the system and making an impact on him. How we do this, it's got to be something that we work with on a comprehensive scale, at a very -- it's got to be a very detailed approach to it.

But when we whittle things down to a 15-minute interview for a patient, and they come in and it's their foot today and you say, "Well, wait on the other one because I can't get to that today," I think that's a part of the practice of medicine.

So I would say that right now there's so many things that we're doing that are important, but this other piece we cannot ignore. And I think you did a fantastic job and I thank you so much, for the two of you.

DR. CROSSON: Craig.

DR. SAMITT: So I don't want to speak for the other senior Commissioners around the table but this is the sixth time we've seen this graph and it hasn't really

changed. And so if this truly were a burning platform I think the platform has already burned down. And to tag onto Warner's comments, I think it should send a message to urgency that we should do something about this.

The comments that I want to make actually pertain to Slide 18. When we offer treatment for a medical condition and that treatment isn't working, we switch to a different treatment. And so as I look at our approach to addressing these challenges, I wonder how effective we've been in impacting the future state of the Medicare program. And I agree completely that we need to think differently or think bolder about how we advance the system so that we don't, or our children don't find ourselves without a Medicare program at some point in the future. I think now would be the time for us to take action. I don't know to what degree we've fully underscored that imperative in the chapter, but I certainly, you know, heading out of MedPAC this year, am feeling a greater sense of urgency about solving this problem than when I started.

DR. CROSSON: Thank you, Craig. Rita.

DR. REDBERG: As another senior member of the Commission, I mean, I also see a crisis, and, you know,

this is clearly of great concern. You know, looking at the numbers, both, you know, with the trends that seem to slow and then are now increasing again in terms of health care spending, and also in terms of value, I mean, I think our job here is to protect the Medicare program and to protect the beneficiaries. And what we see is increased spending and not better outcomes. So that seems to me a very poor return on our investment. You know, we were at 8 percent of GDP. Now we're over 17 percent of GDP for health care.

We still have, you know, the only health care system in the, you know, modern world that does not have universal health coverage for our citizens. You know, even after ACA there are at least 20 million Americans that don't have health insurance, yet we spend more per person than anyone else, and our health outcomes are worse. We're not living longer.

And, to me, all of that -- you know, and I agree with Craig. We need to do something urgently. I mean, I think a big problem is fee-for-service care, because fee for service rewards inappropriate procedures. It rewards harmful procedures. I mean, as you pointed out, we have a lot of low-value care but the problem is Medicare still

pays for low-value care. We have things that we know are harmful and Medicare still pays for things that are harmful to beneficiaries. That seems like a lose-lose to me.

You know, I just returned from medical meetings in Europe, and talking to my European colleagues, you know, first of all they all have universal coverage, they have better access to primary care, and they pay much lower prices than we do, for the exact same things -- procedures, drugs, everything. We're paying not just a little more, more than two or three times, sometimes 10 times as much.

So we clearly have our work cut out for us and I think, really, at a crisis stage. And when you look at the growth of Medicare costs and then the decline in Medicare beneficiaries, you know, I think it went from 4.6 to 2, you know, this program is not going to be here for some of us and certainly not for future generations. And I think that we have an opportunity to improve it but we really need to make some bold changes.

DR. CROSSON: Thank you, Rita. I do want to point out that we have exhausted the time for this topic, and so to be fair to the rest of the Commissioners, I'm going to go another 15 minutes, but please make your point

succinctly. Amy.

MS. BRICKER: Just to pick up a thread from Warner's comments, I think that, you know, with respect to drug pricing and policy we should certainly be more bold but also quite comprehensive in our review and our recommendation, truly looking at the entire supply chain, truly looking at the levers that are available to, you know, to Medicare plans, to plan sponsors, to MA plans, to commercial plans, and really managing costs and looking at, as we look to the future, as we look to the graphs that have already been mentioned, the drivers of projected pharmaceutical spend and where development is occurring today, and without us being more bold and us encouraging greater management of those pharmaceuticals, it's really, I think, not on yet our radars the future of gene therapies and other specialty pharmaceuticals that are going to absolutely exacerbate the spend associated with the program.

So I would encourage us to look at it very holistic, B and D, and across all of the supply chain.

DR. CROSSON: Pat.

MS. WANG: I just want to agree with Amy and

Warner's comments about the drug spend. I think all of the other comments that have been made about the important things that MedPAC has focused on with payment reform and changing incentives, et cetera, are critically important in the provider system but that can all be swamped with the next blockbuster specialty drug, and it will be. So I think it's just too big to ignore.

This is a more specific comment on Slide 17. Fragmented payment system, and there was a reference to it in the report, I really think that we should call out more of the fragmentation between Medicare and Medicaid for duals, disproportionate spend for the proportion of the population. These benefits are very integrated and very significant. This is not just, you know, supplemental policy to pay for cost sharing. It's really the whole cost of care for a person who needs medical and post-acute care services, behavioral health. And I think the lack of coordination there is crying out for some sort of solution that will be better for beneficiaries, for dual beneficiaries, and better for state and federal fisc.

DR. CROSSON: Thank you. Bruce.

MR. PYENSON: Just a response to Craig and the

senior MedPAC Commissioners. Thank you very much. As a junior Commissioner, I'm hoping that when I leave in five years we'll have some -- a different graph to look at. Thank you.

DR. CROSSON: I think we have to be careful about this senior thing.

[Laughter.]

DR. CROSSON: I'm not sure -- we may need to think about the terminology. Dana.

DR. SAFRAN: Okay. So as one of the newest MedPAC Commissioners -- I think it's safe to say -- I will not repeat things but I do want to echo the urgency and also the need to emphasize new payment models.

I really just wanted to make two points. One is on Slide 15, if we can put that one up, you make the point, and you show here, so vividly, the higher rate of growth for commercial. I think there's two things that are worth emphasizing in the text about this. The first of those is -- and I think you've said this in the narrative that went with this slide -- that Medicare has the opportunity to really keep rates contained. That often, because of fee-for-service incentives, drives use up. I think that bears

mention as part of the context for why payment reform is so important.

But the other point I want to make that I don't think has been made is that part of what drives those commercial lines like they do is the cross-subsidization that commercial payers are asked to do, because of Medicare and Medicaid payment rates being contained where they are. This has really important implications for the premium growth that the public experiences through private insurance.

And so all these things are tied together. You know, Medicare's ability to keep costs contained because of the way it sets prices does have spillover effect into commercial insurance that I don't think we've touched on and that are really a big part of what's behind this line, that bears mention.

And the other thing I was going to say, which I think has been emphasized, is that on Slide 18, where we are listing the priorities, we talk about payment accuracy and efficiency but we really ought to have something there about the effectiveness of payment to get the results that we're trying to get, you know, accountability for total

resource use, accountability for quality and outcomes of the care that we're providing.

DR. MILLER: So just a quick marker because we're out of time. We should talk, because we have discussed this cost shift thing and we have a very different view.

DR. SAFRAN: Okay.

DR. MILLER: So we'll take you outside, rough you up.

[Laughter.]

DR. CROSSON: Jack.

DR. MILLER: You'll be fine. You've done worse things.

DR. HOADLEY: I also wanted to highlight Slide 15 and just sort of make a slightly different point. I mean, I think -- and I won't engage the cost shift side, but, I mean, this really, I think, in part, reflects the fact that the fee for service work and the fee for service rate-setting has had an effect, and this is total cost. It's not just prices. It's cost times volume. So, yes, it does drive volume up potentially but it's still showing a net lower rate of cost.

So I do think we should keep in mind that

Medicare does have successes in this reflect, and, you know, there's a very nice discussion in the chapter on consolidation that I think wasn't particularly reflected in the slides, which makes more of that same point that consolidation is having an impact and making it tougher for the private sector to deal with costs, and potentially driving costs up. Medicare has, you know, maybe not an infinite ability to counter that, but has at least to date been able to address that.

So I think this really does -- you know, is an important perspective, not that I disagree with a lot of the other points about the needs for other kinds of reforms, but we do need to keep the attention and traditional Medicare as a role, and we've had lots of other discussions of that.

The only other thing I wanted to mention, sort of struck by David's comment about the notion of where revenue lies. I mean, it is true that we have not been willing to talk about sort of the revenue side. It's obviously not our jurisdiction, as a Commission, but in the context of talking about this. You know, we have a lot of conversations in this country about tax cuts. You know,

there are legitimate questions of whether the level of taxation is adequate and whether that could be on the table as part of this, whether we're talking more narrowly about Medicare payroll tax, which has not been increased for a long time, but whether we're talking about general revenue as well.

So I think it is important that the revenue side stay in the conversation and not always be left off the table, even though politically it's challenging.

DR. CROSSON: Paul, do you want to make a comment on that?

DR. GINSBURG: Yeah, on Jack's first point, you know, whenever we look at the low Medicare per capita trends for recent years, let's not lose fact of the -- lose sight of the fact that at least a half a percentage point a year of that is due to the rapid aging into Medicare, that the mix of beneficiaries is changing. We have higher percentage of young over-65s. And so, in a sense, we are under great pressure in the total Medicare spending. The per capita spending looks temporarily favorable because of this influx of baby boomers.

DR. CROSSON: Kathy.

MS. BUTO: Yeah, so my comments really go quickly to Slide 17 and pages 61 to 64, the challenges slide. And I think Warner started to touch on this, but the issue of the -- sort of the entrenchment of fee-for-service, fee-for-service incentives, is something that I think could be more highlighted than it is, because a lot of -- it really relates to a lot of the Commission's work on ACOs, MIPS, APMs, and so on. So I think it's a good connection. I think if we're going to lay out the challenges, it ought to be related to a lot of what we're focusing our work on.

On Slide 18 and page 64 to 68, I would like to see us acknowledge beyond accuracy and efficiency, and I think others have made this point, that we are looking for structural changes in incentives and have focused on that, so that, for instance, the work on Part D last year and recommendations, post-acute care, et cetera, we've really looked at restructuring those benefits in a way that they're not currently structured. So it's not just about efficiency of payment rates. You know, it really goes beyond that.

And, lastly, between the challenges section in the report and the Commission's work section, I think it

would be good if we could somehow acknowledge that there are new authorities that the agency has in front of it that have given rise to the ability to experiment with ACOs, with bundling. Value-based payment has made a difference. And these are fairly recent developments that come out of the ACA, but certainly other authorities as well. And it sort of sets up better kind of the challenges, some of the new authorities, and then kind of what our work has been and is going to be to address some of these challenges, because we really look at some of the new approaches to more value-based, better sort of, I guess, per member/per month types of approaches, without -- while recognizing the value that fee-for-service brings to the Medicare program.

So I think a lot of our work is around that area, and if we could set that up a bit better, that would be helpful.

DR. CROSSON: Thank you.

David?

DR. GRABOWSKI: Great. Thanks. So I very much agree with Warner's call to be bold. I think we shouldn't just be bold in terms of payment, but we could also be bold in these other domains on Slide 18. And I would

particularly point towards the demand side. The last bullet point there, engaging beneficiaries, I think part of what you mean there is use of cost sharing and co-payments and deductibles, and using those instruments to push beneficiaries towards those high-value services. So not just using payment to do that but also using benefit design.

The other bullet point -- I know we'll talk more about this later in the day around post-acute care -- is the information that we provide to beneficiaries. And I think in many instances we do a really poor job of both sort of engaging beneficiaries in terms of using the information, but then also providing them with useful information. And so I would encourage us, as long as we're going to have freedom of choice in Medicare, we need to build a good choice architecture, and we need to push beneficiaries towards high-quality providers. And so I look forward to kind of thinking about being bold, not just in terms of value-based payment but also on the demand side in terms of how we design the benefit and also how we present information to consumers. Thanks.

DR. CROSSON: Interesting and potentially useful

term I haven't heard before: "choice architecture."

Sue?

MS. THOMPSON: I know we're over time. I will be brief. Thank you. I want to say thank you for putting this chapter together.

I think you heard a lot of consensus among the group, and certainly we all -- having the third time, I am here in the middle, third time of seeing this display of data, and it isn't changing. It seems to be growing, and a problem, certainly to strengthen the statement and add some additional sense of urgency around it. I think one could only put one of those graphs up -- you know, a picture is worth a thousand words, and it tells the story. And if you don't get a sense of urgency, I think we're missing the point.

So a comment that someone made, and I think it was Warner in his opening comment, about likely we will not solve this problem through payment reform, this is going to take other kinds of ideas. And so I just invite all these comments to be incorporated and particularly around innovation, and innovation in payment models and support for the agencies that do support innovative care delivery

models.

DR. CROSSON: We have a ghost in the machine here.

[Laughter.]

DR. CROSSON: Thank you, Sue. And thank you, everyone. So that was a very good discussion, and I think I would say point taken and a good set-up for our work coming up this year. So, Jennifer and Olivia, thank you for the work.

MS. PODULKA: Thank you.

DR. CROSSON: We appreciate your presentation, and we'll move on to the next presentation.

Okay. So now we are going to take up the issue of Medicare coverage policy. It's been an issue that we have discussed on a number of occasions during the last couple of years and earlier than that.

And I think Nancy and Emma are going to do the presentation. Nancy, it looks like you're going first. I just want to make sure.

Is this microphone working? Okay. All right.

Go ahead, Nancy.

MS. RAY: Good morning. Medicare provides

coverage for a broad range of health care services under its Parts A, B, C, and D programs. In response to Commissioners' requests, during today's session we are going to present an overview of Medicare's coverage process for these services.

We will then pivot our discussion and talk about the volume of low-value care furnished to beneficiaries even with the coverage processes in place.

At the end of the session, Emma will discuss the role of comparative clinical effectiveness in Medicare's coverage and payment policies. She is going to highlight the work of the two organizations listed on this slide.

Your briefing paper provides a lot more detail than what Emma and I will be able to present this morning. Please feel free to ask questions on material not covered by the presentation.

So let's talk about coverage for A and B services. In order for a service to be covered, it must be in a Medicare benefit category and must not be excluded by the statute.

The statute also requires that a service be reasonable and necessary for the diagnosis or treatment of

an illness or injury or to improve the functioning of a malformed body member. However, the statute does not define "reasonable and necessary."

The agency in 1989 and 2000 tried to define the term in the rulemaking process. These attempts factored in a service's medical benefit and cost-effectiveness or value. CMS did not release a final rule in both instances because of stakeholder resistance.

CMS' operating definition of "reasonable and necessary" assesses whether there is sufficient level of confidence that the evidence is adequate to conclude that a service improves the net health outcomes for the Medicare population. Note that this definition does not consider either cost or cost-effectiveness.

So there are many ways for a service to be covered under fee-for-service. For many services that fall into a Medicare benefit category and can be paid on the basis of an existing billing code or bundled payment system, Medicare may cover it without an explicit coverage policy.

The statute includes some explicit legislative and there's also executive coverage requirements for

certain services such as preventive services, which we will discuss on the next slide. Explicit coverage policies are made by CMS (the folks in Baltimore, the Coverage and Analysis Group). These are called national coverage determinations. Explicit coverage policies can also be made by Medicare's administrative contractors -- the organizations that process claims submitted by providers for payment. These coverage polices are called local coverage determinations. Policies affecting coverage are also published in Medicare's provider manuals and program memos. In addition, Medicare's coding requirements may also affect the coverage of services.

Via the statute and executive memorandum, Medicare covers: off-label cancer drugs if the drug's use is published in selected third-party drug compendia, routine costs of qualifying clinical trials, coverage of routine costs of care for certain device studies, and coverage of preventive services.

National coverage determinations are developed by CMS and they apply nationwide. They do not vary by region or by state. The national coverage process can result in CMS covering a service (with or without clinical

conditions), not covering a service, or no national coverage policy. In this instance, Medicare's administrative contractors -- specifically their medical directors -- would have the discretion to develop a local coverage policy.

This slide highlights some options in the national coverage process. As part of the process, CMS can request technical assistance from its advisory group -- the MEDCAC -- or request an external technology assessment, for example, from AHRQ.

The outcome of a national coverage determination can include coverage with evidence development when CMS links national coverage to the collection of clinical evidence via a research study or data registry.

Another outcome is the concurrent review of clinical evidence by the FDA and CMS. This is referred to as the FDA-CMS parallel process.

Local coverage determinations are developed by Medicare's administrative contractors -- that is, their medical directors. Local coverage policies only apply in the contractor's jurisdiction so policies can vary from region to region. The one exception to this are the local

coverage determinations developed by the durable medical equipment regional contractors. Since 2006, CMS requires the DMERCs to jointly develop and use a single set of coverage policies.

Like the national process, the local process can result in either a coverage determination with or without clinical conditions, non-coverage, or a no-coverage decision.

Local coverage determinations must be consistent with national coverage policies if they exist, as well as the statute, regulations, and program memos.

This slide highlights some of the similarities between the national and local coverage determinations. Both processes evaluate a service's clinical evidence but do not consider the cost or cost-effectiveness of a service. Both processes allow for public comment, and determinations are posted online.

The biggest difference between national and local coverage policies is where they are applied. National policies are applied nationwide. Local policies are applied regionally in each contractor's jurisdiction. Some argue that local coverage policies permit regional

flexibility, are more responsive to community care standards than national policies, and better allow for the initial infusion of new technologies. On the other hand, some contend that there should be greater consistency in Medicare's coverage policies across regions.

Medicare Advantage plans are required to provide the same set of benefits under Medicare Part A and Part B that are available to beneficiaries in the Medicare fee-for-service program.

Plans are permitted to use tools that are not available in fee-for-service such as requiring providers to seek prior authorization in order to have a service covered. Plans have leeway in controlling utilization through the use of cost sharing.

Under Part D, plan sponsors are responsible for creating and managing formularies, which are lists of drugs their plans cover. Part D law and regulations place some constraints on which drugs plan sponsors may cover and how they operate their formularies.

By contrast, fee-for-service Medicare cannot use formularies for drugs that Part B covers.

Even with these established coverage processes

for A and B services, the Medicare program pays for low-value care. Using measures developed by researchers, we estimated that total spending for low-value care ranged from $2.4 to $6.5 billion in 2014. These spending estimates probably understate actual spending on low-value care as it does not include downstream services that may result from the initial low-value service. These results were presented to the Commission during the April 2017 meeting.

Emma will now discuss the role of comparative clinical effectiveness research in Medicare's coverage and payment polices.

MS. ACHOLA: Comparative clinical effectiveness research allows researchers to compare the clinical effectiveness of two or more treatment options. This research could have implications for improving the value of Medicare spending. In this section, we will highlight two organizations that develop and use comparative clinical effectiveness research. In 2010, the Patient Protection and Affordable Care Act provided funding for the creation of the Patient-Centered Outcomes Research Institute, or PCORI, who sponsors comparative clinical effectiveness

research. Additionally, the Institute for Clinical and Economic Review, or ICER, uses clinical effectiveness research to assess a service's cost-effectiveness and value.

PCORI is a public-private entity that was established in 2010 by PPACA to identify, fund, and disseminate comparative clinical effectiveness research. PCORI is governed by a 21-member Board of Governors who are appointed by the Comptroller General and additionally has a 17-person methodology committee whose members set methodology standards for the organization. PCORI receives its funding from the Patient-Centered Outcomes Research Trust Fund. The organization is set to receive this funding from 2010 to 2019. If PCORI is not reauthorized by the Congress by September 30, 2019, the Trust Fund will expire. PCORI was mandated, by statute, to create research priorities. PCORI established, with public comment, five broad national research priorities to guide their comparative clinical effectiveness research efforts, which are listed here.

PPACA prohibits PCORI from developing or using a dollars-per-quality adjusted life year, or QALY, or a

similar measure as a threshold to determine the types of health care that is cost-effective. However, the statute allows Medicare to consider comparative clinical effectiveness research produced by PCORI when making coverage decisions. This consideration must be done in an iterative process that includes public comment. Additionally, Medicare cannot use an adjusted life year or a similar measure to determine coverage, payment, or incentive programs.

As of July 2017, PCORI has awarded $1.68 billion to approximately 580 comparative clinical effectiveness research projects, data infrastructure projects, and methods projects. Additionally, in 2015, in an effort to focus efforts on comparative clinical effectiveness research, PCORI launched pragmatic clinical trials. These trials are observational studies that compare two or more alternatives for preventing, diagnosing, treating, or managing a particular clinical condition. To date, roughly $289 million has gone to fund 24 pragmatic clinical trials. While PCORI has made these efforts to focus on comparative clinical effectiveness research, some stakeholders contend that its efforts may need to be more focused, particularly

on head-to-head research that compares two or more drugs or devices.

The second organization that I will discuss that uses comparative clinical effectiveness research is ICER. ICER is an independent nonprofit that is funded by various nonprofit organizations and also receives some funding from life science companies, health plans, and pharmacy benefit management companies. Seventy percent of funding comes from the nonprofit sector, while the remaining 30 percent comes from these health care industry entities. ICER reports are publicly available for use, and their analyses are used by payers and others. Most importantly, ICER is able to compare the clinical and cost-effectiveness of a treatment versus its alternative, unlike PCORI.

As previously mentioned, ICER's research assesses both the clinical and cost-effectiveness of the treatments being considered. Their drug analyses use QALY as their primary measure of cost effectiveness, and they also report measures such as cost per life year gained and cost per avoided event, for example, cost per stroke avoided).

Additionally, their reports consider the potential budget impact over a five-year time period. In

public meetings, advisory board members in ICER's three regional bodies vote on a treatment's clinical effectiveness and value, and provide independent guidance on the application of medical evidence to clinical practice and payer policy decisions. Some stakeholders have raised concerns about ICER's methodology and think their work may be too beneficial for health insurance companies. On the other hand, there are those who see the value in ICER's use of cost-effectiveness and see its potential to fill a void in the U.S. health care system.

Today we have discussed Medicare's coverage of services under Parts A, B, C, and D. At this time, we ask if there are any points of clarification. Additionally, we ask Commissioners to discuss possible directions for future work on how Medicare covers and pays for low-value services and to also consider the role of evidence from comparative clinical effectiveness research for coverage and payment policies. Commissioners can also consider this information's implications for developing quality measures based on the provision of low-value services.

DR. CROSSON: Okay. Thank you very much.

DR. MILLER: Yeah, just a quick comment. So

we're aware the mics are acting up. We think they may work, but if they don't, we'll get everything fixed at lunch. If they don't, you may have to speak up. Apologies to the public if for some reason something can't be captured. But we're aware of it. We'll fix it as soon as we break for lunch.

DR. CROSSON: Ghostbusters on the way. Okay, clarifying questions. Seeing a bunch, we'll start over here with Bruce.

MR. PYENSON: Thank you very much, Nancy and Emma, for a terrific report. My questions are going to be on the section on PCORI, Emma, and in particular, a couple of clarifying questions. There's a segment, approximately 20 percent, of the PCORI grants have gone to the National Patient Centered Clinical Research Network, and that's -- do you have information on who they are and what they do?

MS. ACHOLA: So I think you're referencing PCORnet; is that correct?

MR. PYENSON: Correct. Page 31. I'm sorry.

MS. ACHOLA: Yeah. So our understanding, I guess, of the work that the PCORnet does is it serves as the sort of data infrastructure mechanism that they kind of

collect all of this health data information for researchers to do -- to kind of make doing comparative clinical effectiveness research a bit easier and I guess more collaborative. Nancy.

MR. PYENSON: Has anything been produced? It just seems -- in contrast to the particular line items, it seems pretty nebulous, so I'm -- that's why I'm asking.

MS. ACHOLA: Yeah --

MR. PYENSON: We can --

MS. ACHOLA: Yeah, we'll get that. We can check on that and get back to you to see if there's any like concrete stuff that they've been able to produce.

DR. CROSSON: So I was interpreting what you're saying, Olivia, as this is kind of infrastruct -- I'm sorry, infrastructure spending that then facilitates. Is that not what you were saying?

MS. RAY: So it is infrastructure spending. We can get back to you with a little bit more of the specifics as to where the funding has gone and what has been established.

MR. PYENSON: In the context, it's not a trivial amount here. It's $324 million.

DR. CROSSON: Okay. Calling on Jack.

DR. HOADLEY: Just two specific questions. On Slide 5 you talk about the off-label use, and I probably should know this, but is there any provision for off-label use other than for cancer drugs?

MS. RAY: Certainly the medical -- big contractors' medical directors have the discretion based on available medical evidence and peer review and other compendium.

DR. HOADLEY: The general, but there's not a systematic thing comparable to the cancer?

MS. RAY: There is not a -- to my knowledge, there's nothing in the statute on that.

DR. HOADLEY: No, no, on Slide 7 where you're talking about the National -- the NCDs with coverage, evidence development, is there any consideration of cost in those or are they also prohibited from looking at cost factors?

MS. RAY: Again, to my knowledge, there's no consideration of an item's cost or cost effectiveness when the outcome of an NCD includes a coverage with evidence development.

DR. HOADLEY: And I was also struck by the list that you have of all the CED studies, that there is a bunch of them that are more than 10 years old listed as clinical trials. And just sort of what's the story there? It seems like a long time to be -- I mean, obviously, there could be some clinical trials that could run for many years, but it seems odd. Any insights?

MS. RAY: Well, there -- there is no specified endpoint in the coverage with evidence development process.

UNIDENTIFIED SPEAKER: There could be.

DR. HOADLEY: Does anybody follow back on them? Or do we know?

MS. RAY: I mean, I can certainly report back to you on the status of each --

DR. HOADLEY: Thank you.

MS. RAY: -- of each one. To my knowledge, there have been two CEDs that I would say have come to a resolution, the lung volume, which was implemented even before the term CED was published, and then the other one is --

UNIDENTIFIED SPEAKER: F-SCAN maybe.

UNIDENTIFIED SPEAKER: NOPR?

MS. RAY: Yeah, I think it was the NOPR registry. Yeah.

DR. MILLER: And that was my recollection from our conversations, is that we have had this standing concern of there is no structure for follow -- following up. And then there's also who owns and how much access you get to all the information that gets collected through the CED. While my recollection is there was some table we were looking at, and it may be in here, but in some of our conversations where there were a couple of follow backs, but that's all we're aware of.

DR. HOADLEY: Thank you.

DR. CROSSON: Emma, I apologize for misstating your name a minute or two ago. Kathy.

MS. BUTO: Yeah. So a little bit of follow-on to Jack's comment. Coverage with evidence, I think we could maybe describe that a little bit more in the sense that I'm wondering if it's still true that with coverage with evidence development the sites that are actually covered are limited. In other words, it's not broad coverage as long as you submit data, or is it a mix? Do you know?

Used to be it would only be in certain sites or

by certain contractors. The theory was the incentive would be to complete the analysis or study in order to get a broader coverage determination.

MS. RAY: You know --

MS. BUTO: Maybe you could just check on that.

MS. RAY: Let me -- I don't want to misspeak. Let me check on that for you.

MS. BUTO: Okay. And then --

DR. MILLER: I'm in the same place. I hadn't thought of it quite that way, but if I had to answer it -- which I don't -- but we'll check on it. I think it's a mix.

MS. BUTO: Okay.

MS. RAY: And that's what I was --

MS. BUTO: Good to know.

MS. RAY: And that's what I was going to say too, that there is --

DR. MILLER: Right, but we'll check this, so don't take that as a fact.

MS. BUTO: Okay.

DR. MILLER: But that's my sense. It's not -- I know what you're referring to, but that's not always the

case.

MS. BUTO: Okay. So the other -- the other question I have is again, my information could be dated, but used to be that regular coverage could be limited in a couple of ways. One was coverage limited to Centers of Excellence, like for bariatric surgery, heart transplants, liver transplants. So that's a limiting factor that could go -- along with that would be quality or performance requirements before coverage would be granted for some expensive or difficult procedure.

So it would be helpful if we could just describe whether that's still available. Is that still an avenue for coverage?

MS. RAY: So there's -- on page 16 of your briefing paper, we certainly do point out that as part of the --

MS. BUTO: Okay, I see it.

MS. RAY: -- coverage process.

MS. BUTO: Yeah. Good.

MS. RAY: That there are certain services, and this table includes some of them, where CMS does require that they -- the services are either performed at a

particular –

MS. BUTO: Facility.

MS. RAY: Facility or report into a registry and/or both. And I know we've checked specifically with these services in the table, and tell me if I'm wrong, Emma, but coverage with evidence development was not included in the NCD.

MS. BUTO: Oh.

MS. RAY: So it's a little --

MS. BUTO: Confusing, yeah.

MS. RAY: Well, yeah, sort of like these concentric circles going on all over the place.

MS. BUTO: Yeah, I agree. The other one, and I don't think this is covered in an NCD per se, is that coverage sometimes is limited when an alternative exists. And the one that comes to mind for me is not ionic contrast media, where they were -- nonionic contrast media were only covered in situations for patients who couldn't otherwise get regular therapy because the cost was 10 times higher. So even though explicitly the cost wasn't considered, that was one of the considerations, was it wasn't necessary for every patient, and so why not look at some limitations.

So again, I would just offer that up as in the discussion of regular coverage there are these nuances of authority. It's not just a kind of an up or down for everything. And there may be things we ought to consider as we go forward and look at coverage that we feel the agency isn't doing enough of or whatever. But it would be good to know what those are, is my point.

MS. RAY: Right, and I don't know the extent to which those types of conditions are included in LCDs and NCDs. We do point -- I do point out on page 19 the notion of the prerequisite service under the local coverage determination process.

MS. BUTO: Right. Right.

DR. CROSSON: Okay, questions? Down this side, then we'll -- going to start with Brian.

DR. DeBUSK: I enjoyed your work, your discussion on the LCD versus NCD in the chapter. I thought that was really, really nice to see everything there in one place. I did have one question about that in that how -- and I know this is a swag request, but how much variability do the LCDs account for in that let's say we adopted the most favorable policies and then contrasted that against the

most unfavorable policies nationally? Are we talking a $5 billion swing or are we talking a $50 billion swing?

MS. RAY: Oh, I --

DR. MILLER: Good luck, Nancy.

DR. DeBUSK: And again, I apologize --

UNIDENTIFIED SPEAKER: The mic's not working.

DR. DeBUSK: I realize that's an unfair question. I just -- again, I really enjoyed your chapter. It's just as I was reading, I was trying to get a feel for what -- and again, ballpark, please. I'm not trying to kiss off --

MS. RAY: I can't even give you a ballpark with respect to spending dollars. I know both GAO and the IG have looked into the variability of LCDs and have found that indeed I'm thinking -- I can't remember which one of the two reports, but they identified, I think, a set of new codes and of those new codes -- you know, I'll have to get back to you.

But they did find some variability on the -- on the LCD process from region to region.

DR. DeBUSK: I know we're always trying to chase the sources of geographic variation, and I just wondered if this is a significant one or if we're really just trimming

around the edges.

MS. BUTO: Brian, could I just -- you know, the LCD may be too narrow of focus to look at because usually a local coverage determination arises because a contractor feels like they ought to limit coverage in some way, or make it more uniform. I think the bigger variation is in the things they don't talk about. So the coverage is just whatever claim comes in gets paid, and there is a lot of variability there. So I think looking at just the --

DR. DeBUSK: It's really the absence of --

MS. BUTO: -- LCD --

DR. DeBUSK: It's the existence or absence of an LCD. We're going to just make it harder.

MS. BUTO: I think the absence is the greater area of variability.

DR. REDBERG: Related to that, do you know how much is not in an LCD or an NCD that Medicare pays for?

MS. BUTO: Most.

DR. REDBERG: Most.

DR. MILLER: I'm sorry. So a couple things.

UNIDENTIFIED SPEAKER: Killed that.

DR. MILLER: No, no. No, I was just taking some

notes. So I agree with the exchange that Kathy and Brian had. So when you asked your question how much of variability, I don't feel like -- across the LCDs, I don't feel like I've ever come across that in -- just like Nancy would have been very -- it was very stymied by your question.

But if your question was when you look at the volume of geographic variation and use of services in Medicare across the country, do you think the LCDs are explaining a lot of that, I would agree with Kathy that the answer is no, even though I don't know the LCD thing.

We can cast around a little bit for -- has anybody ever looked at the amount of spend difference? I suspect if you find anything it will be a specific case that says for this it's contrasted by this region and it looks different by this much and it won't be the answer to your -- you know, your global question. But we'll cast around a bit.

And then Rita, I think what you're asking, which I don't know the answer to and we'll have to go back to, is if you could look at all of the spend, how much of the spend would be captured by NCD and LCD? And we can take a

look at that. That's what I think just happened there, and I was just taking notes.

DR. DeBUSK: One final clarification. All I was getting at, the reading material seemed to be fishing around, you know, should we do more NCDs or how do the NCDs and LCDs interplay? And I was just curious to see, are we -- are we dealing with a $3 billion problem or a $50 billion problem?

DR. CROSSON: Okay, questions coming down this way. Come to Rita and then -- got Rita.

DR. REDBERG: So back on the LCDs and NCDs, on Slide 8 and Slide 9, I think -- well, yeah, slide -- so Slide 8 describes the LCD process and it's also in the mailing materials, I think, on page 16. But nowhere did I see a mention of evidence requirement for an LCD as opposed to the NCD process, yet on Slide 9 it says "consider available clinical evidence as a requirement."

But I've heard that described as the deficiency of the LCD process, but it's really is when there is a review, it's more a discussion with experts but not any horrible review of evidence.

MS. RAY: I know the IG did a recent study on the

local coverage for Part B drugs, and they did look at the sources of evidence that the contractors used. So I can come back to you with a little bit more information about that.

DR. REDBERG: I remember reading some articles by Susan Bartlett Foote like 10, 15 years ago on the LCD, but the main thing I remember was the lack of evidenSeptember 7, 2017ce in that process, and certainly your description that was page 19, it says they get advice of local medical societies, comments from provider community. In my experience from talking to the carriers is that does not include an evidence review. But I just think we should clarify that for the materials.

DR. CROSSON: Questions. Alice and David.

DR. COOMBS: So Nancy and Emma, one of the questions I had was, you know, I guess page 32 and 33 you do a great job of kind of outlining all the research that PCORI has done. Do we know what the uptake has been in terms of policy that's been developed as a result of some of these studies? Some of them are quite recent, but it's been awhile.

So I'm just curious as to what the uptake in

terms of these policies have been formulated as a result of this research that PCORI has done.

MR. RAY: Right, so that's a good question. I think with respect to the pragmatic clinical trials listed on that table a lot of those weren't awarded until I think --

UNIDENTIFIED SPEAKER: 2015.

MS. RAY: '15. '15. So I think they're still ongoing. With respect to PCORI's other work, we would have to get back to you on that.

DR. COOMBS: Okay.

DR. CROSSON: Alice, I didn't quite hear the end of your question, but I think you were asking, like how much has been achieved. Is that -- was that it?

DR. COOMBS: Right. And how much have we been able to incorporate results of what they've done into actual public --

DR. CROSSON: Into clinical practice? Okay. David?

DR. NERENZ: Thanks. Slide 13, please. Just a question about the concept and definition here. I know this is a list that we looked at a few meetings ago and I'm

just wondering, is it possible within that set to identify a subset of measures that would identify no value or harmful care? Is that possible?

MS. RAY: Yes.

DR. NERENZ: And the obvious point is that the -- this is a strong point as we have it, but it would even be stronger if we were talking about things that provided no benefit or harm that were covered. So I'm just curious if you could do it?

MR. WINTER: Yeah, we tried to use a broader term because a lot of it depends on the context and the specific scenario. So -- and because we're using claims to measure the prevalence and spending on these services, claims, as you know, not – don't tell the whole picture if you don't have the medical records. So we're trying to error on the side of caution.

But certainly commissioners have made comments that some of the measures that we've presented to you really represent harmful or no value, and we've heard the discussion that some of you would prefer we'd call this -- we call this body of work no value services. And so for those comments.

DR. NERENZ: I understand that. That's kind of round two comment. I just was curious for now what exactly is in this set that we're talking about.

MR. WINTER: Yeah, and certainly you could make an argument that some of these measures represent no value or harmful services.

DR. NERENZ: Okay.

MR. WINTER: And in other cases there might be some small value.

DR. NERENZ: Okay.

MR. WINTER: Marginal value.

DR. COOMBS: Eric.

MR. WINTER: Can I go now?

DR. COOMBS: Ariel, on that same point, have you been able to get data from never events, which I know the CMS records?

MR. WINTER: Yeah.

DR. COOMBS: And take that piece and go backwards to find out if you had something implemented that was a contributor to the end result?

MR. WINTER: I'm not following the question.

DR. COOMBS: So you have a database of all these

never events. Have you been able to look at the never events and see if there are any contributing factors? I don't know if this is something that's beyond the scope, but certainly that would be something that would be valuable.

MR. WINTER: So what led to a never event, in other words. Let me talk to my colleagues who work in the hospital area and do research on quality and outcomes and that -- in that sector and we'll get back to you.

DR. MILLER: Okay, Nancy, you have to come back.

DR. CROSSON: Okay good questions. So we are going to start now on the substantive discussion, and Rita is going to lead us off.

DR. REDBERG: Thanks very much. And first, this was a really excellent chapter. It was a lot of material and I thought it was an excellent summary.

I want to start off sort of with -- on Slide 3, where you put the definition for what Medicare should cover on reasonable and necessary and how it hasn't been able to have rulemaking but that the operational definition is adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the

Medicare population. Because I think that's a really, really important point and it's kind of prima facie that, you know, what we're talking about, and sort of what we were talking about in the last discussion earlier this morning, is that we're really looking for the program to cover things that help our beneficiaries.

And that really brings us to looking at what is the evidence, and that's why I thought it was really important to look at, you know, how much of what Medicare covers actually undergoes an evidence review before we cover it, because, otherwise, how do you know if it's beneficial? And I suspect that, you know, the reason we spend 3-point-something trillion dollars a year on health care yet our outcomes are much worse than countries that spend much less is because we are spending a lot of money on things that aren't helping patients, that have no value, or are harmful. And so I think it's really important in coverage to try to improve, you know, our -- that we are covering things that actually improve clinically meaningful health outcomes.

I will say, in that regard, you know, my own interest in research has been in medical devices, and

unfortunately a lot of very expensive medical devices don't have evidence that they improve meaningful clinical outcomes, and certainly the move with the recent 21st Century Cures Act was to lower the standard for evidence. And, you know, that is understandable if it's a lifesaving device that we don't have treatments for, but I think there are a lot of things that don't fall in that category that are still being rushed to market, and that means that it really is even harder to then apply this standard that is improving clinically meaningful health outcomes, because so many drugs and devices are now getting on the market on clinically meaningless health outcomes, and not using clinical health outcomes at all but using biomarkers. And, you know, people don't, I don't think, care so much about their blood level or things. They care how they feel, what their functional status is.

So I think it's a big challenge for Medicare but that we need to really get back to this prima facie definition that our role is to cover services where it improves clinically meaningful health outcomes.

So getting to that -- and I'll just say I did chair MEDCAC. I rotated off just a few months ago but I

chaired for the last four years, and I served previously on MEDCAC 14 years ago, for four years, and I think MEDCAC does careful evidence review, but even with the careful evidence review MEDCAC's decisions -- and I can think of two examples, or several examples -- one in my first term when we looked at cardiac CT and the committee clearly did not see evidence of benefit for cardiac CT. And really, for political reasons, CMS took a non-coverage decision because the committee had clearly voted that there was no evidence of benefit, and then CT -- there was a big lobbying campaign. There were local coverage decisions made very quickly, and CMS was spending a lot of money of cardiac CT of unclear value and great cost, and lots of radiation.

And then more recently there was -- and I'll just say, I chaired this so I didn't vote on this lung cancer screening, but a few years ago MEDCAC again evaluated lung cancer screening. You know, the preventive services task force had made a recommendation and gave it a grade B, based on the National Lung Screening Trial. MEDCAC came to different conclusions and voted low-confidence that the evidence suggested that there would be benefits exceeding

the harms in Medicare populations, for multiple reasons. I'll just briefly say there were several other randomized clinical trials besides the NLST, none of which found benefit for lung cancer screening. There was very little data in the elderly, but even in the middle-aged population, you know, the false positive rate was 96 percent. It was very hard to read these scans. There was a lot of risk from the radiation from the scans themselves.

And recently JAMA Internal Medicine, the journal I edit, published a review from the Veterans Health Administration, from Linda Kinsinger, which showed that they were finding -- that for every 1,000 people screened there were 10 people with early stage lung cancer but 5 -- which would be potentially beneficial -- but 5 were advanced stage, so incurable. But then, of greater concern, 20 of the 1,000 people screened will undergo unnecessary invasive procedures such as bronchoscopy and thoracotomy, and 550 would experience unnecessary long and repeated CT scanning because the incidental finding rates exceed the lung cancer detection rate by 40 to 1.

And so it's just an example that this is something Medicare is covering. You know, it's causing a

lot of additional procedures, you know, way more expense, and that it's very hard, I think, to maintain that sort of -- that policy that we're going to cover things that actually improve health outcomes. And I think, again, you know, we can talk. There were a lot of other considerations in this process, but I don't think that it's a good way -- I think it's why we see the graphs that we saw in the last chapter.

So just the last thing I wanted to say about the coverage with evidence development, I think there are some examples where this works really well. It's certainly one way to be able to cover a new technology when the evidence isn't fully mature. But I think it's important to actually use the evidence, because some of the problems is that the evidence, for example, the ICD registry has collected but there's no requirement to ever go back and re-evaluate Medicare's coverage or to look at the outcomes. And so data is collected. It may or may not be available and often these aren't proprietary registries so they're not publicly available data, but that the data isn't actually used to then change, either expand or to rescind or narrow coverage policy.

I think the most successful, in my opinion, example of coverage with evidence development was the collaboration between NIH and CMS for the lung volume reduction surgery, but I think the reason that worked is because that surgery was then only available within the context of that trial, and so the enrollment was complete and we had very good data for the randomized control trial.

The last thing, actually, back to lung cancer screening, we also, in JAMA Internal Medicine, published a study showing that since the expansion or the coverage for lung cancer screening by both the private insurance and Medicare, the number of people getting low-dose CTs have increased, but most of those people are not in the group that's recommended to get them. They're either never smokers or low-risk smokers, and the only people that would possibly benefit are high-risk smokers. And so that's another problem is that we're paying for a lot of services that are not -- can't possibly afford a benefit greater than the harm, and yet people get these thinking that there's going to be a benefit greater than the harm.

Now this really is the last. The oncology drugs, I will just say I think is a big issue that Medicare has to

pay for the off-label use if they're in those drug compendium, because there have been a lot of publications suggesting that there are not very strict conflict of interest policies for the compendium, so that the evidence, again, is not strong to support it, and my oncology colleagues say that there are a lot of people getting over-treated with chemotherapy for cancers, and certainly, again, that's not anything that I think anyone would knowingly want to do or want to receive.

So I think that we have a lot of opportunity in terms of improving sort of informing evidence as a basis for coverage policy and trying to work towards at least reducing the amount of low-value and no-value care that the program covers.

DR. CROSSON: Okay. Thank you, Rita. Can I see hands for discussion? Okay. Let's see what we have. Let's start here with Paul.

DR. GINSBURG: Is it working? Yeah.

It was a really good presentation and chapter and report. But I just was reflecting on our previous discussion on the context chapter, and about a concern with the spending trends, the resolution to be bold, and this

presentation mentioned, and seemingly accepts the fact that Medicare, on coverage decisions, cannot look at costs at all. And I'm wondering whether MedPAC should just accept this or start to raise the question.

I'm not going to be very hopeful that we're going to get this turned around, but I think it's important for us, given our responsibilities for the program, you know, to point out that there is the ability now to measure costs for treatments and to distinguished between, you know, things that are low value, as we were talking about, or high value, and that the cost should be a factor. And we are kind of getting around the edges, saying, well, a lot of use of low-value services is an indicator of poor quality, whereas we might want to also do something much more direct, saying that, you know, this is something that really should change. We might even have ideas about somewhat practical ways of doing this, and I think that would be a contribution.

DR. CROSSON: I'd like to comment that I completely agree with you. You know, you can't listen to the first presentation we had this morning and then listen to this discussion and not get sort of slapped in the face

with the incongruity present.

DR. GINSBURG: Yeah. Absolutely.

DR. CROSSON: So it seems incomprehensible that we would have a program that carries with it the threat to the national economy and maintain a position that cost doesn't matter. So I think I would like to see us go in the direction that you're talking about, Paul. I mean, maybe start by understanding what cost-effectiveness research encompasses, because using and end point of quality adjusted life years, which seems to be pointedly, both with respect to PCORI and respect to Medicare, difficult. For my way of thinking is not the only way of looking at cost-effectiveness. I mean, somebody earlier in the discussion said, "Well, what about if we have" -- and I'm adding to that, but "What about if we had Treatment A and Treatment B, and you looked at which treatment prevented strokes, and there was a dramatic difference in terms of that particular specific outcome and inherent cost?" And -- well, I won't go any further, but I just think that, you know, I don't see how we can avoid further work in this direction. Bruce.

MR. PYENSON: Well, thank you very much for

terrific work, and as an actuary I love real-world data and observational studies. And as Rita knows, I disagree strongly with her view of lung cancer screening and I think the real-world evidence, is one way to resolve that. However, I agree with you, Rita, on the issue of overtreatment in general, and effectiveness.

Although the real-world and observational studies is something I enthusiastically support, I would caution us to not fall into the trap of paralysis by analysis. I believe that we, today, know more than enough, with very, very strong evidence that's been around probably for years, about ineffective spending in Medicare. In the last session, we went through post-acute care as ineffective spending in many cases.

So I would suggest that we not wait for the years it's going to take to find the results of the PCORI studies and other studies before acting. When you look down the list of the particular studies, those should not be our priorities or we should not wait for those, but we should act quickly on the things where there's very broad consensus and we know enough to act.

DR. CROSSON: Thank you. Dana.

DR. SAFRAN: So just a quick comment prompted by the discussion of cost-effectiveness, and to totally agree with that, and just to underscore two things. One is the methodologies that are used in other countries that systematically incorporate cost-effectiveness into determinations about coverage are largely developed here. We have enormous expertise in these methodologies in the U.S., and then to choose not to use them, particularly, you know, given the points that have been made about the financial perils that this program faces just seems hard to fathom.

And the other point to make was, you know, in noticing that PCORI is set to expire at the end of '19 unless reauthorized, it does seem like a moment to raise this issue and see whether the -- what will take its place or how PCORI might get reauthorized, might be charged with actually assuming this function.

DR. CROSSON: Jack.

DR. HOADLEY: So I really did appreciate this chapter. I learned a bunch of things from reading it and also from the discussion we've had so far, the things I mostly agree with. You know, I really do support the

notion of sort of thinking more about the cost-effectiveness. I think that's important. I mean, I was in HHS when the year 2000 round of sort of rulemaking occurred, so I appreciate the political land mines that that can be associated with, but I don't think that should keep us from trying to raise this issue again. There are lots of interesting things, in terms of the coverage with evidence development stuff, and sort of why -- you know, is that really working? So I think there's a bunch of good things to pursue here.

The one new thing I wanted to try to add to the discussion is to think about, are there ways to improve the input of beneficiaries into the process? Obviously, beneficiaries get involved when it's, you know, get the thing I need covered. That's a whole separate issue. But I'm thinking about, you know, where we should try to think of better ways to bring a beneficiary voice into these broader kinds of discussions about how to make coverage, you know, done in an effective and -- you know, beneficiaries don't want to get things that aren't useful to them if they actually understand what that concept is.

And most of these processes, the NCD and the LCD

process, have public comment roles, and that obviously, you know, is one method. But there are other ways that beneficiary input can be brought in, and I wonder if it's something we could try to think through a little bit. I'll mention three things. One is sort of the proxies. Obviously, you know, many practitioners will bring a beneficiary interest to a table, and that's helpful as far as it goes. We also have the issue to worry about, of sort of paid beneficiary interests, where manufacturers or others, you know, sort of create beneficiary organizations to come in and sit into these things, and that's a concern.

But there are some models out there. You know, some states have offices of insurance consumer advocates, where there's a state office, a state official who is really charged with bringing a consumer perspective to the table, and to find ways to solicit consumer input. I've watched some of that process work in a couple of states. In a total non-health world, in the public utility world there's a whole model of consumer advocacy that's sort of built in as a state function to do that. And then there were efforts -- I mean, in the quality arena, I know some of the stuff that Robert Wood Johnson funded with the

consumer and purchaser disclosure project to try to develop better consumer and purchaser, in that case, but consumer input into some of the NQF and other kinds of things, including trying to develop more expertise in the consumer community to try to bring their voices to the table and provide resources that, you know, the consumer world doesn't necessarily have within it.

And so I just think it would be useful to try to figure out, are there some ways within some of these decision-making processes to bring that beneficiary, consumer, patient -- whatever word you want to use -- voice into the table -- up to the table more, and try to think about ways. And that might be a way of counteracting, or another voice that would, in some cases, counteract the device or the manufacturer having interest in these conversations. So I'll just throw that out there.

DR. CROSSON: Kathy.

MS. BUTO: So thank you for the chapter. I, I think, like Rita, have thought we needed to dig into coverage policy for a long time. I also view coverage as a very -- it's a fabric, in a way. So I'm hoping that we can delve more into whether we think the current tools that are

available to the agency ought to be beefed up in some way or used more frequently, like limited coverage, where evidence may not be compelling or whatever it is, coverage that's limited to patients who will clearly benefit, et cetera.

I'm not -- and I'll get to cost-effectiveness in a minute -- I do think that could be used more frequently and isn't because it's hard to do. You've got to put edits into claims processing to pick up on the differentials or differences between patients and claims. But we ought to look into that.

The other tool that I don't think, based on Rita's experience, is being used, and this happened long after I left the agency, is MEDCAC. So I'm not sure what the disconnect is there, but we, it seems to me, ought to be looking at whether there needs to be a more formal relationship process that goes on between MEDCAC and the agency.

I think we've got to answer for ourselves the question of whether we think there should be more NCDs, what we think the problem is with LCDs, if we do think there's a problem, and does the agency have capacity to do

this well, because I'm remember, I think it's the Office of Technology Assessment, or the Technology Assessment Committee of HHS that lose authority way back when -- I think it was in the '80s -- because, you know, orthopedic surgeons rose up against back pain guidelines. So I think we want to be careful that we look at, you know, what the capacity is to do a good job before we, you know, sort of insist that a bigger job be taken on.

So I would look at existing tools and look at the implications. And then I can we also help urge the agency to identify areas where we think there is consensus that low-value care exists. So if they're going to take a more limited view or try to apply some prior authorization, if they could get authority to do that, what areas do we think that really are sort of ripe for that, like imaging, diagnostic testing? There are some off-label use that Rita was mentioning, that kind of thing. So I really would like us to better understand existing authorities and how we can suggest the agency do a better job.

On cost-effectiveness -- and I was very involved in the 1989 rule that added that, proposed that as an authority for the agency -- we had a very tough time, just

within the department, of coming up with examples where we thought we could come up with a total non-coverage based on cost-effectiveness versus some other nuanced approach. And I think where we settled out was something like if we use cost-effectiveness in the agency, we would need to apply it in developing payment policy, because we had difficulty coming up with examples where no patient would benefit from a given treatment or technology. And unless you can do that, for Medicare to say we will never cover this is an incredibly difficult thing to do. We got pushback from every conceivable group.

So I would just say that if we are going to get into cost-effectiveness, we also have to think about how would Medicare apply this? In other countries, cost-effectiveness is used to negotiate prices. So again, you will remember we've all talked about how Medicare has limited ability to get into a direct negotiation. So we need to think about the process. You know, it sounds appealing. How would it be used and how would it be implemented by the agency, because it's hard to do a go-or-no-go in Medicare and say we'll never do this, because if you're dealing with some procedure of technology that

applies mainly to the elderly, and you say we'll never cover this, it will never be used in that population, and you'll never have data as to whether or not it could have been useful.

So I think when it's -- you know, when we get into that we can discuss it further, but it's a tough thing to actually operationalize under current law.

DR. CROSSON: So Kathy, I just want to be clear, and perhaps I wasn't. What I was talking about was not so much cost effectiveness with let's say a quality adjusted life, your endpoint, or some other endpoint saying, this is too costly; we're not going to do it. What I was talking about was what's called, you know, comparative cost effectiveness. In other words, choices are met between treatment A and treatment B where the evidence is very clear that there is at least equal outcomes or better outcomes and differential cost.

MS. BUTO: And so I think what you're talking about, Jay, is implementing that by saying in effect it's sort of the least costly alternative payment approach, and that is one option for doing that, so we're not going to not cover this, but we're not going to pay more for it, I

think is what you're saying.

DR. CROSSON: That would be, you know --

MS. BUTO: So again I think that's --

DR. CROSSON: That would be one -- that would be one derivative of that, yes.

MS. BUTO: Totally an option. And when we get into it, we should talk about how would this get operationalized? Because the idea of a no -- no-go in Medicare is a very tough thing to actually --

DR. CROSSON: I completely agree with that point. David.

DR. GRABOWSKI: Great, thanks. I'll be brief, because Paul largely made my point. But I was really struck by our earlier discussion of rising spending and all of us thinking about ways we can find value in this system and then this idea that we can't consider costs. You really can't have a discussion about value without considering costs.

There are obviously examples like Rita described where there's no benefit or there's harms, and that's pretty obvious. You don't need a researcher to go and do those analyses. But there are many instances where there's

marginal benefit. In those instances, I do think, Jay, we want to do that comparative cost effectiveness you described. So I do hope this is an area that the Commission will take up going forward. Thanks.

DR. CROSSON: Thank you. Sue.

MS. THOMPSON: Again, quickly. I agree with Rita's comments. I appreciate that as the backdrop for this discussion. Also very much on face the definition of what meets the criteria for being covered by -- I just think that's an important point to keep in mind. Also, Paul, thank you for your comments. It's hard to sit through previous discussion and then the weight of the opportunity here.

My question would be, or I guess the challenges, I would agree with you, David, we need to continue to take this up. It feels a little bit like we're trying to continue to solve the problem with the old methods. And I'm curious, is there an opportunity here to give this problem to the innovation center and say, what would you do with this in a defined population and help us think about a new way in a care delivery model to get after this business of no value, low value care?

I just think this is one of the problems. We need some new thinking.

DR. CROSSON: Okay. Thank you. Start down here with David.

DR. NERENZ: It's really a question then, I guess jointly to Kathy and Rita, because I'm thinking, Kathy, about your comments. I think you're speaking from experience and wisdom on this and we need to keep that in mind, because it's very attractive to me in concept to say Medicare should -- simply shouldn't pay for things that do no good or harm people, and I sort of believe that, but you're pointing out, okay, it's easy to say; it's hard to do.

Do you think this situation has changed in any meaningful way between 1989 and now in terms of either science base or informatic space or claims processing technologies? Is there any way that more could be done now along that line than could be done back then? Meaning, to be clear, we will not pay for this period. Could -- is there anything could be done now that could not be done in '89?

MS. BUTO: I think there is, and I think one

thing that's happened is the turnaround for data is a lot quicker than it was then. What hasn't changed, as Rita has pointed out, is any requirement for data to -- before coverage is provided. So I think you'd have to -- you know, the mindset hasn't changed that much, and I think what has happened over time is the feeling that as you move to more accountable payment systems, that job falls to someone else, that somehow the national government doesn't have to go down that road.

It has been a difficult road for the Feds to go down, and so whether it's, you know, the Office of Technology Assessment or the National Committee, or whether it's CMS. So I think that is part of the thing that's changed, is a hope that more of that demand will happen at a lower level. But I think as other people have pointed out, leadership has to come from somewhere, so how do you -- how do you change that?

So I think things have changed.

DR. REDBERG: I would say -- I mean, there are things we could do now. Informatics has gotten better, but even -- you know, looking at cancer screening -- first of all, I should point out, you may know that U.S. Preventive

Services Taskforce, even when it recommends a grade A or B, it's usually on the cancer-specific mortality. So they're not using all-cause mortality.

So even though they're commonly referred to it as lifesaving, they're not actually shown to be lifesaving, and the data often suggests they're not. But for most of those recommendations, they have an upper age cutoff, say 75. But Medicare continues to pay for those screening after age 75 even though the harms exceed the benefits, because in those -- you know, they are generally slow-growing cancers we detect, and there's so many other competing causes of death in the older age groups that you don't see the benefit from a cancer screening.

So -- but people, I think, aren't really focused on the harms. Everyone thinks they're going to benefit, which is unfortunately not true, and I think we could do much better at being clear about the harms exceeding the benefits. But Medicare could -- also that doesn't currently not, you know, cut off payment.

You know, we do pay positively for things in the age group, but then we continue to pay for things past the age group when there was a benefit, or for example, and

this was very controversial, but when PSA was grade D until a few months ago, Medicare continued to pay for PSA, even though the -- it was widely regarded still by many that the harms exceed the benefits, including the man who invented or discovered the PSA.

DR. CROSSON: David, you have another comment?

DR. NERENZ: I just want to also say I tend to agree with Kathy's point about I don't know if it would be decentralizing or somehow pushing the decisions closer to the actual point of care, and maybe it's both things simultaneously, but I think it would be good if we looked favorably on mechanisms like MA, ACOs, bundled payment whatnot, so that it go -- don't go into a decision on a certain treatment; it's not all made in one office in Baltimore, but it's made in multiple places where there may be a little easier ability to look at local circumstances and even do case-by-case determination.

DR. CROSSON: Alice.

DR. COOMBS: I actually like Kathy's historical reference, and I thank you for it, because it's actually helpful and it's a contributor to how we got to where we are today. And, you know, I like what Susan said about

putting this in someone's camp to actually resolve the issue, because it seems like on a national scale we have regional differences that could result in certain innovations being propagated in some areas, and it may be that that is another mode for marketing as well for certain things.

So I think that Kathy, your history is very important, and I like the idea that Sue put forth regarding the CMMI. Thank you.

DR. CROSSON: Craig.

DR. SAMITT: So three quick points. One is, I think it's relatively easy for us to point to the tools as the problem, but I think we also have to remember that it's not just the tools. Yes, I agree that we can't think of clinical effectiveness without consideration of cost, but assuming that we can improve upon the tools, we also have to assure that we have applicability in those tools.

You know, one of the slides, it talked about Medicare's use of effectiveness research. It felt like a thud as you read this that there really isn't any evidence that Medicare is applying the results that come from either ICER or PCORI in any substantive way. And so the reality

is we also have to think about what makes the use of these tools applicable, and otherwise, it's just an exercise in futility that we do this comparative effectively and the research that we never use.

So what would the point be of doing that research if we're not going to put it into action? And I think there are already some good suggestions about how we would think about doing that, whether it's, you know, a comparable reimbursement or whether it's differential cost sharing. I think there are other things that we could pilot that is not just a coverage or non-coverage decision, that there are other ways that are very much used in formulary management in Part D and in other approaches that we could apply more broadly through -- to high value and low value services.

The only other thing that I would say is I began to think how the commercial plans think about this and act on this differently than Medicare, and I just -- I would be curious to see if you could compare them side by side. Where do we see some stark differences? Because that may point to where we should start.

You know, if we're going to have an organization

begin to think about and innovate how we could address this, you don't want to boil the ocean. You know, where do we see already some distinct differences in coverage determinations? And maybe we look and stare at that and figure out a suggestion that we can make to Medicare as a result.

DR. GINSBURG: Excuse me, Craig. I've always been under the impression that Medicare's coverage rules de facto constrain commercial carriers a lot. They didn't want to diverge from them. So I'm not sure if there's actually an opportunity to have these differences. And that may actually make these issues that much more serious.

DR. SAMITT: Well, I think we may begin to see some softening of that alignment. You know, the commercial plans are facing the same constraints and cost escalation that Medicare has. And so going back to our former discussion, we're all going to collectively need to think about getting bolder in assuring high quality accessible care at a lower cost.

And commercial plans are facing that same desire and outcome, but perhaps have lesser constraints than CMS may have. So I think we may begin to see a divergence.

And I would expect that where we'll begin to see the beginnings of that is the applicability of the evidence from a PCORI or from an ICER on the commercial side where it may not be implemented on the Medicare side.

And I think it's only going to widen the divide in truly adhering to the evidence, to Rita's point, as we make coverage decisions for our membership.

DR. SAFRAN: But Paul, you're right, that historically commercial coverage designs have just followed what Medicare has done.

DR. GINSBURG: But Craig sounds very encouraging. At least we've gotten to the point in the commercial sector, which has always had incentives, but perhaps they're much more present today because the affordability for the clients is so much more stressed that maybe that will open the door for some serious progress.

DR. MILLER: We could -- I'm sorry to interrupt you guys. We could take a look at -- I have to say in my own experiences, I don't know how many times I've been in a room where commercial insurers are like the problem is, we can't make a different decision even if we wanted to because legally it puts them on shaky ground if Medicare is

covering it and they decide not to.

But I'm not sure I've looked at this recently. And, you know, one thing we might do is follow up on whether is -- you know, who is using ICER? Where is that information going? And are they acting on it? That might be a way to find your case studies to look at.

DR. SAMITT: Or a PCORI.

DR. MILLER: Or a PCORI, but I feel like --

DR. SAMITT: Yes, absolutely. I've said the other one because, you know, does integrate a cost effectiveness, you know, more directly into its process.

DR. MILLER: So I'd be curious who's using that, because that would strike you as the people who are leaning forward the furthers.

MS. BUTO: Mark, you know, there are so few national coverage decisions, I really question that assertion. I mean, maybe Dana's got examples, but -- of where Medicare has constrained private insurers. But there really are no more than seven or eight per year at most, and LCDs don't have the same weight.

DR. MILLER: Then we may be talking past each other. This is -- this is what I would say, because I get

hammered by this, not recently, but back in the day, get this all the time. And so maybe I'm not getting it. But I think it's more the issue that so much passes into Medicare untouched by human hands that they then say, well, you guys are paying for that back procedure which we know doesn't work, but it's in the DRG, and --

MS. BUTO: Totally agree with that. That's the -- back to Brian's point -- the group of not mentioned but always paid for kind of things.

DR. CROSSON: Okay, Warner.

MR. THOMAS: Just a brief comment. You know, as I read through the chapter and looked at the information, and even, you know, querying some of our folks that had PCORI grants, it's hard to see that there's anything that's come out of the studies that actually has been implemented. And I would just -- I would just make a comment. If that's going to be the case, I think, one, going back to Craig's -- we either need to implement, or should we just take those funds, shut them down and redirect them elsewhere to other types of payment reform?

I think Sue brought up the comment, going CMMI, because otherwise we're just going to continue to do these

-- I mean, they're essentially science projects that don't drive any change in the payment system, which is what they're there for. So I would just encourage us to take a pretty strong stance that if there's not going to be changes in what happens with the data, then let's redirect the funds.

DR. CROSSON: Brian.

DR. DeBUSK: I share the other commissioners' views. Some of them have studied about the need to incorporate cost effectiveness into coverage policy. What I hope we do though -- by the way, I'd rather us do it sooner rather than later, so I hope we can expedite that. But what I hope we do is as we do that, incorporate companion policies around development of clinical evidence. And, you know, the chapter -- I could tell the chapter was taking us that way by presenting sort of the two poles of PCORI and ICER.

But I hope that we can bring some specificity to that because I think we wouldn't be doing this cause a service if we said, oh, well, you should incorporate cost effectiveness into coverage and then not really talk about the specifics of how to do it and what that framework -- at

least that framework would look like. And that would include protecting the integrity of the clinical evidence development process, for example, addressing medical ghostwriting -- maybe that needs to be revisited again -- then also addressing some of the infrastructure issues around, you know, do we need to make claims a little bit smarter? Do we need to collect a little bit of additional information?

Now, again, I hope we bring more than just the recommendation to incorporate costs, but we also bring some specificity around how we do it.

DR. CROSSON: And I think Kathy made a similar point in many ways, and very important.

Last word.

MS. WANG: I think that there are a lot of shades of gray in the conversation. Everybody has, you know, grabbed on to the fact that it's an incredibly important topic that people feel passionately we need to do something about. But there are a lot of shades of gray. There's -- to Kathy's point, you know, when you talk about coverage, it's a big deal to say Medicare will never pay for this. That's kind of tough.

I think that just listening to the conversation -- I'm no expert here --- I would think that the list of procedures or medical treatments, that people would say this has like a one in thousand benefit or one in a hundred thousand people who get this will receive benefit but it's just so extremely low benefit and that a lot of what we're talking about with low value care is in the application of a treatment or a surgery that is beneficial many times but is perhaps overused or misapplied. And I think that that is very difficult to get at.

I don't know how many friends of yours or acquaintances have been recommended to have back surgery and then you recommend that they go see somebody that you trust who tells them you don't need back surgery. It's not to say that back surgery itself is wrong. But it's in the application of it, and I don't know how you get at that.

The one thing that I think we need to include in the discussion of this though is the beneficiary, because I don't think that there's any medical beneficiary or her family who, if knowing that what they were being recommended is on a list with clinical effectiveness research as being dinged as low value, would voluntarily

expose themselves to radiation, surgery, treatment, and I think that that has to be a part of the conversation.

To the extent that things are a little bit more black and white, maybe certain treatments should come with a warning label. You know, this has been determined by clinical effectiveness research to be a low value service that really doesn't help more than one and ten thousand people. And give that information to beneficiaries and the people who are consulting with them so that they can make better decisions.

In the commercial space, I think that one of the things that's also interesting is that as more cost gets shifted to covered individuals through high-deductible plans and otherwise, there are other tools that are being used in private insurance to affect treatment decisions where the beneficiary, for better or for worse, has a lot more skin in the game.

So that Medicare really has not explored. I just point those out. The beneficiary has to be a part of this conversation.

DR. CROSSON: Dana, last word.

DR. SAFRAN: Just one final thought. Maybe this

is really obvious, but in case it's not, this last piece of the conversation suggests that we could make the point about how important this area of research is. Even if it next to impossible to have it incorporated into Medicare coverage policies as a kind of yes/no switch, but that, you know, the increasing use of accountable care and global budget contracting, for example, means that provider organizations, to David's point, like making the decisions more locally, need that information to -- and don't have it today, to really know in a formal and systematic way which -- which treatments have more value than others.

And to the point that David was making earlier about, you know, beneficiary engagement, and that Pat's just picking up on, that increasingly, you know, we may want to be empowering Medicare beneficiaries to have access to this kind of information to inform themselves. So I was just wanting to underscore the importance of the research even if it can't inform Medicare coverage policy, that we can take a stand on why it's so necessary given, you know, all the rest of the context.

DR. CROSSON: Okay. Yeah, Mark.

DR. MILLER: Can I just say one quick thing? Two

quick things. So I've been taking all your comments down, and I've also been keeping a running list of all the problems. But because I'm a really positive guy, like Jim, I'm not going to go through the issues. There are many things here that would have to be thought through, but there are two things that I just wanted to say back to you.

You said them, but just two of the things that I want to emphasize. If you want to go down this road, I'm with Kathy that you think about it as a payment issue, not an on/off coverage issue. I think that does -- it does not make it easy. It just relatively changes the dynamic a lot, and I think it's important to consider that. And many of you said it, so I know I'm not saying anything that you didn't already think of.

And the other thing -- many of you said it. I think the last person to say it was Brian -- is I think what makes the Commission different than a lot of other actors in the environment is we don't just do the, oh, yeah, you should do that, or you should do that, you know, bumper sticker thing. We try and come behind it and at least in a structural or principled way talk about how it should be approached.

And I think that brings much more credibility that it's been thought through and that there is something there. And that's the long way around saying, so this would be hard because we'd have to end up with directional and at least principled types of processes that we'd like to see happen behind this to make it real. I don't think impossible and I agree truly, even though I can see lots of problems.

And I was present in 2000 as well and have had the scars that I can show anybody. I do think this is an area of importance and I think keeping at least those two things in mind -- what -- those two things I'd ask you to keep in mind. That's it, Jay.

DR. CROSSON: Very good. Great discussion, really.

Nancy, Emma, thank you so much. More work to come, as usual.

Okay, so now we have time for public comment period. If there are any members of our guests who want to make a public comment -- this is the time to do it -- on the subjects we've discussed this morning, please come to the microphone.

[Pause.]

DR. CROSSON: Seeing no one, we are adjourned then until 1:30.

[Whereupon, at 12:27 p.m., the meeting recessed for lunch, to reconvene at 1:30 p.m. this same day.]

AFTERNOON SESSION

[1:34 p.m.]

DR. CROSSON: Okay. Everybody's back, it looks like, just about. Who's missing over there?

DR. CHRISTIANSON: I'll try not to step on the cord again.

[Laughter.]

DR. CHRISTIANSON: Unless you want me to.

DR. CROSSON: Okay. We're going to start this afternoon with a discussion about telehealth. Zach and Amy are here. Zach, looks like you're going to start up.

MR. GAUMER: Yes, sir. Okay. Good afternoon. This is the first of several discussions that we'll have this fall on telehealth services. As you recall, Congress mandated MedPAC to write a report about telehealth coverage under the Medicare program.

Our goal today is to walk through each of the items listed above. First, we'll review the language of the mandate itself; we'll discuss the project plan for this report; and, we'll define telehealth services and also frame the issue a bit by describing the current debate and other key information. Then we'll dive into answering the

first question of the mandate concerning Medicare coverage of telehealth. And, finally, we'll gather your thoughts on the information we've provided and lay out our next steps for the project.

So through the 21st Century Cures Act of 2016, Congress mandated MedPAC to provide a report by March 15th, 2018, answering three questions. The first question is what telehealth services are covered under the Medicare Fee-for-Service program Parts A and B, and that is our focus for today's session. Second, what telehealth services do commercial health plans cover, and we'll focus on that question in October. And, third, how telehealth services covered by commercial health plans might address -- might be incorporated into this -- into the Medicare Fee-for-Service program, and we'll talk about that in November. But to complete our work and deliver it by March, we'll come back to you again in January to review the entirety of our findings and gather your final thoughts before we publish.

Okay. Telehealth services are defined broadly, and they continue to evolve. These services encompass a variety of combinations of clinical services such as

primary care, mental health, and neurology, technologies such as two-way video, e-mail, and telephone, and modalities such as using the internet, internal IT system, or even telehealth monitoring center systems.

And for the sake of our discussion, we organized these services into six general categories. Three of these categories, in the green box above, involve the provision of basic medical care and physician consultations. This includes patients in the presence of a clinician connecting with the second clinician in a distant location for a telehealth consult. For example, as a part of the telestroke care programs out there, clinicians inside an ER connect with stroke specialists in a distant location. Another category is when patients are at home and they connect with a clinician in a distant location. Companies like Teladoc and American Well largely exist in that space. Another category involves clinicians connecting to a second clinician in a distant location when the patient is not present.

Now inside the blue box above there are two categories of remote monitoring. One of these involves patients inside a facility being monitored by clinicians

down the hall or even at a distant location, and this commonly occurs in hospital ICUs. A second category involves patients in their homes being monitored by a clinician in a distant location. This is what we commonly refer to as remote patient monitoring, or RPM, you'll see it written down.

Finally, in the purple box is the asynchronous transmission of data. This is also referred to as store-and forward telehealth, and what that means is that the patient or a clinician takes an electronic image or a video of the patient, saves it, and then sends it along to a second clinician at a distant site for evaluation.

There's been growing interest in telehealth in recent years by a variety of different stakeholders. Advocates of telehealth assert that telehealth expands access, increases convenience, improves quality, and reduces costs. Others assert telehealth services increases costs because it supplements in-person care rather than substitutes for in-person care.

In our June 2016 report, the Commission concluded that existing evidence on the efficacy of telehealth was generally mixed and that the incentive for using telehealth

services differed among the various types of payment systems. We also, in this most recent report, or mailing material, told you about how we know that several government programs cover telehealth services but to varying degrees, and in addition, to date, 34 states have passed telehealth parity laws requiring commercial insurers to cover certain telehealth services equal to in-patient, or in-person services, excuse me.

MS. PHILLIPS: In answering the first part of the mandate, I'm now going to walk you through telehealth coverage in four areas of the Medicare program where these services are covered with varying flexibility. Flexible coverage exists in around 70 to 80 percent of the Medicare program which covers several fee-for-service payment systems, the Medicare Advantage program, as well as CMMI initiatives which include two-sided risk, accountable care organizations. Under the fee schedule for physicians and other health professionals, telehealth coverage is most constrained. The key takeaway is that coverage is broad in areas where providers or plans bear financial risk, such as the one-third of the program that's in managed care, and that when discussing a lack of flexibility it's in the fee-

for-service program which represents about 12 percent.

I will now walk you through the four listed areas and explain in detail their coverage policies for telehealth. As I previously mentioned, Medicare currently covers telehealth services under four different areas of the program with varying flexibility.

For this slide, I'm going to review the most constrained coverage, which exists in the fee-for-service physician fee schedule payment system, which accounts for about 12 percent of overall Medicare spending. Under the physician fee schedule, there's a limited set of telehealth services on a fee-for-service basis. These services are covered if they originate in rural areas at one of several different types of facilities. However, there are no restrictions on the location of the distant site, which is defined as where the consulting clinician is located.

Medicare permits two specific types of telehealth modalities eligible for reimbursement. These are two-way video and, in Alaska and Hawaii, store-and-forward technology.

CMS determines which fee schedule service codes are covered of telehealth services, and these currently

include general services, like evaluation and management visits, and specific services, like psychotherapy. You can refer to page 39 of your mailing materials for a complete list of covered services.

All consulting physicians are paid 100 percent of the facility fee schedule rate while originating physicians, or sites, receive a flat facility fee payment of roughly $25 for each visit, and the beneficiary pays 20 percent of both these fees.

Within the physician fee schedule, there's no explicit incentive to curb use of telehealth services, and there is concern for a volume incentive. This volume incentive is the motivation for the above outlined coverage parameters.

Within the physician fee schedule, telehealth services are also included in several other codes which differ from what we just described. CMS does not consider these to be telehealth codes. For some of these codes, telehealth is contemplated in a larger fixed payment, and some of these codes more closely resemble remote patient monitoring activities. These other codes in which telehealth services payments are contemplated include

transitional care management and chronic care management codes and bundled payments for such things as the 90-day global surgery bundle and payment for cardiac monitoring devices. While telehealth services are not separately payable, payment for the use of telehealth in these billable codes is already contemplated in the fixed payment. Since they are not part of the official telehealth code list, they are not required to observe the same regulations, and therefore, the originating set rules do not apply.

As previously mentioned, other Medicare fee-for-service payment systems have more flexibility to use telehealth as they see fit. These Medicare fee-for-service payment systems include in-patient hospital, out-patient hospital, SNFs, IRFs, LTCHs, dialysis facilities, home health, and hospice. Such systems usually have a fixed payment for patient encounters. This differs from the physician fee schedule telehealth payments, and the payment these providers receive for using telehealth services is contemplated in that fixed payment. Because of this, the incentive to use telehealth is only there if it reduces costs. This is different from the physician fee schedule.

Most fee-for-service payment systems permit providers to include costs related to telehealth services on their annual CMS cost reports as allowable costs. These providers include hospitals, SNFs, IRFs, dialysis facilities, and LTCHs. However, under the home health and hospice payment systems, they are not allowed to include the cost of telehealth services in their annual cost reports.

There is more flexibility to use telehealth in the Medicare Advantage program, where one-third of beneficiaries are in managed care. Under MA, payments to plans are capitated, and plan coverage must include telehealth services that are covered in the fee-for-service Medicare program. These mirrored benefits are constrained to the same rural and originating and distant site rules as the physician fee schedule.

However, plans also have the flexibility to finance the coverage of additional telehealth services through a supplemental premium or through their rebate dollars. These telehealth services offered by plans as supplemental benefits may not be built into the bid, but any savings from their use can be captured by the plans.

For MA plans, the incentive to do telehealth is dependent on how they perceive it to lower or increase costs since they are at risk if the beneficiary costs exceed payments. If telehealth can reduce costs, they have an incentive to do telehealth when financed properly.

Under CMMI, organizations selected for several programs have waivers to use telehealth services beyond the limits of the physician fee schedule. These are outlined in your mailing materials, and for the purposes of this presentation, we're going to focus on two-sided ACOs. The Next Generation ACO Initiative has waivers to use telehealth services covered under the physician fee schedule in urban settings and in the patient's home. In the case of the Next General Initiative, ACO physicians receive fee-for-service payment rates for telehealth visits, and the ACO remains at risk for the patient's total spending. ACOs can be incentivized to use telehealth if they see it as a way to curb costs since a reduction in beneficiary costs can result in shared savings returned in a bonus payment and any increases in cost of care can also impact them through loss of a bonus payment.

I will now pass things off to Zach, who will go

over current utilization trends of telehealth in the physician fee schedule.

MR. GAUMER: Our knowledge of the use of telehealth services under Medicare is limited to the physician fee schedule where individual telehealth visits are reported on claims. This information is not included on claims data for the other three areas of the Medicare program that Amy described. Therefore, we do not know the extent to which telehealth is being used under the other fee-for-service systems, under Medicare Advantage, and with ACOs.

But under the physician fee schedule, the use of telehealth services has been low. In 2016, 108,000 unique beneficiaries had a telehealth visit, and that's about 0.3 percent of all Medicare beneficiaries for Part B. Use amounted to roughly 9.5 telehealth visits per 1,000 beneficiaries, and that's extremely low relative to the use of physician services overall.

Spending on physician telehealth amounted to only $27 million, and this was for just over 300,000 encounters.

Telehealth use was highly concentrated into a small group of providers and beneficiaries. Ten percent of

providers accounted for 72 percent of visits, and 10 percent of beneficiaries accounted for nearly half of all visits.

The most common physician services used via telehealth were basic office visits and mental health services, such as psychotherapy, as well as follow-up care. In addition, we found that only about 2,000 ESRD-related visits occurred and 2,000 telestroke visits occurred.

While use was low, the growth in telehealth use has been rapid. Between 2014 and 2016, the number of telehealth visits per 1,000 beneficiaries increased roughly 79 percent. Similarly, spending increased about 65 percent. This is very rapid growth considering that all Medicare physician services increased no more than 3 or 4 percent over that 2-year period.

The most rapidly growing services were for subsequent nursing care, psychotherapy, and pharmacological management. Each of these services grew by over 140 percent over the 2-year period. Keep in mind, however, that one factor in this rapid growth is that the base of use in 2014 was extremely low, so that's what's driving the large numbers.

We also saw the growth was faster in certain states that had large rural populations, like Mississippi, North Dakota, and Virginia.

Beneficiaries using telehealth services under the fee schedule were disproportionately dually eligible for Medicare and Medicaid. Approximately 62 percent of telehealth users were duals in 2016 compared to about 20 percent of all beneficiaries that were duals. Telehealth users were also disproportionately rural, and they fell into chronic care conditions -- chronic condition categories, excuse me, such as mental health, diabetes, and COPD.

Finally, we found that the average telehealth user had higher use of physician services overall in 2016, with an average of about 49 physician claims, compared to the beneficiaries who did not use telehealth; they had an average of about 29 physician claims.

Okay. In today's session, we covered material intended to answer the first of the mandate's three questions. We found that Medicare broadly covers telehealth in various institution-based fee-for-service payment systems under Medicare Advantage and within various

CMMI initiatives, such as two-sided ACOs. In each of these areas, which accounted for about 70 or 80 percent of the Medicare spending, providers or plans bear some financial risk and telehealth services are contemplated as a part of the fixed payment. Because of this, these providers and plans have the incentive to use telehealth if it is efficient and good for patients.

By contrast, under the physician fee schedule, which accounts for approximately 12 percent of the Medicare program, coverage of telehealth is less flexible. Specifically, coverage is constrained to rural areas and certain approved services. The physician fee schedule's telehealth coverage is less flexible because services are largely paid for on a fee-for-service basis.

Therefore, providers have an incentive to increase volume. In addition, there is concern that telehealth services may increase costs in cases where they act as a supplement to in-person visits.

We also pointed out that there are a few care management codes within the fee schedule where telehealth services are contemplated as a part of the fixed payment. With regard to utilization, we also found that the use of

telehealth services has been low under the fee schedule but has grown rapidly.

We'd like to focus today's discussion on Medicare coverage and utilization. As I said earlier, in October, we'll discuss trends in commercial health plans; then we'll come back to you in November and discuss potentially incorporating commercial plan coverage of telehealth into the Medicare fee-for-service program; and then we'll be back in January again to wrap things up. Thank you for your time, and we're happy to take your questions.

DR. CROSSON: Thank you, Zach and Amy, and we'll start off with clarifying questions. For questions, I see Amy, Jack. All right. We're getting -- so let's start with Amy and go down that way.

DR. BRICKER: Could you go back to the payment? I'm just struggling with the concept. So the originator/originating site receives $25, and the distant site receives 100 percent of the fee schedule facility rate. So who bills? They both are billing? The originating site is billing?

MS. PHILLIPS: Yeah. Both locations will be billing, but we often find that the originating site

doesn't for the $25.

DR. BRICKER: But they're entitled.

MS. PHILLIPS: Bt they're entitled to, yeah.

DR. BRICKER: So that's interesting. Okay. Thank you.

And then second question, unrelated, there was a mention of pharmacy management here. What specifically is that?

MR. GAUMER: So there's a code that's been approved, that's called pharmacological management, and I think this is management that occurs between the physician at a distant location, or a pharmacist, and a patient that's with their physician. That's the way I think it actually happens.

DR. BRICKER: Like consultation on side effects or?

MR. GAUMER: I assume so, yeah. The description of this in the CPT manual is not crystal clear to me, but, yeah.

DR. BRICKER: Okay. Interesting. Thank you.

DR. MILLER: And I think we've run into things where it's getting advice on how to get rid of redundant

drugs and, you know, multiple prescriptions, that type of thing. Rationalizing the sets of prescriptions across patients, that type of thing.

DR. CROSSON: Okay. Warner.

MR. THOMAS: Just a comment on that. I think one of the things we see is actually for rural facilities and places that don't have pharmacy coverage at night or on weekends that, you know, they're essentially connecting with a larger facility that can provide pharmacy services to them, you know, on nights, weekends, or when they don't have that type of personnel. So that's one of -- I mean, I'm not saying that's all of them but that's one of the things that we see.

A question I had was really around -- I mean, intuitively, if you would think that MA and organizations that are at risk use telemedicine, you would think that they must view this as being cost-effective. Otherwise, they wouldn’t necessarily use it. But yet we seem like we're coming to the conclusion that this is going to be more costly. So what's driving our thinking on that?

MR. GAUMER: I think what we are seeing in the Medicare program is that you've got kind of this bimodal

thing, right? And there seems to be a similar dynamic happening in Medicaid programs around the country, where -- and even in DoD we see this, and some other places, where payment for -- in fee-for-service systems you're seeing kind of more constrained coverage. And I think people are reluctant because the jury is still out on whether or not telehealth is a supplement or a replacement for these in-person services. And there's also a lack of clarity or understanding about which telehealth services might be a supplement or a replacement, and people are experimenting and trying to figure this out, it seems.

DR. MILLER: And, you know, in a managed care environment you can also set rules around the circumstances that you use it. The question gets complicated in the sense of when you say telehealth or telemedicine, what are you referring to, because it could mean a lot of different things. But I think that the conversation you're implicitly having -- and you can correct this if this is not what you're saying -- is how free are you, as a patient, to consult with your physician remotely?

And I think in the fee for service environment -- and there may be other telemedicine types of strategies --

that's the one that gives people pause. So if you're pressing the return key on your computer and initiating a telehealth visit, whereas in a managed care environment you can say things like these are the circumstances under which you can do it, or your cost-sharing might be different if you do it, that type of thing, whereas in fee for service it would just be billing out. And I think that's the risk and that's the concern. And if you think about it, in our morning session, you know, the discussion of the incentives in fee for eservice, this is kind of the epitome of it.

MR. PYENSON: Just in the commercial insurance world, of course, it could be an attractive feature they use to attract members, and that has value to commercial insurers.

DR. MILLER: Exactly. We've heard that as well.

MR. THOMAS: So I definitely -- so I see that, where the incentive on fee for service. I mean, I think the other component is that, you know, at least where I've seen it used a lot is where there are just not services available. So certainly, you know, physician to hospital, or hospital to hospital, where there's really just not a -- you know, especially in things like stroke, stroke

telemedicine, psychiatric services. You know, in our experience we've actually seen, you know, reduction in utilization, not increase in utilization.

I'm just -- but, Mark, I get your point about -

DR. MILLER: And I get yours.

MR. PYENSON: -- if you just open this up you've got an opportunity that it could drive utilization. But I certainly see, in the rural environment, that there's just not access to many of these services, and I think we need to be mindful of, you know, maybe this is an area that, given the innovation, we should think about taking some risk and experimenting to try to do some things different.

But anyway, I was just trying to understand what's driving the thought process on the utilization increase, so thank you.

DR. MILLER: And we're in round one. You know, hold that -- I mean, if you will, hold that thought for round two, because I think there can be discussions about even in a fee-for-service environment, are -- right. We have some thinking there.

DR. CROSSON: Okay. Questions? Craig.

DR. SAMITT: So I have a question on Slide 12.

It was remarkable for me to see sort of the high concentration of the visits in a lower percentage of providers, and I wonder if that is an artifact of the circumstances of coverage. So to Warner's point, are these happening in areas where services are not available or in rural markets and is that why we're seeing a concentration of visits? So this should not necessarily represent interest in the use of telehealth but more of the circumstances of constraints of coverage. Is that fair?

MR. GAUMER: Yes, I think that's right. There are -- I looked at this list of providers to see where they were located and they are distributed around the country. And, you know, they exist in different parts of a market, you know, near urban, right on the outskirts of cities, dealing with people all around rural areas. So they are distributed but it is a circumstances, I think, of coverage.

DR. REDBERG: Were they a particular type of provider, Zach?

MR. GAUMER: There were a couple of different types that seemed to be the most common. There were a lot of social workers, so mental health, I would categorize all

of it as kind of mental health. And then there were also some primary care doctors in there too, but mainly mental health is where the biggest clump is. And what happens is the patient is receiving both their primary care and mental health consults at the same time, in some cases, or in a lot of cases.

DR. CROSSON: Alice.

DR. COOMBS: Slide 7. If a patient is going in and they're getting a claim, an E&M claim, because there's an access issue, obviously, so that they're getting a different cost-sharing because of that mere fact that they are in telehealth. Is that correct?

MS. PHILLIPS: Different cost-sharing in that it's the 20 percent of the facility rate, as opposed to the office rate?

DR. COOMBS: Right.

MS. PHILLIPS: Yes. Yeah, that would be a different price.

DR. COOMBS: So they are being dinged and it's because of the telehealth service, in a way.

MS. PHILLIPS: Yeah. There's not parity between the two.

DR. COOMBS: Okay.

DR. CROSSON: David.

DR. NERENZ: Slide 14, please. Just a quick question on the first line. It's an interesting difference there. So more detail on the duals. Is it under 65, over 65? If it's under is it a reflection of the third line about the chronic mental health? What do those numbers mean there?

MR. GAUMER: So this is -- I think we took some of the stuff off of this slide because the story was all about duals, but duals under 65 both represent about 60 percent of the population, and they're disabled as well. That's how they're eligible for the Medicare program, through disability. So it's mainly the -- you know, among the sicker people and people with a lot of chronic conditions that we're dealing with here.

DR. NERENZ: Distinction between mental and physical both?

MR. GAUMER: There is both but it appears as though, you know, as you can see, 56 percent of them, of these telehealth users, were in mental health chronic conditions.

DR. NERENZ: I'm just trying to figure out what's independent, what's the same thing.

MR. GAUMER: Gotcha. So just to clarify here, the three rows that are mental health, diabetes, and chronic, or COPD, there is -- those are not mutually exclusive, so one person could be in all three of those things. We didn't have a way to parse that out.

DR. NERENZ: Okay.

DR. CROSSON: Okay. Questions over here. Kathy.

MS. BUTO: I just have a question about Medicare Advantage. It says here that it's got to mirror coverage under fee for eservice. And I read that and I looked at it. They've got the flexibility to cover telehealth if they charge a supplemental premium or use rebate dollars. To, I think, Warner's earlier point, if they decide it's a more efficient way to provide a service, why can't they just do it without having to charge a supplemental premium? Do we know? Is it just the way it's built in the statute, or --

MR. GAUMER: So this is a statutory thing. I'm looking at the guys. Yeah, a statutory thing. And, you know, I think the way they've taught us to think about it

is they have to -- the plans have to mirror what's in fee for service, right, so they have to do everything that's in the physician fee schedule that we just talk about.

MS. BUTO: Right. Right.

MR. GAUMER: And then there's kind of a gray area where there's things like the transitional care management and the CCM. So that's in fee for service and you can do telehealth through those things.

MS. BUTO: No, I get that.

MR. GAUMER: And they can do those as well.

MS. BUTO: It just strikes me as --

MR. GAUMER: So, but anything beyond that, any extra benefits that --

MS. BUTO: -- they have to charge for.

MR. GAUMER: -- the MA plan has to charge for. Either they charge the patient, through a supplemental premium, or they do it through their extra rebate dollars, if they're below -- if they came in below the benchmark with their bid.

MS. BUTO: Right. But it just looks to me --

DR. MILLER: Can I just --

MS. BUTO: Go ahead.

DR. MILLER: But you don't have to charge the patient. I mean, you can finance it out of your rebate dollars.

MS. BUTO: In other words, just say that you're doing it -- I don't know. It just strikes me, if the plan decides that a telehealth service is a more efficient way to interact with a patient than having the patient come in, why do you have to run that through a gauntlet of whether you're using a rebate? It's a statute, I think is what Jack is saying.

It just looked to me, in looking at the slides, that ACOs have more flexibility. Let's say you're an MA plan that serves an urban area. You can't actually offer telehealth as a service as part of your benefit package, even as a substitute, unless you either do it through rebate dollars or charge a premium for it.

DR. MILLER: And I guess –

MS. BUTO: But you can if you're an ACO and you get a waiver.

DR. MILLER: -- and Carlos, why don't get over near the table. And I want to do this carefully because I know there is a legislative bump here. But, I mean, if you

offer a telehealth service because you think it's going to make you more efficient, and, in fact, all else equal it does make you more efficient, then you're more likely to actually generate a rebate dollar and benefit, as a plan, from the offering of a service. And all I'm doing, for a moment, is saying don't be distracted by the supplemental premium yet, but just for a moment, that's one way it could work. I think this will actually reduce my total spend. I did AB. I actually come in and, you know, relative to a benchmark, and I get a rebate dollar based on the fact that I came in below the benchmark.

That is one way it could happen. Another way it could happen is to say, oh, well, I'm going to offer this benefit and I'm going to build it into a premium, which will be a supplemental premium. Those are the two ways you could finance it.

DR. DeBUSK: May I ask a related question to that, because wouldn't it -- that feedback, though, let's say it was just a substitute for an office visit. As an MA plan, I'm still going to gain the advantage of only having to pay the facility-based rate plus the $25, you know, if the destination or if the originating site charges that

$25. I mean, even on an even transaction I could come out ahead, even if it was just a substitute, because I'd be enjoying not having to pay the facilities.

DR. MILLER: But the --

DR. DeBUSK: I think there's two things.

DR. MILLER: -- I hear that and I'd want to process through it. But what I was responding to is over here, is in MA they have to offer the rural origination -- you know, they have to offer that as part of the AB benefit. I took Kathy's point to be like, well, what if I want to do, you know, yeah, for, you know, Mark. You know, why can't Mark do it? That kind of thing. And then I was trying to explain that they had two different ways that they could make that happen, where just I'm now initiating or --

DR. DeBUSK: Well, I thought that when you -- and the concern was is why would -- let's say they wanted to do an urban originating site. Why would you want to force them to count that as an extra benefit? And I'm just sort of running it through my head and I'm thinking, even if they did honor the urban site and billed it as an extra benefit, if it were a substitute for, say, an office-based

visit, because they would enjoy the facility-based rate -- you know, the delta between the facility-based and office rate is still probably greater than $25, so I think they win on both ends.

MS. BUTO: I was just trying to go for flexibility here. I was trying to understand why, on the one hand, they are paid a capitation rate, we allow MA plans to do things more innovatively, in a way, to deliver care, but not in this area, and I guess probably not in other areas too, they are constrained by the way the statute is written. It feels like that's the problem.

DR. CROSSON: Just to be clear, this is on the table for us, if we want to move towards a recommendation in that direction. So, Pat, you want to comment on –

MS. WANG: Simply, you know, to Brian's point, I think that's just the dollars are so at the margin, I agree with Kathy. Because, you know, if you save five bucks and you're getting five bucks lower, then you have to split that with Medicare. I mean, it doesn't -- plus, which, and this goes to Warner's question, what is utilization? It could be that somebody feels like there's not enough access to licensed psychiatrists for their population and so they

want to add a telehealth benefit as a way of increasing access. It might not be a cost-saving measure but it might improve quality at some level.

DR. MILLER: And that is what you want to think about. And so my point is not to say that this is -- first I was trying to explain how it is. I don't think it's probably a huge deal to change this. But if it turned out that telehealth, or some version of telehealth actually was a cost, that means the bids don't come down. That means the bids go up. And by changing the structure of the bid, that's the risk you run, and that's an example.

DR. CROSSON: So, Mark, let me just ask a question here, based on what I just said. What the mandate says, I think, is to --

DR. MILLER: Oh, yeah, right, the mandate.

DR. CROSSON: -- is relative to the --

[Laughter.]

DR. MILLER: Oh, well. Whatever.

DR. CROSSON: -- is relative to the Medicare features.

DR. MILLER: If you're going to be that way about it.

DR. CROSSON: Yeah, right. No, because I said the same thing. But if we fulfill the mandate and we decide that there's something extra here, like we want to create parity between MA and ACOs, or we want to just deal with the MA issue, we could still do that.

DR. MILLER: There's nothing -- you could always do that, and you're absolutely right, and we have touched on this issue previously, and it's probably the MA and how you count it. It's probably a reasonable source of conversation. And the other thing to keep in mind is if you change something in fee for service and you say, you know, to Warner's thing, telestroke makes sense, then that automatically becomes one of the covered benefits in MA, and is, in fact, covered by the bid. So anything you make in --

DR. CROSSON: Okay. Okay. Okay.

DR. MILLER: -- will track through, but if you also want to do the flexibility on how they -- we can talk about that as a separate transaction.

DR. CROSSON: Okay. So let me just see where I am. Did I interrupt somebody. Bruce?

MR. PYENSON: I was just going to suggest that

changing the way MA bids are done is not -- I don't think is going to work for just telehealth. So I think it's a broader issue on how the extra benefits get considered. So perhaps not for --

DR. CROSSON: Fair enough. Fair enough. But we might want to include -- that said, we might want to include something in the telehealth report, if we chose so, to do so.

MR. PYENSON: Maybe.

[Laughter.]

DR. CROSSON: Okay. Well, we've got that clear.

[Laughter.]

DR. CROSSON: Where are we? Jack.

DR. HOADLEY: I'm going to switch this deck to Slide 12 and the numbers. Two questions. One, I think when you presented this you said that the telehealth use under the ACOs, under the waivered policies would not show up in these data. And is that because -- I mean, normally anything that's going through the ACO is still being billed on a fee for service basis.

MR. GAUMER: That is correct. So you're right about that. So these numbers could include some ACO

utilization. We can't determine –

DR. HOADLEY: You can't break it out.

MR. GAUMER: -- which is which.

DR. HOADLEY: Okay.

MR. GAUMER: So there is some evidence. GAO did a study last year, this year, about what was going on with the ACOs, and they show light use, low utilization.

MS. PHILLIPS: It was low utilization and it was all concentrated within one ACO, so it wasn't very representative.

DR. HOADLEY: But if this is relatively new that could change over some time.

The other comment I had, you know, you used this figure of 0.3 percent of Part B beneficiaries, and that's clearly, you know, an important anchor to say overall in the program. But it seems like it would also be useful to show the number of beneficiaries with a denominator of sort of the -- and this may not be well defined, but the eligible beneficiaries. And the simplest way, in my mind, would be of those beneficiaries living in a rural area -- although I guess the actual rule is that the service is in a rural area.

MR. GAUMER: That's right. And so we did this and we looked at the rurals as the denominator, and I think the number goes up to 0.8 percent --

DR. HOADLEY: Okay.

MR. GAUMER: -- of eligible benes. So it doesn't make a huge difference.

DR. HOADLEY: But I think that's useful to present in this, and I know that you show some of the breakouts at the state level, which is another way to sort of see that. But I think the health people -- because, I mean, I'm thinking maybe it's 20 percent among rural beneficiaries that still only averages out to 0.3, and you're saying, no, that's not the case. It's a little bit higher. But I think that's just helpful to give readers and consumers of this report a better sense of sort of where this fits.

I think other -- and maybe with some of the other numbers you had some different data in the written material about, you know, numbers of services and things, and some of those could be worked out sort of on a rural denominator, again, with whatever caveats you need to say that's not quite the, you know, parallel, you would

obviously include those. But just to give a sense, because part of our mandate is to say sort of what is the nature of use --

MR. GAUMER: Right.

DR. HOADLEY: -- to be able to give that sort of thing. That would be useful.

MR. GAUMER: So that point is very well taken. The one thing I'll point out here, if you look at the rural row up on the slide there, you'll see that 57 percent of the users are rural.

DR. HOADLEY: Right.

MR. GAUMER: And I was a little surprised that that was as low as it is, because I thought it would be a lot higher. But, you know, I think what we're seeing -- I'm going to guess that what we're seeing here is that you have a lot of urban-dwelling folks going out into rural areas and having services out there. You know, maybe it's a televisit in the ED, visiting their parents, or something like that, on vacation in Aspen, whatever, you know.

DR. HOADLEY: Right, and I think it would be useful to sort of make some of those points as well, because I think part of the function of this is to sort of

help people have the nuanced picture of what's going on, and so we can all come in knowing the coverage restriction with some assumptions, and this is just a way to tease those out a little bit.

MR. GAUMER: Okay.

DR. HOADLEY: But it's really helpful stuff.

DR. CROSSON: Bruce.

MR. PYENSON: Well, thank you very much. I have two questions, one on Slide 11, and this is on the CMMI two-sided ACOs. I've heard from some ACOs that the waiver is automatic for NextGen but it's not for one-plus and three, and those are two-sided. Does that sound right?

MR. GAUMER: Okay. So we think you're right about the NextGen. It's automatic. I think we'll have to get back to you on the other ACOs because I don't know that detail and I don't know if I want to put these guys over here on the spot. But if they want to speak up now, they can.

MR. PYENSON: And, of course, the question is, if not, why not.

The other question I had, early on you categorized very useful list of six different types, and

suppose there was an FDA-approved something that would monitor me and tell me that I was going to have an exacerbation of my COPD in a day, and I should make sure to take a puff of my whatever, inhaler. So suppose that was something there, out there. I don't think -- that sort of technology is maybe not, you know, maybe believable –

MR. GAUMER: -- in the future, but it exists. Yeah.

MR. PYENSON: So, you know, so would that fall under this physician fee schedule? But that kind of device service, whatever it is, there is no physician involved. How would Medicare pay for it?

MR. GAUMER: Well, I'm not sure I can answer that. Medicare right now does not have a code or a plan for that robot.

MR. PYENSON: Okay.

MS. BRICKER: Those devices exist. We offer them to our plan sponsors. They're monitored within, like, a centralized location that Express Scripts manages, you know, teamed by pharmacists, but Medicare doesn't pay for them. But absolutely it will know that you're having an exacerbation, that you've entered into a geography where

high pollen counts are, what have you, and will ping you and say you could be in trouble. But it's not reimbursed by Medicare.

MS. BUTO: Holter monitors, I think, are reimbursed by Medicare. They're ordered by physicians and there is a payment rate.

MR. GAUMER: That's right.

DR. CROSSON: And monitored, as well.

MR. GAUMER: There is some implantable cardiac devices. That's become large in recent years and Medicare will pay for that. That's in the chapter. You can read about that.

MR. PYENSON: With no offense to the physicians in the room, I mean, we're talking about things that don't involve physicians. So I'm -- since that's not just a future technology, it's here now -- so my question is, how are we going to deal with that?

DR. CROSSON: Are you saying I should have done something else other than go to medical school?

[Laughter.]

DR. MILLER: Yeah, I mean, this obviously goes beyond round one so we won't do a lot.

[Laughter.]

DR. MILLER: I got it, and I assume the exacerbation was to Kathy's question about MA. But there's a few things. You know, let's say there's -- and not necessarily this monitoring thing, because this is about a drug -- to the extent that, say, somebody wanted to monitor you in your home, you know, because of, you know, gaining weight, water weight and that type of thing, you know, that might --

DR. CROSSON: And that's being done, for congestive heart failure.

DR. MILLER: Yeah. So if you were a home health -- right. If you were a home health patient and a home health agency felt that that was a good investment, they would have that potential flexibility. There are certain pieces of DME where it might get picked up, and then, I think, you're off into kind of the gray area where what happens if there is no provider involved?

And then to the extent that, you know, back over to Warner, you're in the fee for service world and you're having something that's supplier-generated and no physician involvement, then I think you've really got to think hard

because we have a lot of experience in that area with things leaving the rails.

But, anyway, we can talk when we get to round two, about how to think about the fee for service environment.

DR. CROSSON: And we are getting to round two.

MS. WANG: On Slide 14, I realize that this is a really small sample size, but the demonstration that telehealth users have more claims, is this in any kind of context of -- I don't even know if it's feasible to do this -- like the year before they used telehealth they had 60 claims, or they had the same number of claims? It just seems to me to show that telehealth users may be sicker? I don't know.

MR. GAUMER: So I can color this in a little bit. So these claims are 2016 claims. I didn't look to see what their use was in 2015, but I did look at their HCC scores, which would have been prior use, and I think those HCC scores are consistent with this, which would show that those using telehealth have higher risk scores than those that did not use telehealth services, and it was on the order of something like 1.4 versus 1.1, something like

that. So it was fairly significant.

But we haven't jumped too far much further than that. What I can say is that 6 percent of the 49 there are actual telehealth claims, and the rest of them are non-telehealth claims. So 6 percent extra.

DR. CROSSON: Oh, well, that's interesting.

Okay. So we're going to start our discussion and Craig is going to lead us off.

DR. SAMITT: Thanks, Jay. So I find some significant irony that we're talking about telehealth following the discussion we had about high-value and low-value services, because the nature of the last talk was that we are concerned that we're currently covering and paying for a large number of low-value services. And in this particular case I feel that we're having constraints and resistance to covering what I believe is a very high-value service.

And, you know, we've had this topic several times before. I think the concern that I have is we seem to think that telehealth is not equivalent to in-person health, and I think part of the problem is there's a misnomer. You know, we don't use the expression "clinical

health," "ER health," "hospital health." You know, telehealth, in some ways, implies this message that it is supplemental when, frankly, it's a substitute. It's a modality that enables providers to deliver complementary care, perhaps more efficient in higher quality, through an alternative modality. It's not something additional.

And I think we also seem to think that we're going to drive abuse and added ambulatory surgery, or ambulatory service costs, when that does not seem to be high risk. I think the potential value of telehealth is the reduction in total cost of care, and this slide, Slide 15, makes that point. Where we're seeing the most rapid increase in telehealth use is in nursing care. So, you know, if we're providing nursing care through telehealth, is that an alternative to care that would otherwise be provided in a SNF?

If we're seeing increased psychotherapy, well, I think the reality is that many members and beneficiaries don't want to have to present face-to-face within a mental health clinic. And so perhaps we're actually getting necessarily behavioral health treatment through telehealth that would otherwise not happen, for fear of the

implications of being live for mental health services.

And then drug management, you know, if, again, otherwise drug management would not occur and drug management offers management of total Part D costs, that this is not a, you know, a replacement or a supplemental visit against a physician visit. This is a way that we can avoid multiple downstream or other elements of total cost of care through telehealth that we would otherwise not capture in the absence of it.

So, you know, I'd love to jump into the debate about the way that telehealth is factored into MA plan benefit packages, and I completely concur with Kathy that this should be included within the benefit package, as opposed to being a supplemental benefit that's entangled in the rebate process. And even the implication that it's a supplemental benefit implies that we're offering telehealth simply as a convenience, when, in all reality, it's not just a luxury. It's not just an added convenience. It very much helps contribute to the necessary innovation in care delivery reform that is needed.

And so I certainly would be an advocate for removing the barriers and restrictions to payment, as well

as rethinking and working to influence a change in the MA bid process to include telehealth has a subcomponent of that.

DR. CROSSON: So I think, and I don't want to put words in your mouth, but I think what I was hearing you say was that the distinction between substitute and supplement is perhaps a false dichotomy.

DR. SAMITT: I would say that's fair.

DR. CROSSON: Right. And so that, you know, it has implications for how one goes about -- well, a lot of things, but certainly how one goes about measuring whether something is additive or is likely to, in the end, reduce costs and perhaps improve quality. So if you just measured the number of contacts -- and we've had some discussion of that already -- that might lead you in one direction. I think you're suggesting perhaps it would lead you in the wrong direction, and to the extent it's possible, some more comprehensive measurement of impact would be a better to go about it.

DR. SAMITT: Yep, and I look forward to the subsequent discussions reviewing what the commercial plans are doing, because in contrast to the prior discussion,

where there are going to be instances where commercial plans are following the evidence and aren't covering things that are not value add, I think what we would likely find is more and more commercial plans will be covering telehealth, because they see the value in telehealth, whereas CMS may not see the value in telehealth and is not reimbursing as it should.

So I think we would see the countervailing opposite scenario as we look at commercial plan coverage of telehealth.

DR. MILLER: So do you cover it?

DR. SAMITT: Yes.

DR. MILLER: And how do you cover it?

DR. SAMITT: There is a reimbursement mechanism for a telehealth-related visit, but there isn't --

DR. MILLER: Any difference in the beneficiary's copayment, or I mean the insuree's copayment?

DR. SAMITT: I'll have to get you the specific details of the nuances of the differences in the copay, but I'm not aware that there's actually a distinction between a virtual visit versus a live visit.

DR. CROSSON: Yeah, and I hope Dana makes it back

into the room because you will remember, she was talking a bit about this at one point. I think they had a bit of a different experience, kind of put it out there and pulled it back, I thought.

DR. CHRISTIANSON: Yeah, I think the plan -- as an anecdote, the plan I was a member of started out with a very low cost and maybe even free, I can't remember, telehealth consultation, and then very quickly went up to a substantial enough copay so I stopped doing it. Although I did figure out how to manipulate the system. If it was a visit related to a recent in-person visit then you could get it free. So I sort of tell that story sometimes.

[Laughter.]

DR. CHRISTIANSON: But anyway, the point is I could never tell whether they did that because they wanted to -- they knew it would discourage, or they were getting too many, they thought, and they knew it would discourage it, or they did it because they didn't think it would discourage it at all and it was just a new source of revenue that they hadn't tapped yet.

But anyway, there was a big -- to your point, Mike, there was a big change. So I suspect it's going to -

- I suspect we're going to see a lot of different approaches.

DR. CROSSON: Or they may not have been measuring the right thing.

DR. CHRISTIANSON: Or they may not have been measuring the right thing. I think they were overwhelmed by it, is what I think.

DR. CROSSON: Okay. So we are now going to go into -- let me see hands for discussion. Okay, we'll start with Alice and come up this way.

DR. COOMBS: So I was interested in the whole issue with the copay. Obviously it's an area where I would like to see a little bit of comparison with the non-telehealth encounters. So I think that's important.

Secondly, I think that, from the data, what we're given in this chapter is that the cost may not be affected by this quantity of -- this collection that we have here, but I have to believe that there's probably some variation with how long the providers have been in telehealth. So I'd like to see maybe some reflection of, say, someone who has been in telehealth for a substantial amount of time and see how they do with cost, because there is a learning

curve to this whole process, and I think that what we're seeing is a mixed bag in terms of the newcomers.

I think that telehealth is important, especially for acute events, in terms of management, especially for emergencies and time-sensitive things like code stroke and MIs and things like that. I think there's no question. My whole concern is whether or not it becomes just a tagalong and then you have additional cost.

E&M coding and how that's done and what that looks like for telehealth becomes important in terms of whether or not you say there's a relationship that's been established and then you go on from there with the telehealth management, with your CCM and your TCM. And I think that's very different than someone who says what they're doing down in Texas at Teledoc in a Box, who gets, you know, $28 to do this thing where they are doing the practice of medicine. And I'm not sure that that does what we want in terms of quality and outcomes.

So I would be interested in stratifying the providers and looking at the ones that have been farther along, and that might yield a different result in terms of both cost and quality and outcome.

DR. CROSSON: So, Zach, how far back does the data go?

MR. GAUMER: Medicare claims data on this, I mean, prior to 2012, was extremely light. So we have telehealth data from probably back to 2006, but from '12 to about '16 is kind of, I think, comparable years.

DR. MILLER: I don't think you're going to be able to do much of what she's asking. So the data that you're having a conversation about right now is looking at the buildout telehealth services under the current coverage rules, which are very nominal and very, you know, peculiar to rural originating and all that bit. And then to the extent that anybody else is using telehealth inside a bundled payment environment or an MA environment, you're blind.

And then, you know, she was saying things like -- Alice, you were saying, you know, outcosts and outcome, and the ability to then capture those kinds of outcomes relative to the data, I think is probably --

DR. COOMBS: Well, you might be able to do it with mental health services, which I think may have had a longer entry into telehealth. You definitely probably

would be able to do it with emergency services coverage. I think that's one area that's very important, but the comparison probably is lacking. But mental health would be a place to start.

DR. CROSSON: And going forward as well. Okay.

DR. MILLER: Yeah, going forward, definitely.

DR. CROSSON: Where are we? Coming up this way. Rita.

DR. REDBERG: Thanks for an excellent chapter. You know, I think you summarized it well when you said, you know, there are lots of different kinds of telehealth -- Slide 4 shows six definitions -- and that the evidence is mixed. And I think it's very hard to say it's a supplemental or it's, you know, replacing other services because I think all of those things are true. Telehealth is very loosely defined. You know, it means -- sometimes it's video monitoring and sometimes it's the digital monitoring, and sometimes it's just telephone, sometimes it's online. You know, clearly, you know, for some applications like dermatology or specialized things in areas where there aren't dermatologists, or even in areas where there are dermatologists, it's just more convenient.

But there are also areas, and, you know, I think, Craig, anything that can be useful can also be overused, and, you know, used inappropriately, and to just kind of say we're going to embrace it, I think, would be exactly the opposite of what we've spent the morning saying that we want to try to promote high-value care, because we don't know.

And in terms of evidence, I think the evidence, particularly on outcomes, is pretty limited, in terms of telehealth. But having said that, it seems like, you know, it certainly could be very useful but it seems most potential is in a kind of capitated, you know, bundled payment, where it's not going to be up to Medicare to figure out if it works but up to the people, you know, the plan sponsors, because if it is improving patient care, improving patient satisfaction, and decreasing cost, then it will be used, and if it's not, it won't be.

I mean, I've seen useful and I've seen useless applications of telehealth. I mean, and I also just -- you know, I have like lots of patients now who come in with all kinds of monitors and give me -- I mean, I don't want to read weeks and weeks of heart rate. I don't think anyone

does. It doesn't do anyone any good. I mean, the potential is kind of explosive now, because we can monitor so many things.

So I think it's important to kind of keep in mind, you know, back what we were talking about, what is the evidence that this is going to lead to better patient care. It's a big area and clearly there's potential, but I think we have to be kind of wise going forward.

DR. GINSBURG: You know, stimulated by Rita's comments, I'm wondering if the situation is that we don't have something called a telehealth service. We have a fairly large number of discrete services, and some could be very useful and some could be less useful. And this, I think, is the danger in policy-making in this area of kind of painting a broad brush and applying it to everyone. I guess that's the advantage that an organized system like an MA plan has, that they can have the ability to pick and choose what they're going to cover more generously and when. But if we're making rules for the fee for service program it's much more challenging.

DR. CROSSON: I agree and I think it's part of the challenge for the work that we're doing, which is, you

know, if you go back to Slide 3, we're supposed to comment on ways in which telehealth services covered under private insurance plans might be incorporated into Medicare fee for service. And so sort of what we've got on the table, and I agree with it, is kind of like, well, if we're really going to do that, can we do it generically or do we have to do it, you know, on a one-off, one-at-a-time, or pick the most important ones, maybe mental health? I mean, that's something I think that is yet to be determined.

DR. MILLER: And that's what I -- and, Craig, if I could just go back to you, because given things that you've said on the Commission, you know, throughout your stay here, when you said, yeah, you know, you should just do it, did you mean just like open-ended fee for service?

DR. SAMITT: No. I think it's --

DR. MILLER: That would be an important distinction.

DR. SAMITT: No. It's a relaxation. I mean, it's taking a look at the categories where we think that others are expanding their use. I mean, it's not a free-for-all use of telehealth. It's the use of telehealth where, you know, perhaps the evidence isn't exactly where

we want it to be, that it's evidence, but we're seeing expanded use of the telehealth service, endorsed by commercial plans, who recognize its value. And should we be thinking of relaxing constraints on the Medicare side to mirror, to some degree, some of the innovation that we're seeing on the non-Medicare side.

DR. MILLER: Okay, and that sounds a lot more like the Craig I know.

[Laughter.]

DR. MILLER: And I think, you know, to Jay's comment, you know, if MA becomes part of the conversation and inside bundled payments, but within fee for service you might begin to think of things like by certain services, or by certain conditions. So if somebody is getting ESRD at home and they don't -- you know, home-based, not facility-based ESRD, and they want to consult with their nephrologist, you might say, yeah, it makes a lot of sense. It's not like people are going to be clamoring to be calling the ESRD patients. You know, telestroke may make a certain amount of sense. You might want to think about the fee for service environment that way, where you kind of -- I can put a circle around this and be pretty comfortable

that this is a value add as opposed to a free for all.

DR. SAMITT: Or we look at the areas where we're seeing some significant growth, as opposed to all the bells and whistles monitoring. You know, the three categories that we believe you can see somewhat direct tradeoffs in total cost of care, those are the areas where we may want to see some relaxation of the policies.

DR. MILLER: Okay. Thanks, Craig.

DR. CROSSON: Okay.

DR. MILLER: Sorry.

DR. CROSSON: All right. So we're coming up this way. David, do you want to go?

DR. NERENZ: This is just -- I think on this point, I'll do it very briefly. I just wondered along this line of thinking, you know, open the door/close the door, if this is a point where some site-neutral thinking might help us in that, you know, we're talking a lot about do you pay for the telepart, but actually what might make more sense is to say what you want to think about is paying for the content and then be sort of agnostic as to how it happens. So if a specialty consult during a stroke is valuable, we pay for that whether it's in person or whether

it's remote. If an hour with a psychotherapist is valuable, you pay for that whether it's in person or remote. And you just frame the thinking a little different, and it's kind of in the middle between do you open everything wide open or do you have constraints.

DR. CROSSON: Okay. So I lost track here. Warner and then Amy.

MR. THOMAS: Okay. I guess just to maybe add to Craig's comments. So I think going back to your point, Mark, probably not openness of wide open in the fee-for-service arena, but I do think we ought to pick the areas that we do think that this could be helpful and then make a bet here because I think it comes back to: This is new. It is evolving. There is a significant potential to provide access in areas where there is no access, quite frankly, and to provide services where there are not. And I just think we are -- we don't want to limit innovation in this area because I think there are a lot of opportunities here.

I also think, you know, going back to the comments around or some of the stats on dual-eligibles, my guess is a lot of that is in the home area as well because

you get a lot of folks that are dual-eligible that have difficulty coming to see a physician and what not. So I think home monitoring should be looked at very carefully because I think there's an opportunity to monitor and do preventive care in the home that may be difficult for folks that cannot come to an office.

But I would encourage us to -- if we're worried about this growing out of control, then let's pick the handful of areas that we really believe this can be successful and, you know, basically make a bet there. We can track it over the next several years and take a look at it, but I would encourage us not to be incremental in the areas that we think there's going to be value.

DR. CROSSON: Amy.

DR. BRICKER: I would second the remarks that Warner just made. And I was just thinking about, or reminded of, conversations we've had in the prior year around, you know, lack of or fear of reduction in the primary care space or, you know, decreases that we're seeing with access to those that are able to -- or psychiatrists or psychologists. And if there's a way to have telehealth supplement that, to shore up those gaps, I

think that we should embrace that. So I'm in wild agreement with my colleague.

DR. CROSSON: Brian.

DR. DEBUSK: From the reading materials, I was at least left with the impression that we haven't really hobbled telehealth now. I mean, it's small, but it's growing at a good clip. And it seemed like the appropriate visits, for example, physician visits and psychotherapy, were being used. It seemed like it was all occurring in the right location. To me, it almost had a feeling that it's generally on the right track; we're just limited by probably provide adoption and beneficiary adoption. And I think time is on our side.

Alice, you made a comment earlier about looking at people who have been in the system longer. And I realize it's a tough measurement to make, but it would be interesting to look at a cohort of, say, people who have been engaged in telehealth or providers for one year versus the ones that have been engaged two years versus three years, maybe to treat them as a cohort, just to see once I begin and become familiar with telehealth do I ramp up to a certain point, does it become 12 percent of my visits and

level off, and you know, is there a saturation, or are there people that just keep going and going and going because there are some breaks that could be released, as some of the other commissioners have pointed out. But at the same time, you know, induction is always there as a fear in the back of your mind. So that's my only comment.

DR. CROSSON: Pat.

MS. WANG: I think that telehealth has a lot of potential, but it's sort of one of those things where maybe it's almost too good to be true. I see the potential at first cut more in areas where treatment modalities are evolving. You know, integration of behavioral health into primary care practice. If people are going that way, maybe they don't have to struggle with finding, you know, shortage personnel and they can adopt these kinds of modalities and open up that model a lot faster, and you wouldn't want to stand in the way of that.

Similarly, medication reconciliation upon discharge from a hospital might prevent a readmission. And instead of hiring a bunch of pharmacy techs, which is an expense that you would otherwise incur to do that, maybe telehealth with, you know, pharmacy techs could be, you

know, another way of going.

I think the danger of it, though, is that that all sounds really good, but maybe, as somebody pointed out, there are a lot of different modalities for telehealth. The definition of telehealth is not very specific right now.

I agree that when an organization is under some sort of budget there is a much greater chance that the high-value telehealth services will be identified and used. And so in the MA context I do think those restrictions should be removed because it will be up to the plan to weigh costs with increased access, quality, member satisfaction, and they'll make that equation within their budget, similarly with ACOs or what have you. With open-ended fee-for-service, I get really nervous about just sort of saying, you know, just put it in because there is no budget. So I have two thoughts on that.

One is to continue the work of really trying to -- or encourage, the identification of the high-value telehealth services as measured by quality, member satisfaction, total cost of care. If you can, you know, reduce an admission, who cares if there are a couple of

extra ambulatory care consultations ahead of time.

But the second is I'm wondering whether there is such a thing as making the benefit more available when a member might be in any kind of advanced APM, not just an ACO. But it could be a bundle. It could be, you know, sort of to try to incentivize people to -- clinicians to get involved in those arrangements, as well as beneficiaries, to the extent that they are aware. You know. So there are no more mandatory bundles, but to the extent that the bundles are voluntary, it might be an added attraction to pull clinicians into those if they knew that a telehealth service would be available and similar for beneficiaries. And something to think about.

DR. CROSSON: All right. Very interesting.

Okay, Bruce.

MR. PYENSON: Just a couple of thoughts on this, that one of the questions I had which was mentioned in the report is this licensure issue across states that has come up, and I think that's of course a broader issue. But in an era when we're not charging long distance for phone calls, does it -- what makes sense for multi-state licensing? And perhaps telehealth isn't the -- certainly

not the only thing affected by that, but it sort of jumps up here. So I'm glad that that was recognized as an issue. I'm not sure if there's any appetite to go into that on a broader basis.

The second comment I have is that to make clear in our report that we're not talking about the advanced robots, if you will, and that's outside scope because telehealth sounds a lot like that. And I think since it's unclear how or if or under what benefit those might be reimbursed we don't want to have our discussion, which seems to be some of which is narrowly focused, applied more broadly.

So those two comments.

DR. CROSSON: So, Dana, you may have missed some of the discussion, but fundamentally, you know, I think you know what we've got on the table here, which is: What are plans doing about telehealth? What was the progression, for example, in your own organizations? And then to what extent, you know, can we extrapolate from what commercial plans are doing to the fee-for-service Medicare program?

DR. SAFRAN: Yeah. So I apologize that I missed a lot of the discussion, but I'll just share a little bit

about what our experience has been and make the offer that if we'd like more detail than what I carry around in my head about what our experience is, then we can look at that.

But I do know -- so we have made telehealth benefits available to our members. I think that began in January of 2016. We did that by creating a relationship with American Well but also with encouraging our own provider network, almost all of whom, as I've shared with this group previously, are in global budget contracts with us, hoping to encourage them to implement technologies that will enable this.

So we've seen some adoption, bit by bit by bit, more in mental health, for behavioral health visits, especially for brief medication check-in types of visits, than we have for what I'll call urgent care types of visits, but some of both. We've seen it happening more with American Well than in our own network. And that probably taps the limit of my walking-around information about the specifics of what we've seen.

I think the other few points I'd make is, number one, you know, I think it is really important that we

experiment with this area and begin to move away from kind of the tyranny of the office visit and the sort of building-centered care that we've had.

On the other hand, you know, I have the same concerns that I've heard expressed by some about, you know, outside of a budgeted model will this really just add to volume and cost overall. And I'd say, as I think I might have shared once before, that if a decent metaphor for this is urgent care settings that we thought were going to be a good substitute for emergency rooms, our experience has been they're not. They have added visits that just used to not happen, and now they happen in urgent care settings, and people still go to emergency rooms as much as they did and for the things that they did, even non-urgent things.

So to me, that gives me some pessimism that this will be a replacement for other things, but you know, for certain things maybe it does create access that has been missing, and that's a good thing.

And then I think the last thing I would say is that even in the case of a budgeted model I have some worries about it being inflationary because not every part of the system cares about the budget constraint equally.

And so you know, for example, we're seeing with hospitals that are experimenting with hospital-at-home it's again so that there can be additional revenue, not so it can be a substitute. Right? So there's hospital-at-home, and then you backfill those beds, and then you're getting revenue from both the hospital-at-home and the beds that used to be filled with those patients that have now gone home.

So I do think a budget constraint is the best place to be experimenting with this and we can learn a lot if we have Medicare emphasize experimentation there, but we should still be mindful that it could be inflationary.

DR. CROSSON: And I think -- and you alluded to this -- that probably in the end we're going to find out what I have had experience with, which is that improved convenience induces demand.

Jack.

DR. HOADLEY: So several comments, some sort of inspired by some of the other comments on this very last point. I mean, part of the tradeoff is: Is there induced demand, or is there unmet needs filled?

DR. CROSSON: Fair enough.

DR. HOADLEY: And there's obviously both.

DR. CROSSON: Fair enough.

DR. HOADLEY: And that's where it gets hard. I mean, it's not -- substitution is one thing, new supplemental things. But if some of that is filling unmet needs, that's a good thing; if it's inducing unnecessary care, obviously not. And that's the hard part of sorting out.

You know, I was going to mention the same point that Bruce raised about the licensing issues, and it does -- you know. I just don't have a sense of how much that's a problem, whether that's a barrier to the ability of an originating site to be able to get a certain distant site to help out because suddenly they're not in the right licensing area, what happens in areas where there's a lot of states close together. So I don't know. You know, it would be interesting to get some help with if there's any way to know how big an issue that is.

It seems like one part of this that in all this conversation about experimentation and budget settings and non-budget settings and so on -- the biggest restriction, it seems to me, that the Medicare rules have today is the rural. I mean, that means that 80 percent of the cases, 80

percent of the beneficiaries are sitting in locations where for the most part, with the exceptions we talked about before, they're not eligible to do this.

So if that was an option to lift, that opens up in a good way or not a good way. But I mean, it seems like we need to think about: Is this really something we think of mostly as a rural thing, and therefore, that's one of the limiting rules, and therefore, Medicare has got a good restriction, or is it more a question of, you know, the unavailability of certain kinds of providers that could happen in all kinds of settings -- inner cities or just inconvenient locations that would involve a lot of travel even within a more urbanized area? So we should just definitely remember to keep that piece of it in mind as we think about it.

DR. CROSSON: And --

DR. HOADLEY: And then --

DR. CROSSON: Oh, sorry. I was just going to add to that point the point that keeps coming up, which is we're talking about telehealth and rural versus non-rural. Well, which kind of telehealth? And it may very well be, I would suspect, some forms of telehealth that are really

appropriate for the rural setting more than any other setting, and there are other types of telehealth for which there may be no difference at all in value.

DR. HOADLEY: And that sets up nicely my last point, which if you can go back slide -- well, it's a little up, Slide 4. It seems like maybe an analytical approach we could use as we're even looking at the next couple of questions -- and I can't say if this is the right six categories, but assuming for the moment it is. If we could -- I sort of think about a table where those are the six columns, I mean the six rows, and we're filling in a lot of boxes along the columns.

So first question, which you've mostly covered although I don't think I could quite fill the whole box in, do all six of these situations fit Medicare coverage under today's rules? To the point you just made, how do these vary in the sense of where the need is created? Is this something that fits a rural situation? Certainly some of these are going to be especially acute. And those others, like the transmission of data of a scan to somebody else to read it, you know, that's not -- that's just something that's done in certain places.

And then when we get to what's the experience in thinking about how this might play out and where there's more induced demand, where there's more unmet needs kinds of issues, if we maybe thought about it broken out into these categories -- and it goes to some of the points of different kinds of telehealth. You know. This might be a good metric to sort of set up and think through.

And we might come down in the end and say, you know, here's an area that seems ripe for more generous coverage rules; here's one where we're a little more worried about adding generosity; here's one, no way we want to go there. Maybe it won't be that easy, but it seems like if we talk about that and we get to the point by the end of this conversation, three meetings from now, where we're saying are there things we want to recommend or just sort of perspectives we want to give, if we can sort them out by those categories, it seems like that might be a pretty useful way to go.

DR. CROSSON: Okay, Kathy.

MS. BUTO: So first of all, I look forward to the next round where we talk about the commercial insurance experience and use of telehealth services, but so far, what

my instinct is that where we think -- and I think, Mark, you started to touch on this -- there's some definite utility, like an ESRD patient or a stroke patient or something like that, in fee-for-service because that's the focus of this report, right, and we feel that there is some ability to improve access or quality, that that's an area in fee-for-service that we really need to explore. Mental health is another one, I think.

But I think it would also be helpful for us to then take on the issue, I think as Pat and Dana were talking about, which is we are willing to, or we might be willing to, as a commission, provide greater flexibility to MA plans, to APMs, maybe to -- and to ACOs but maybe to our new per-beneficiary capitated amount, where to the extent there's a management responsibility and something of a budget, we would see that there should be more flexibility. But I'd like us to kind of think about it that way, where we look at not just a single policy but really how might this vary, and then could the incentives be in the direction of greater management and then greater flexibility that goes with that.

DR. CROSSON: David.

DR. GRABOWSKI: Thanks. So similar to others, in fee-for-service, I'm definitely wary of broadly covering telemedicine. I think there's probably high-value applications and low-value applications, and unlike Medicare Advantage or the APMs, it would be hard in fee-for-service to identify those high-value/low-value without a budget. So I very much agree with others.

In terms of thinking about where those high-value models and how we might think about going forward, Mark, you and I talked offline. I just wanted to use an example from my research and then maybe use that as a launching point.

So we did a study, a big problem in long-term care is just a lack of physician coverage in nursing homes, for example. And so -- especially off-hours, weekends, and evenings. So we did a study where we randomized nursing homes that have physician coverage during those hours and found, sure enough, that they prevented a good number of emergency department visits and hospital transfers, and the savings from those prevented transfers was actually greater than the cost of the telemedicine. Yet, because the nursing home was paying for the telemedicine while the

savings went to Medicare, the nursing home chain quickly disbanded the program after the study ended.

And so, Mark, you and I talked about that, and I think we might be wary of just covering off-hour nursing home telemedicine coverage. That may not be the way we want to go without a budget or a limit. But potentially, if there was a way to put that nursing home or other sort of entities at risk, maybe they do want to go in. And I can imagine that nursing home, assuming we did our analyses right, being able to recoup those dollars from Medicare that they invested into the program.

So I do think having providers potentially go at-risk is one way that we might think about this outside of sort of an MA/APM sort of model. So, thanks.

DR. MILLER: Yeah. And on that, I mean, that almost feels like a case for shared savings. And that also then kind of leads you pretty quickly into ACO type of environments and a question of whether, yeah, you go into an ACO, you can do all that, or whether we're going to say, well, even outside of the ACO you can do that.

And of course, just to make it more complicated because it's not complicated enough, does that then mean

people are less likely to jump the fence into an ACO, or do you want to say, no, go into an ACO, you can do all that, and you can share in the savings? That's something to just -- another layer of complexity.

DR. CROSSON: Sue.

MS. THOMPSON: I think Mark just made my comment.

Well, first and foremost, I do think we need to spend a little more time defining what do we mean by telehealth, because I think when we talk about the transmission of EKGs and interpretation of results that's one thing, but when we're talking about neurology visits to a potential stroke patient out in Pocahontas, Iowa, versus a behavioral health integrated primary care office, potential for improving the outcomes in, you know, do those integrated care models, I do believe it would benefit us in this discussion to more clearly define what are we talking about in telehealth.

However, building on the comment that Mark just made, it just strikes me this discussion around telehealth builds well on our entire conversation today, and we opened this morning about we need to be building incentives to providers to want to get out of fee for service and into an

environment where there's more accountability and there's more risk-sharing. So to Mark's point, I mean, perhaps telehealth is one of those things that you have an opportunity to do in a risk-sharing environment, in an APM that involves risk, in a Medicare Advantage, in an ACO that has upside and downside.

Because there's so many other benefits that also relate to work we have done in a previous year, including -- I think we would have an easier time recruiting providers into the behavioral health modalities and the family practice modalities if we could talk about, folks, this creates a lifestyle that's pretty attractive. And if we're not talking about supplement but we're talking about substituting the kinds of services in an environment where our incentives are truly in alignment to what we're trying to accomplish to save this Medicare program, I just think telehealth is one of those pieces to our puzzle that offers all kinds of opportunities.

DR. CROSSON: Very good. Thank you. Great discussion. I think this really elevated the topic a significant amount, and I think, my guess is by the time we get to January we will have found it even more sharply. So

thank you very much, everybody.

Okay, and thank you, Zach and Amy. We will move on to the next presentation.

Okay. Now we are going to have an initial discussion with some background information on the PBM industry and specialty pharmacies, and we've got Shinobu and Rachel. Rachel, it looks like you're starting out? Okay.

DR. SCHMIDT: This afternoon, Shinobu and I will provide background about pharmacy benefit managers and specialty pharmacies. This work is a follow-on to two presentations we gave in 2015, about the drug approval process and supply chain. And issues also came up when putting together the Part D recommendations in 2016, and we've also heard expressions of interest from some Commissioners.

To put today's presentation together, we reviewed literature and interviewed stakeholders at 11 organizations including PBMs, health plans and payers, specialty pharmacies, auditors, and consultants. We spoke with stakeholders about their trends in their commercial business, but also with Medicare plans if they had them.

And before we describe what we learned, we'd like to thank the interviewees, our colleagues Emma, Sydney, and Amy for their help, and two other individuals, Elizabeth Hargrave and Jay Smith.

Our objective in covering this material is to get a sense of the Commission's interest in looking at related Medicare policy issues. In today's presentation, we'll describe what specialty drugs are and talk about trends in the PBM and specialty pharmacy industries. Manufacturers often manage the distribution of specialty drugs differently than for traditional drugs, so we will describe that. We will touch on the variety of business approaches to operating PBMs and specialty pharmacies, which can affect the incentives they face and we'll conclude by looking at three related Medicare policy issues and their potential to influence drug spending.

Let me say at the start that this material can be quite complicated, and industry practices are evolving. We are early on in this work and some of you are experienced in these fields, obviously, so we are looking to you to help frame the relevant issues.

Specialty drugs have some of the characteristics

on this slide. They are used to treat diseases like cancer, multiple sclerosis, and hepatitis. Some specialty drugs fall under medical benefits because they are administered by a provider, for example, chemotherapy infusions. Others fall under the pharmacy benefit because the patient can administer it to him or herself, for example, self-injectable drugs and oral pills. There's often greater need to educate patients about the drug, monitor them, and report data about adherence and clinical outcomes.

Distributing specialty drugs tends to pose logistical challenges, such as needing to keep products refrigerated, and specialty drugs have very high prices and high per-patient spending amounts. In 2014, only 2 percent of beneficiaries took drugs on the specialty tiers of a Part D plan, but those prescriptions accounted for 16 percent of Part D spending, and that proportion is growing. In commercial plans, it's more extreme. The small share of members who take specialty drugs make up about one-third of spending.

Here are the 10 specialty drugs that, in 2015, had the largest spending under Medicare Part D. These are

gross spending amounts before manufacturer rebates. You can see that average annual spending for a beneficiary on one of these drugs is extremely high. For example, per patient spending of nearly $93,000 for Harvoni and $7 billion in aggregate spending before rebates. Given these high amounts, commercial payers and Medicare plans are very interested in making sure that these treatments go to the right patients and are well managed. The organizations that payers use to do that are PBMs and specialty pharmacies.

I'm sure you already have an understanding of what PBMs do, how formularies work, and what rebates are. What I want to focus on with this slide is how the PBM industry has been evolving. When Part D began, it expanded the number of people with pharmacy benefits that were managed. In subsequent years, we have seen a lot of changes to supply chain actors, including PBMs, and there's been a lot of consolidation in the PBM industry. Today, the top 3 PBMs process about 70 percent of prescription claims. There is still significant rivalry among PBMs, but the industry is more consolidated today.

Under Part D, CMS requires that plan sponsors

report all the rebates and discounts that PBMs negotiate with manufacturers on behalf of plan sponsors. This is to return a portion of the rebates to Medicare and offset some of the benefits that the program pays for. Mechanically, it is often the PBMs that put together rebate information for plan sponsors, and we heard that some sponsors don't have full line of sight on that data. We'll return to this issue later.

Over the years, larger numbers of commercial payers have been asking for pass-through pricing in their PBM contracts, as in Part D. That's when the PBM passes along some or all of the rebates back to the payer. In place of that revenue, clients pay their PBM fees for specific services like administering rebates and running prior authorization programs.

Another change to note is that with the growth of spending for specialty drugs, all of the largest PBMs now own specialty pharmacies. We will talk about the reasons why in a few slides, but for now let me point out a drawback that there is potentially a conflict. On the one hand, payers and plans hire PBMs to manage and help control drug spending. On the other hand, the PBM's specialty

pharmacy would like to expand revenues by dispensing more specialty drugs.

The specialty pharmacy industry has developed to address some of the challenges in dispensing specialty drugs. Most fill prescriptions through home delivery or will send the drug to a location that is convenient to the patient such as their workplace. Although a wide variety of establishments call themselves a specialty pharmacy, PBMs require that those in their network be accredited by organizations such as URAC. This gives the PBM more assurance of competency at things such as managing supply logistics, managing patient care, and data reporting capabilities.

Although the specialty pharmacy market has been fairly active with mergers and acquisitions, it is less concentrated than the PBM industry and there are a variety of ownership arrangements. Major PBMs own them, but also retail pharmacy chains, health plans, drug wholesalers, and GPOs. About half of specialty pharmacies are independently owned. Manufacturers generally don't own specialty pharmacies, with a few exceptions, but there are nonetheless ways in which they can influence them. For

example, all specialty pharmacies report data to manufacturers on each prescription dispensed and, in return, manufacturers pay the specialty pharmacy's fees for their services, and sometimes rebates. Another way manufacturers may be able to influence specialty pharmacies is through limited distribution networks.

Manufacturers can use either open or limited distribution. With open distribution, the manufacturer makes the drug available through wholesalers and then any retail pharmacy can purchase the drug and dispense it. With limited distribution, the manufacturer manages the pharmacy channel more tightly. They typically use a competitive process to select among specialty pharmacies, based on their experience with running clinical programs, encouraging drug adherence, and data reporting capabilities.

Manufacturers use limited distribution for a number of reasons. Sometimes specialty drugs have special handling protocols. If you've got an expensive drug with a limited shelf life, having a smaller number of dispensing pharmacies helps ensure that each has a large enough number of patients to supply the drug in a timely manner. Limited

distribution can also help ensure more consistency in patient services and in how data are collected and reported. However, remember that PBMs have to negotiate with specialty pharmacies on a payment rate, so a concern with limited distribution is that when you only have a small number of specialty pharmacies dispensing a drug, the PBM may not be able to negotiate competitive discounts in the pharmacies' payment rates.

So now that we have described some of different supply chain actors, let's think about three categories of ownership arrangements for specialty pharmacies. On the far left, we have a large health plan that owns a PBM and a specialty pharmacy. With this amount of vertical integration, you have a certain alignment of financial incentives. The plan likely directs its members to use its own specialty pharmacy in order to keep those dispensing margins in-house rather than paying them to other pharmacies. You have got a greater volume of patients using the drug, so there is more bargaining leverage with the drug's manufacturer over pricing and rebates. And since the plan is providing medical and pharmacy benefits, it may have more incentive to think about the combined

costs. Today, organizations with this degree of vertical integration account for less than 15 percent of total U.S. prescription revenues from specialty drugs.

In the middle we have a PBM that is independent of any health plan and that owns a specialty pharmacy. It makes sense that PBMs would want to do this -- they can direct plan members to use their pharmacy and capture the dispensing margins they would otherwise pay elsewhere. It also gives the PBM greater volume and negotiating leverage over rebates. Owning a specialty pharmacy also gives the PBM more control over utilization management requirements.

At the same time, there can be conflicts between the interests of this type of vertically integrated organization and its clients. The client wants the PBM to try to restrain its drug spending, but the organization may also want to expand dispensing revenues. Today, these types of organizations account for nearly half of total U.S. prescription revenues from specialty drugs.

On the far right, there is an independent specialty pharmacy. Its business model is more directly focused on its volume of dispensing and fees associated with monitoring patients and reporting data. Some analysts

believe that with this ownership structure, the interests of drug manufacturers and the specialty pharmacy are aligned. Today, independent specialty pharmacies account for about 10 percent of total U.S. prescription revenues from specialty drugs.

This slide is obviously simplified, and if you have kept track, we have left off other types of ownership situations that account for about a quarter of the specialty drug revenues. Other types of owners include retail pharmacy chains, wholesalers, hospital systems, and physician practices. So these three aren't all there is, but they account for much of the market.

Now that we've taken a look at the market generally, let's shift to specific policy issues within the context of Medicare.

MS. SUZUKI: During our interviews with PBMs, plans and payers, and specialty pharmacies, several potential policy questions came up that relate to managing specialty drugs in Medicare.

The first is the use of exclusive specialty pharmacy networks. In the commercial sector, payers using an exclusive network most frequently mentioned lower cost

as the reason for using it. They claimed that they could negotiate lower payments with pharmacies because higher volume gave pharmacies greater leverage and larger discounts from manufacturers. Another benefit we heard was better management and improved patient care from avoiding pharmacies with close ties to manufacturers and those with low quality.

When asked about allowing exclusive networks in Part D, some stakeholders raised concerns that, because of the size of the market that would be affected, competition among specialty pharmacies could be negatively affected.

Currently, in Part D, the any-willing-pharmacy rule precludes the use exclusive networks. But some of our interviewees suggested that PBMs may be able to get around this rule by setting fees that discourage certain specialty pharmacies from participating in their networks.

Given that most PBMs own a specialty pharmacy, there was a general consensus that exclusive networks in Part D may have significant implications for the viability of independent specialty pharmacies over the longer term.

We also heard a general concern about PBM-owned specialty pharmacies because of the mixed incentives they

face that Rachel explained. For Medicare, it may also affect program costs, which I will come back to in a few slides.

Before going into other policy areas, it's important to understand two types of data that are reported to CMS. CMS requires reporting of all manufacturer and pharmacy rebates and fees that are received by plan sponsors and PBMs, not reflected at the POS. One is direct and indirect remuneration, or DIR, which includes all price concessions, such as rebates and discounts. The other is non-DIR. It's all other payments. This is typically administrative fees for actual, or "bona fide" services. To be classified as non-DIR, fees have to meet the fair market value test. Any amount above the fair market value is a DIR.

The key distinction here is that DIRs are passed on to plans to reduce beneficiary premiums and to Medicare to reduce program costs, while non-DIR fees are not used to lower premiums or Medicare payments.

Another important point to remember is that CMS's reporting requirement applies only to plan sponsors and PBMs, and to the extent that PBMs receive rebates or fees

at specialty pharmacies, CMS guidance does not explicitly require reporting to plan sponsors or to CMS.

Data reported to CMS is used to reconcile Medicare's prospective payments to plans with actual costs, and to ensure savings negotiated by PBMs are passed on to taxpayers and beneficiaries. The data also may allow plan sponsors to evaluate the performance of their PBMs, determine whether they have acted in the sponsor's best interest, and make an informed choice of a PBM.

However, in our interviews, we heard that Part D sponsors do not always have access to their own data. To remedy this situation, CMS could provide Part D sponsors access to their own data when requested.

Some have opposed more PBM data transparency on the grounds that it could harm competition. Some also argue that data disclosure is not necessary because the PBM industry is competitive. At the same time, it is not clear whether the current Part D transparency requirement has harmed competition. But transparency and its goals may not be achieved if, for example, PBMs shift away from rebates and fees that are treated as a DIR to non-DIR service fees, which would still be reported to CMS, but are not used to

reduce benefit costs.

PBMs may also evolve to receive more of their rebates and fees through specialty pharmacies. They are not required to report those rebates and fees to CMS or to plan sponsors, and this point is related to the use of exclusive networks, which, if allowed, could increase prescription volumes at PBM-owned specialty pharmacies. And if that happens, there may be more rebates and fees that are not reported, which in turn may mean that there are less rebates and fees available to lower benefit costs.

The third issue relates to how specialty drugs used to treat the same condition can sometimes fall across both medical and pharmacy benefits. We heard a general consensus among the stakeholders that it is important to integrate the management under the medical and pharmacy benefits to effectively manage specialty drug spending.

In Medicare, MA-PDs provide both medical and drug benefit. But CMS currently does not allow them to use formularies or certain management tools, such as step therapy, under the medical benefit.

MA-PDs and their enrollees could benefit from consistent management of specialty drugs under the two

benefits. If appropriately structured, it could help providers and patients choose a combination of drugs and therapies based on clinical effectiveness, safety, and value regardless of the site of service. It may also drive more competition on pricing among competing manufacturers.

One potential drawback of this idea is that to implement this in Medicare, there are likely programmatic changes that would need to be made.

To summarize, specialty drugs will increasingly drive growth in overall drug spending, and PBMs and specialty pharmacies will be the key entities involved in the management of specialty drugs.

The market for specialty drugs is complicated. There are multiple transactions among the supply chain actors and different incentives reflecting ownership and alignments with other actors.

We introduce three policy questions related to the management of specialty drugs in Medicare that the Commission may want to explore further.

First is exclusive specialty pharmacy networks. In the commercial sector, payers claim that it lowers costs and improve quality, but over the longer term, there is a

concern about its effects on competition. More importantly, for Medicare, if more of the rebates and fees for specialty drugs shift to specialty pharmacies instead of PBMs, it may mean less are available to lower costs for Medicare and beneficiaries.

Second is related to the data transparency requirement in Part D. This is essential for accurate payment, program integrity, and from plan sponsor's perspective, in evaluating PBM performance. But some oppose policies that require PBM data transparency on the grounds that it could harm competition, though this argument is not typically made in the Part D context.

The third is allowing MA-PDs to manage specialty drugs under the medical benefit. The commercial sector appears to be moving in this direction. For Medicare to do this, it likely would require programmatic changes.

This is a very complicated area, and as Rachel mentioned at the beginning, we are at an early stage in this work and we would be interested in learning more from the Commissioners who have experience in this area. We are also interested in getting your feedback on policy issues we raised.

DR. CROSSON: Perfect. Thank you very much. Now do clarifying questions. Let me see hands for clarifying questions. Why don't we start with Pat?

MS. WANG: [Off microphone].

DR. CROSSON: Microphone.

MS. WANG: On Slide 11, I just want to understand the last bullet point. And thank you guys, I just really enjoyed hearing about your reports. They're really interesting and substantive.

The concern about transparency, is that for specialty pharmacies overall, or just the PBM-owned specialty pharmacies? I took from the prior slide that there's something -- if it's your own subsidiary you're not required to report DIR. Is that the issue, or is it all specialty pharmacies?

MS. SUZUKI: So what we're saying in the last bullet point is that currently specialty pharmacies are not required to report the rebates and fees that they receive. However, if we, for example, allowed plans to have exclusive networks and, you know, that was limited to PBM-owned specialty pharmacies, and we're just -- you know, we're just thinking through all the effects that could

happen. One of them could be that some of the specialty pharmacies may get some of the rebates and fees that could have occurred in other areas and those would not be reported.

MS. WANG: Okay.

MS. SUZUKI: And in general, specialty drug spending is growing, so a lot of the fees that are paid to specialty pharmacies is going to account for a larger chunk of the fees.

MS. WANG: Is a solution to this problem that subsidiary specialty -- specialty pharmacies that are subsidiaries of a PBM must report to DIR? It's not that simple.

DR. MILLER: I don't think it is that simple.

MS. WANG: Okay.

DR. MILLER: And, you know the way -- because if you do that then, you know, people reorganize their business relationships, you know, move it. They potentially respond by reorganizing their business relationships. I think the transparency -- and I know you'll want to get in here -- I think the transparency issue kind of runs in a number of complicated directions,

which is even if you're just talking about what's happening now between the PBM and the plan and the movement of things between rebate and discounts and into other types of fees, like, you know, how much transparency should you have there, and who should have it?

I mean, part of the complaints we get, and which I don't fully understand, are the plans, you know, saying we -- we don't know everything that's happening here. Then there's the question of further upstream, or downstream, whichever way you think about it, the subsidiary transactions, and then if you -- your question, if you just did it for some actors and not others, does that create disadvantages, an un-level playing field and people start moving around that?

And then another big arching transparency issue is transparent to whom? Like could you give the data to CMS and not to the public, to the plan? But, you know, who -- when we say -- when anyone says transparency, what do we think we actually mean by that?

DR. CROSSON: Amy on this?

MS. BRICKER: So I think that the term rebate here is probably causing the confusion. Pharmacies

generally do not get rebates. Rebates are given to PBMs or other entities for formulary replacement. Pharmacies don't manage formularies. So if it's a purchased discount or if it's a fee associated with services that the pharmacy is providing the manufacturer, that's what's in question here.

I think rebate is confused when we're talking about, you know, formulary management and rebate and what planned sponsors demand from their PBM as part of hiring and firing PBMs. But being a subsidiary doesn't mean that you have any incentive to get fees different than someone that's not a subsidiary.

UNIDENTIFIED SPEAKER: [Off microphone].

MS. BRICKER: It's a bona fide service that's defined in regulations.

DR. CROSSON: Brian.

DR. DeBUSK: And again, just to clarify, if a manufacturer then pays cash terms to a specialty pharmacy or pays for maybe sales tracings or some other information, that -- the fees that that specialty pharmacy collects are not subject to DIR?

MS. SUZUKI: Correct.

DR. DeBUSK: And that would be the same for

wholesalers as well? Okay, I'm good.

DR. CROSSON: Amy.

MS. BRICKER: Of those that you interviewed, how many plan sponsors said -- plan sponsors said that they didn't have access to the DIR at the level in which they were requesting it?

DR. SCHMIDT: It was primarily consultants, and we tried to interview a variety of consultants, some from major firms and some from smaller ones. We did interview one pair who was going about trying to have audits and that sort of thing, but was finding it to be quite a process. But others -- other pairs that we interviewed, other planned sponsors, had very -- they would audit regularly. They would have market checks. We saw a variety of circumstances in the contracts that they negotiated with their PBMs and the degree of access to the information about rebates.

MS. BRICKER: Certainly, but the question is around DIR, and as I understand it, and the ability to have access to claim level information with respect to DIR reporting and the regulation, as I understand it, is a requirement -- the plan sponsor to report that to CMS, yes?

So I can just speak on behalf of the company that I work for. We certainly give that level of transparency to our plan sponsors, and they report to CMS.

So I don't know that there's this widespread issue that we're addressing in this forum. If that's happening, and with the consultant that you spoke to, they should probably hire a new PBM, but I don't know that there's this widespread sort of, you know, lack of disclosure.

DR. MILLER: And, you know, we -- and I said a minute ago, I'm not quite sure I understand it. We hear in this complaint, and we are well aware of what path --

UNIDENTIFIED SPEAKER: Press that button.

DR. MILLER: We hear this complaint and we have this -- you know, we have the same questions and reactions that you have, which is, you know, you're -- you're required by law or regulation to pass this information through.

So how can you not have -- have access to it? Some of the things in -- you know, remember, I'm kind of this -- the remedial memory here is they would say -- there was some complexity in getting it and getting it in the

detail that they wanted. These are -- these are people just saying this, so, you know, I'm just putting across to you what we heard.

And then the notion of hire and fire and it -- you know, we have the same kind of reaction, so it's like, you have a business transaction with this person, you know, get rid of him, and then they would say, yeah, but you know, the industry's really concentrated and you can't always just toss a PBM out the door, that type of thing. And again, this is what people are saying, and so that's what we're trying to get a foothold on.

DR. CROSSON: Questions, questions, questions, questions. David.

DR. NERENZ: Amy may have answered this, but I'll ask it anyway. It was very kind of you to assume that we all understand rebates thoroughly. I don't. Could you just say just a little more, just a minute or two, of rebates? What's the scope of it? A rebate is paid always by a manufacturer to --

DR. SCHMIDT: It's generally to a PBM.

DR. NERENZ: Only to a PBM? Or could it be paid to a different entity?

DR. SCHMIDT: Amy has just said that -- this is kind of a problem with nomenclature. We saw some reports of rebates to pharmacies.

MS. BRICKER: Post-purchase discount.

DR. SCHMIDT: Okay. We'll call that post-purchase discounts.

MS. BRICKER: It's based on -- so rebates generally are in exchange for formulary replacement. A health plan can negotiate with Pharma, a PBM can. It's a matter of placement on the formulary. You get a rebate for that.

DR. NERENZ: Do you get a rebate for anything else?

MS. BRICKER: Potentially for post-purchase discounts. So maybe if there's a volume or if there's some -- within a pharmacy arrangement, but it has nothing to do with formulary replacement.

DR. NERENZ: Okay. No, I'm just trying to understand what -- what money flows from where to where for what? And -- okay. Is there anything else that we haven't -- there is an example?

DR. SCHMIDT: Amy knows this better than any of

us.

DR. NERENZ: Okay. That's -- it helps me to understand, because otherwise, what's a rebate, what's a discount? It sounds like we've got a rebate in response to discounts.

DR. SCHMIDT: The notion is it's after the point of sale. It's, you know, if your -- if your drug is on a formulary, if you've been able -- if the PBM's been able to move market share towards your drug, those are the general sorts of things that the PBMs earn rebates for.

DR. NERENZ: So that would be driven after a period of time by the observation of market share and that would all be contractually set? Okay.

DR. COOMBS: Can I go into that? It's never -- is it safe to assume that this money, the rebate, never gets translated to the back to the patients for the plan?

DR. SCHMIDT: That's a big point of contention, right? Some of the larger PBMs have started point of sale or rebates, but generally speaking, it's lowering the benefit costs. So the rebates, you know, can be used to lower premiums. Some of it might take the form of higher profits. Those are kind of the general things. But more

recently, because of concern about, you know, the rebates and the high cost of certain drugs, these specialty drugs, you see interest in point of sale rebates.

DR. COOMBS: Do we know a range of the magnitude?

DR. SCHMIDT: It really varies from cost to cost. Specialty drugs, you know, probably can have lower percentage rebate associated with them but can still be high dollar amounts because of the high price.

DR. CROSSON: And just a point on that, Alice, is there's a difference between using the rebates to reduce -- this is obvious, but there's a difference between using rebates for just the premiums for everyone and in some way using the rebate dollars to help individuals who have high out-of-pocket expenses.

DR. MILLER: At point of sale?

DR. CROSSON: At point of sale, yeah. Okay. So on that point, Jack.

DR. HOADLEY: On Dave's original question here, I mean, one of the things when I last did interviews on this, which was quite a few years ago, was sometimes the distinction -- and Rachel was starting to make this. I mean, rebates can be for formulary replacement, but it can

take the form of, you know, you put me on the preferred tier, this is what I'm going to get, or you put me on the preferred tier and I see a shift in volume, market share.

So those two can kind of layer on each other, and I think that's -- and then probably some other kinds of arrangements like that. So it usually, as I've heard about it, usually it is related to formulary replacement, but the form it takes, you know, just getting on the tier, getting on the formulary, or seeing a shift to volume as a result of the formulary might -- would be at least two variations on how that might play out.

DR. CROSSON: Hey, Bruce, you're on this point?

ME. PYENSON: On this point, I think we can narrowly define rebate, I think, as -- for formulary placement if we want or volume. But there's -- there's other things that might fall in the commonsense notion of rebates, I think, such as payments or house brands to pharmacies from the manufacturer to the pharmacy, or there's payments made by distributors by wholesalers. GPOs have their own arrangements.

So there's -- I may be clarifying the terminology here at some point with -- you know, have a Thesaurus here

or something here would be terrific.

DR. CROSSON: Okay, so we're still on clarifying questions. Let's talk down at that end. And I see Kathy.

MS. BUTO: Okay. So Slide number 12. As I understand it, we're only recommending or considering whether MA-PDs should manage specialty drugs that are under the medical benefit, as well as part D drugs, because there's -- there's no opportunity for PBPs to manage medical benefit drugs and there's no opportunity for ACOs to manage Part D drugs, correct?

Okay, so that's the only subset we're thinking about. Because I think that that is the argument you make, which is a really good one, of the interchangeability, and to achieve the best clinical benefit would actually apply to either those other entities, but there's no clear avenue to make that available.

DR. SCHMIDT: It's the programmatic change that was mentioned.

MS. BUTO: The programmatic change for the MA-PDs, right. But they're -- you can't -- I can't imagine a programmatic change that would work with PBPs to take on the medical benefit. I mean --

DR. MILLER: I'll just give you one of those weird --

MS. BUTO: Am I right?

DR. MILLER: -- weird angle on it? And I actually think this is --

MS. BUTO: I wish there were, but there isn't.

DR. MILLER: Well --

MS. BUTO: It would be the same for AC --

DR. MILLER: I'll give you one weird one, but just before that, I think this is a good topic of conversation. There's a real logic within the MA-PD environment to talk -- talk about this, and if you cast your mind back to the PBP discussions in Part B, drugs, in a sense, that's what we're saying, is allow people to use formularies. This would be a way to kind of drive the formularies into the B side when you're managing, you know, the A, B -- the A, B, D benefit through a managed care plan.

The only other angle when you were saying PDP, I'm with you, I don't see how you do it, or at least easily. Maybe somebody else has got an idea. And in ACO, we had a passing conversation at one point, and I don't

remember it going well.

MS. BUTO: I kind of do. The one about the -- not everybody takes Part D and then you get into this whole --

DR. MILLER: Or you have a designated D plan for people in ACO.

MS. BUTO: But not in an ACO. You don't enroll.

DR. MILLER: You go into this ACO; you go into that D --

MS. BUTO: Right.

DR. MILLER: Right, and then people were sort of not into that.

DR. CROSSON: That's what I remember. Okay. Jack.

DR. HOADLEY: I mean, there -- there was an option that was discussed many years ago soon after Part D was created, which is should some of the drugs currently on Part B be shifted into Part B, or presumably vice versa? But mostly it was not that. And that runs into some -- a number of obstacles, particularly for those that are administered and the purchase chain is through the physician. But at some level there was a report that CMS

had to do way back in the year '01 or '02 after the MMA that sort of dressed the policy issues around that, and of course, it didn't go anywhere.

DR. CROSSON: Okay, questions. Bruce.

MR. PYENSON: Thank you. Question on Slide 8. Actually, it's not really about Slide 8, but this is, I think, a useful construct to think about the flow of product and perhaps money, ignoring the ownership issue. So here there's some interaction between the manufacturer and the specialty pharmacy, but there's also interactions along the way of distributors, wholesalers, GPOs.

And do we have any -- what insight do we have into those financial transactions?

DR. SCHMIDT: You know, we thought this was a pretty murky presentation as it is, but certainly that adds another level of complexity altogether. For purposes of -- I mean, this is useful feedback for us on what level of complexity you want to get into in a chapter, because yes, there are -- there are other related issues in all of those relationships.

MR. PYENSON: Just a follow-up question, not to make it more complicated. But specialty pharmacies handle,

as you know, both the PBM side of things, the retail pharmacy, as well as the medical benefit side, as the last question -- question addressed. To what extent are those two financially tied?

So a corollary question is just for Medicare, when you look at specialty drug spending, perhaps almost all of Part B is specialty, or a lot of it is. When you add that to the what's quote/unquote "specialty" in Part B, what's the split there?

DR. SCHMIDT: We'll have to come back with an answer later for that.

MR. PYENSON: Okay. Thanks. Another -- another related question. This morning there was very brief mention of physician-owned distributorships for the medical device side. I think there are practice-owned pharmacies and dispensaries. And how do they -- they fit in with this?

DR. SCHMIDT: So there's a separate channel for specialty distributors. Many of them are owned by wholesalers. Like Amy can jump in at any time. But they supply those types of dispensing arrangements that are within physician offices, physician practices. Is that

good?

MS. BRICKER: Yes, there are physicians that also own pharmacies. Is that what you're saying, dispensed directly to the patient?

MR. PYENSON: I think so.

MS. BRICKER: I'm saying there is.

MR. PYENSON: Okay.

MS. BRICKER: Is that what you're asking?

MR. PYENSON: I think that's what I'm asking.

MS. BRICKER: Maybe you're not talking about distributors, like physicians distributing to pharmacies. You're talking about physicians distributing to patients.

MR. PYENSON: Yes, so there's another channel that has its -- that Medicare is paying for and --

DR. SCHMIDT: Under the -- but these are outpatient drugs, not the physician-administered ones. These are just outpatient drugs that the physician office happens to be dispensing out of convenience, a number of reasons.

MS. BRICKER: It could be B, right?

DR. SCHMIDT: They do --

MR. PYENSON: Could be both. So -- and

presumably, any of these have some impact on DIR, whatever -- however we define --

DR. SCHMIDT: Again, they're outside of DIR because it's a specialty pharmacy. So they don't have to be reporting those arrangements.

MR. PYENSON: So they're outside of it, but there is the potential to influence the choice of drug financially through those -- those mechanisms presumably.

DR. SCHMIDT: Well, it's the prescriber there, you know, in the office, helping to select the drug, yes.

MR. PYENSON: Okay. So a different question. Just a -- if it's -- if it's relatively not too hard to do, I think some of the companies have publicly audited financial statements in perhaps a relatively pure form for PBMs, for wholesalers, distributors, perhaps GPOs, and it's been a few months since I've looked at them, but I think some of the issues could be identified as accounting line items to understand what the aggregate volumes are, and does that sound like something --

DR. SCHMIDT: We haven't looked at GPOs and wholesaler SEC forms, but we have looked at PBMs, and the variety of ownership arrangements make it more complex than

you might think. And the -- I'm not sure what particular you're thinking we exactly look for, but for example, I think rebates tend to be considered a reduction of cost of revenues, or something along those lines, so it's a little more not too obvious.

MR. PYENSON: I think for -- I think there's one company that's relatively -- doesn't own drug stores. It might be a little easier to identify and since the -- we think the market is competitive, perhaps that's a good representation of the market. If I recall right, there's even detail on Medicare separate from commercial in there. I'm wondering if that would be -- would fit into this analysis.

DR. MILLER: And that's where I'm lost. This analysis, even as it stands, has been very complicated to work through, and the three issues were -- you know, and you're free to -- as the commissioners, you can define whatever issues you want to pursue, but at this point on the table, we have sort of a transparency question, which in response to Pat ran in about four different directions.

We have this MA versus, you know, BD question, which actually is a kind of separate animal, and then this

issue of kind of, you know, what's defined in and out of DIR and how up and down the subsidiary chain you go looking for any of that. You know, there's a number of asks here, but I'm trying to figure out do they fit into these issues or is there a different issue you're pursuing?

MR. PYENSON: I think they fit very much into this issue because --

DR. MILLER: And if you were to say a sentence, I'm like a sentence on how --

MR. PYENSON: The reason why is that audited financial statements are believed to represent accurate information, and to the extent there's line items in those financial statements that are very relevant to these topics, I think it would be very helpful.

DR. MILLER: And do you think of it as a source of data or just knowing the scope of the problem? Because if there was a policy change that said this information needs to be made available to the plan or to CMS or whatever we were to decide, that would be a matter of regulatory. You know, even now have to report this and it wouldn't have to be sought out through that source. That's why I'm asking.

MR. PYENSON: Well, when we're addressing issues like what is DIR, what is not DIR, which is part of the question -- questions here, I think the financial statements can shed light on that.

DR. MILLER: I see. Okay.

MR. PYENSON: I'm sorry. I was asking Rachel and Shinobu if they thought that was useful.

DR. SCHMIDT: We'll be happy to take a look at it.

MR. PYENSON: Okay. Thank you.

DR. CROSSON: I think it's something that could be looked at.

Let me just ask an irrelevant question. What's the difference between a distributor and a wholesaler? Okay. Forget that.

[Laughter.]

DR. CROSSON: Okay. Time for the discussion. So we have Amy who is going to start out, and then Jack and then Bruce, and then we'll have everybody else.

MS. BRICKER: I think you're right. This is really complicated, and I think we may have made it a little bit more by trying to put all of this sort of in the

same document.

I think there's still a question around how does a drug go from the manufacturer to the patient. So I think if the Commission's interested in kind of looking under the covers from manufacturer to the wholesaler to the pharmacy to the patient, we can certainly have those discussions about how those transactions kind of go about. Separate from that is the role that a PBM plays and how then a plan sponsor hires a PBM and what the role of the PBM is. It's a highly, highly, highly competitive industry. And there's sort of a notion throughout the document around acting in "the client's best interest."

PBMs are bound by contract to meet certain discounts and to provide certain levels of rebates to their clients. So even if as suggested all rebates went away and they all went somewhere else, that wouldn't work because clients require a certain level of rebate be given to them. The PBM is at risk for that. Okay. So I think that's important.

Page 24 of the reading material, in a footnote you address the issue of conflict of interest, and you note that the FTC has already weighed in on this issue with

respect to mail order and found that they're actually -- when it's owned by a PBM, it actually results in lower pricing than when a mail-order pharmacy is not owned by the PBM. So there's that, and that's important because I think there's already been an agency weigh-in here.

Thing two, page 22. You mention that the CBO and the FTC have weighed in on disclosure and the harm of publicly disclosing net pricing. So I think that's important to ground us, and we can continue asking the questions, but they've been asked, and I think there have been respected entities that have weighed in on these very issues.

And as a Commission, I know that we've talked a lot about why are we here. Well, we're here because we want to make sure that patients have access to care, and I think in this case we want to ensure that plan sponsors have the ability to manage costs associated with pharmaceuticals.

I'm absolutely in favor of exploring exclusive pharmacy networks. You have in the materials provided the number one thing that the interviewees stated, if they were going to reduce costs, would be the narrow their pharmacy

network.

There's mention in the document of PBMs requiring their clients to use their pharmacies. That's not true. There aren't relationships that require. There are options. So you can have an open network, you can have a narrow network. You can have an open formulary or you can have a narrow formulary in the commercial space. And the PBM administers that benefit.

So if you want to have an open specialty network, fine. If you want to use the pharmacy that is owned maybe by the PBM or someone else, that's also your right to do that, and the PBM will administer that benefit.

So those are important distinction, though, because I think that to suggest that there's some requirement or some leverage over the client isn't the case because of the competitiveness of the industry. If you're not lowering costs for the plan sponsor, if as a specialty pharmacy you're not servicing the patients appropriately, then you're going to be fired, and they'll find someone else to do that.

A couple other points, if I might. I'm in wild support of allowing Part B to be managed drug pricing or

drug management as in Part D. I'm thinking back to recently in the news right now is PCSK9s and how PCSK9s were feared to -- before they were actually on the market, that they were going to have incredible costs across the health care system. They're actually covered under Part D, and because of that, their utilization was dramatically less than what was originally thought to be, and that's because of really, really stringent utilization management by specialty pharmacies that ensured that they were not being used, you know, wildly and that they were only being used for the right patients. And so if it had been actually covered under Part B, what might that look like? I think that's a question we could all sort of consider. And now the manufacturers are thinking that because of new research and new guidelines around cholesterol levels, there will be renewed interest. But, anyway, just something to consider.

Manufacturers with respect to limited distribution, in the notes you highlight that manufacturers, if they select a narrow network for the distribution of their drug, it's done in a highly competitive way. They're looking at the pharmacies that

can provide the best patient care, that have the right clinical resources to patients, that are able to have an infrastructure to support their drug and the dispensing of that drug.

So, again, I want to highlight that all of these things are done in the context of competitiveness with respect to pharmacy dispensing, but it is really important, I think, for us to pull these things apart. Specialty pharmacies owned by PBMs aren't different than retail pharmacies owned by PBMs or the revenue streams of a specialty pharmacy shouldn't be highlighted differently than the revenue streams of a retail pharmacy. These are pharmacies separate from PBMs, and they're hired by plan sponsors, and they have very stringent requirements around discounts and service levels that are to be met, and they are a matter of contract.

DR. CROSSON: Amy, can I ask you just to go over one piece because I'm not sure I picked up everything. The issue of potential conflict of interest where the PBM owns a specialty pharmacy, and as you pointed out, the PBM works out an arrangement with the plan sponsor for certain discounts.

On the other hand, as was pointed out in the paper, if they own the specialty pharmacy, then there's an additional incentive, and that's for the specialty pharmacy to move as much business and dollar volume through it. Right? I mean, that's how it makes money, no?

MS. BRICKER: So in order for the specialty pharmacy to fill any prescriptions at all, regardless if it's owned by the PBM or not, it has to be implementing the benefit that the plan sponsor has elected. So if you say, "I don't want any prior authorization, I don't want any care management at all," that's -- you know, that's rare, but, okay, that's an option. And, you know, any specialty pharmacy and any pharmacy can dispense that. Versus other spectrum, "I want you to implement all of the clinical criteria that you can to ensure that my drug is being dispensed appropriately." I want to narrow the network so that I have control over that. I know what the clinical criteria is at one pharmacy versus having to understand them sort of across the spectrum of pharmacies.

So I don't see that, because it's owned by the PBM that there's a conflict in that the rules are set by the plan sponsor and the PBM is administering the rules of

those products being dispensed. The specialty pharmacy can't get around those.

DR. CROSSON: Let me put it another way. I thought -- and I may be mistaken here in what I heard. I thought you said that the situation was discovered that prices were lower when the PBM owned the specialty pharmacy.

MS. BRICKER: Sure.

DR. CROSSON: But that's not the same as total dollar volume going through. Or is it? Right?

MS. BRICKER: Well, again, you could -- this is the same in retail or specialty. It's not unique to specialty. When you're negotiating for discounts, if you're able to narrow the network, it's because the retailers wouldn't give you a better discount for that than if the network is wide open. And so in this case of an exclusive pharmacy relationship, you're going to get a better discount with one versus --

DR. CROSSON: No, no. I got that part. But let me see if I can -- so I think what you're saying is from your perspective, there is no potential conflict of interest or not even conflict of interest but competing

interests when a PBM owns a specialty pharmacy.

MS. BRICKER: That is my position.

DR. CROSSON: That's what you're saying, okay.

MS. BRICKER: And, lastly, on DIR, very different also. DIR arrangements are implemented at the request of plan sponsors. So PBMs don't do this on their own. So the biggest DIR, as you noted, was from manufacturer rebates. Right? So plan sponsors are aware of that. They sign up for that. They ask for that. They demand higher rebates in exchange for their business. So that's aboveboard. And I think if we want to examine DIR, we need to do so also as a separate discussion point. I don't know that they're -- they're not related to specialty pharmacy per se. It's a totally different animal.

DR. CROSSON: Okay. Jack.

DR. HOADLEY: So I really want to thank you for this chapter. It's a really strong analysis of a complicated topic, and I think in my eyes, what you've revealed is a real maze of financial what I would call entanglements, and I'd hope we really do continue looking at the issues of concentration, conflicts, pricing mechanics and so forth. And I'm not as comforted as Amy is

by the notion of the amount of competition in this market. I mean, the studies you've cited of ten years ago, it's a pretty different world than ten years ago. Ten years ago, we had, you know, more companies in the PBM business. We had relationships then with manufacturers as opposed to relationships with plans. I mean, the shifting around of who owns what has changed a lot, and I think it would be interesting to go back and revisit -- or if those agencies were to choose to go back and revisit some of those questions, whether they really would come out the same today, it's just a very different set of business relationships than we saw a decade ago. And I think there's actually been some ups and downs in terms of the amount of sort of conflict, and I could talk about that at another time.

But I think it really is unclear where the system saves money, the way the system works saves money, and where it adds costs. And I think there's evidence of both, but I think that's what we need to continue to try to untangle.

I want to sort of raise two issues and then come back to the three that you raised. One is in a way really

illustrating where I think you see the evidence of where the markets aren't working out the way they need to. And I look at the example of RA drugs. I think you can do some of the same with MS drugs. But where you've had competing drugs in the Part D world with Enbrel and Humira and now newly to the market there will be a Humira biosimilar, but we've seen those prices go up pretty constantly over time.

Now, we can't see what the net prices look like, and perhaps there's been activity. But I have not, at least when I last looked at it -- and it's been a few years now -- not seen a lot of formulary competition where, you know, one plan goes with Enbrel, one plan goes with Humira, and the kind of thing you would expect to see if you really were seeing a strong competitive kind of thing going on. MS drugs is another area where prices have gone up even as new competitors entered the market, sort of the opposite of what you would normally expect.

So, you know, to me these are concerns of what else is going on. Is there discounting that's so hidden that we're not seeing it? That's obviously a possibility. Or has there just been not enough sort of competitive forces to sort of deal with it? And I think, you know, I

would love to see some illustration of what's gone on that particular drug class or other drug classes like that, that are high-priced drugs, specialty drugs, and so forth.

The other issue I want to raise is one I've raised before, and it came up a little bit in the clarifying round. You know, I think we really need to continue to look at what's the right way to share rebate savings with beneficiaries, particularly obviously those beneficiaries that have deductibles or coinsurance and other ways for facing some share of the price. And as you say, there's been some experimentation with some kind of rebate averages being provided at point of sale.

And you could also think about ways to look at the benefit in terms of making sure there's less coinsurance or caps on coinsurance so that the beneficiary is not as affected by this. But this is something that I think is getting a lot more discussion not just in Medicare but in the private sector as well where people under high deductibles are facing the full cost of drugs and yet it's the full gross cost, and as all the evidence seems to show us lately, the gap between gross cost and net cost has been growing over the last several years. And so that's just

making this issue a greater one. I think this really is an issue -- and, you know, we can walk through all the issues about, you know, the -- assuming the savings is fully passed on, it's showing up in the premium, and Mark or maybe somebody else brought this up earlier, versus showing up for the people who take that particular drug, and that sort of equity issue of where those savings belong I think is -- I think maybe, Alice, you brought up that question.

So I really would like to see us try to address that. I think that's one of the big issues that's sitting out there.

In terms of the three issues you raised, I'm still struggling with the exclusive specialty pharmacy network model because of all the financial entanglements that are around. When we talked about this a couple years ago, the biggest concern I raised was access. I think I'm more comforted by what I've heard in the sense that, you know, these are mostly done by mail order, mail delivery, so there's not the question of do you have a particular specialty pharmacy convenient to you. So, I mean, I think some of the access issues seem less serious, although I wouldn't want to put those away completely. But I am

concerned about all the financial relationships and what it does, and you've raised a number of those. So I'm not ready to say that that's, you know, something I'd like to see Medicare loosen up.

On sharing the disclosure of the DIR data, again, you know, I'm certainly open to hearing more about the discussion. My general instinct here is yes, I mean, from what Amy said, these shouldn't exist. But from what you're hearing, these situations do exist. So I think we need to get to the bottom of that, whether, you know, this is a real issue, and if it is, you know, it's part of the broader transparency issue that goes to, you know, are the interests of the Medicare program being served by these various types of transparency, whether it's the basic pricing mechanisms or these kinds of DIR things. I think that's something worthy of more attention.

Then the third issue raised was on the MA-PDs, and it is interesting. I mentioned before, you know, there is the question -- and RA is another example here where you have directly competing products, Enbrel and Humira on the Part D side, Remicade on the Part B side. And, you know, back before there was a Part D, that was a strong incentive

for Medicare beneficiaries to use Remicade because at least that was covered; whereas, the others weren't. Now it's more complicated. You're covered, but you've got the gap and the different co-pays, and it's 20 percent one place and 25 percent or more on the other place. And, again, it's sort of like our site-of-service kinds of issues. You know, you've got these sort of weirdly designed financial incentives to set up which way to go. So that's across the board, not in MA specific. And I guess the point here would be whether MAs should at least have the ability to sort of look at those kinds of situations and many others that are, you know, different flavors than that and be able to do something to it.

I think one of the questions becomes: What does that do to the whole notion of how the Part D benefit is priced? Do you essentially take the -- have to go all the way to the step of saying, well, you know, if you're in MA, you've got an integrated -- not just an option to get -- right now the rules say you can only get -- if you want Part D, you can only get it through that MA plan that you have, partly because some people either don't want the Part D benefit or they still have an employer benefit or

something else like that. You know, do you basically go to the system where you fully integrate and say we're no longer going to price it out separately? I don't know what all the things would be involved, all the steps involved in going through that. And then what does that do to people who are making comparisons?

I think that could be a way to go because generally you're not shopping between an MA-PD and a PDP since you can only go in the MA-PD if you're already in MA. Sometimes that may be the incentive for you to look into the MA market because you're looking at these deals among the MA-PD plans.

So I guess there seems like there's a number of unanswered questions about what would this really do, how would you price it, how far would you have to go to do it. Are you just loosening some rules? But if you just loosen some rules, then you've got some dollars that are not clearly sitting on the B side or the D side or the A-B side versus the D side. And at some point, you know, what do you do for pricing? And at that point, do you just go to a fully integrated with a single bid across the whole A, B, and D benefit? So those are at least some of the issues

which seems like we'd have to take up to get somewhere on that.

DR. CROSSON: Okay. I note that we're within three minutes of finishing our time, so I think we can't let this go much more than another 20 minutes. Bruce?

MR. PYENSON: I'll echo everything Jack said to make it quick, but in particular to compliment you on the investigation that you've done and the work you've done. It has the right scope, I think, and touched on a lot of issues.

Just one point I wanted to make for the other Commissioners and staff is that the types of things we're talking about are particularly difficult to model because the incentives for the players can change very quickly and very dramatically, and there's been some of the -- some actuarial colleagues have tried to do this simply, and Jack picked up on that a month or two ago, and that's, I think, taking the time to really look at how things like point-of-service rebates would change financial dynamics for lots of different layers in the food chain I think is well worthwhile.

I don't want to lose sight of the excellent

recommendations MedPAC made for reform of Part D before I became a Commissioner because I think those are very relevant to a lot of the issues we're addressing today. So just I'd like to make sure we're reminded of those, not lose sight of those.

Thank you.

DR. CROSSON: Thank you, Bruce.

Let's see hands for discussion. Okay. So we'll start with David and come up this way.

DR. NERENZ: Thanks. Just a couple things. I'll try to do it quickly because I assume this is moving forward to other iterations and we'll see it again before it's done.

On the issue of conflicting interests or competing interests, I just would observe that this kind of situation runs up and down the health care system. It's certainly not unique here, and in some cases we encourage it, ACOs being the prime example. The participants in an ACO make money on the fee-for-service side if they do more, but then they get shared savings if they do less, and those things for many participants directly compete with each other. And I guess we've said that's a good thing.

So I guess if we're going to include that concept here as a concern or a negative, I'd want to see a little more about why is it sort of uniquely a problem here. At the moment I don't see it. I mean, I understand the points you're making, but we see it elsewhere.

A similar point, I guess, on transparency. If I'm understanding the relationships correctly, PBMs are working in the role of a consultant or a supplier or a subcontractor to the plan sponsors. And I would guess in general that CMS does not require such consultants or subcontractors to disclose elements of their own internal finances. And I was thinking -- I'll put Bruce and Warner on the spot. You know, if Warner hires Bruce to do a consulting job, I don't think CMS typically requires disclosure by Bruce to Warner or by Bruce to CMS of Bruce's cost of doing that project.

So I guess if we're also going to have that issue in play, I'd like to see just a little more about why is this situation different. Why should there be transparency or disclosure here if it's not typically the place? Now, if I misunderstand the larger environment, that's fine. But those two things.

MR. PYENSON: Actuarial fees do show up as a line item in the statutory statements, so there's some transparency there.

DR. CROSSON: Okay. Coming up this way, Warner -- sorry, Rita first, then Warner.

DR. REDBERG: So, again, thanks for an excellent chapter, but, you know, it's hard not to be struck by how complex this is for all of us. You know, we are all pretty expert in this area, so that just makes me think it's just -- it's very complex, and to me more complex than it should be for good care and for efficient care. I feel like there's a lot of moving parts and there's a lot of secrecy and there's a lot of fees, and this whole rebate thing that is secret and goes we don't know where makes me very uncomfortable because we don't really know what the actual costs are and who's paying and what the -- you know, and all I can see is that -- and the whole designation even of specialty drugs basically means if you raise your prices high enough, you're a specialty drug because that's -- there are just a lot of drugs and clearly going to be a lot more in this category. But, you know, these drugs, the gross annual spending per user are mostly more than the

median income in the United States. I mean, these are just incredible prices.

Again, getting back to what are Medicare beneficiaries getting for this kind of expenditure, I'm not sure these billions of dollars is really good value. But, you know, just this does not seem like a very efficient system and one that we can evaluate because so much of the prices are in secret.

The paper that was referred to in the mailing materials, Dusetzina paper, had some other suggestions for, instead of rebates, other kinds of pricing and less -- more transparency.

And the last thing I just wanted to mention is it does seem much more complicated to me to have drugs covered under Part B and Part D, and I realize that's done, but I wonder if it's worth considering whether there should just be one sort of drug benefit in Medicare and not to separate it like this, because it's very artificial and it's a lot harder to kind of get around the program when there are some drugs for the same diseases in these two different plans. And it seemed like it would be better to have it under one plan.

DR. CROSSON: Okay. Warner.

MR. THOMAS: Just a couple of comments. First of all, I would agree with the complexity, and I wonder if -- I was actually a little more confused after reading the chapter than less, so I just wonder if -- and it's no criticism of the people writing it. It's just I think it is a complicated situation. I wonder if we should have more thought put into how we really try to peel the different pieces apart and make sure there really is a solid understanding of how the whole system works, because I think one could have, you know, the view that Rita's saying, there's all these fees and there's different -- you know, things go different ways and people don't understand it. So I think, therefore, you come to the conclusion, well, gee, this could be a problem. But I don't think we really know because I think it would be helpful to kind of unwind it a little bit and have a little bit more simplicity put into the model. So maybe that's not possible, but I would ask to maybe think about if that would be possible.

The second piece, and I think it comes back to a fundamental that's not in the chapter, is where's the

manufacturer. There was really no discussion around the manufacturer and kind of where the pricing starts. And I would just -- and maybe that's because this is just focused on PBMs and what-not. But I think to now have some sort of comment or outline that, hey, this pricing cascade all starts with the manufacturer and how they get paid and what they get paid, and they get paid essentially by setting their own price, I think needs to be a backdrop of which all of this discussion is put within. So I would just encourage us to add that component to the chapter and indicate that that's the marker that sets this whole cascade of funding in place.

DR. CROSSON: Brian.

DR. DeBUSK: I would echo Warner's comments and what Bruce alluded to earlier, but I do think we need to look at this whole thing as a system. It's impossible for us to get together or pick up an industry magazine without seeing something about drug pricing. And I think the system's complicated enough and enough money is flowing in so many directions that I don't think singling out a PBM and saying you have to be transparent in this one specific aspect is the solution to our problem. But I do think we

need to look at wholesalers, we need to look at specialty pharmacy, all the different elements of the system more comprehensively.

The other thing that I would ask, just sort of back of your mind as you guys go forward with this -- because this was wonderful work, by the way. Two things that I'm really interested in.

First of all, when there are reference prices, like on the Part B side with ASP, it would be really interesting to see what ASP is and when there are flows of money before the ASP and when there are flows of money after the ASP, basically like DIR and non-DIR-type funding, sort of before and after the ASP and sort of how that would change the calculation.

The other question that I have -- and, again, it's an unfair one to ask today -- why do wholesalers sell to hospitals and pharmacies at negative distribution rates? Why is cost minus 6 a typical price scheme for a pharmacy? You won't answer that one today, I don't think but -- no, if you look at, for example, a purchasing -- like the cost-based markup coming from a wholesaler to a pharmacy to see a -- well, they'll use a cost reference. Yeah, but it'll

be something like cost minus 5, cost minus 6 on that pricing. And I'm just interested in how those negative markups come into play?

DR. CROSSON: Well, somebody's making up that money somewhere.

DR. DeBUSK: Well, maybe they're just chipping in to help out with rising drug prices.

[Laughter.]

DR. CROSSON: There's always that.

Oh, I'm sorry. Do you actually know the truth?

MS. SUZUKI: So our understanding is that -- I think you're talking about WAC minus X percent, and WAC is a list price. And so they're selling to pharmacies at a certain price that's a percent off of the WAC.

DR. DeBUSK: So, for example, if I'm a hospital and I'm purchasing, say, a drug through a Vizient contract -- a GPO contract, but I'm also in a GPO contract with that distributor -- so there's a GPO established price for the drug and there's a contract -- GPO established contract. I have seen contracts that are at minus 6, minus 7, minus 8 percent. But that's reference to the Vizient acquisition price. That isn't to some published WAC. And, typically,

the GPO negotiates a price that's below WAC from what I understand.

So if that price is set and then the markup is negative, where does the difference come from?

MS. SUZUKI: So wholesale acquisition cost, it's just a list price, and we don't know exactly what the actual acquisition cost is usually. I think there are arrangements between wholesale manufacturers, prompt-pay discount or, you know, other types of discount that are probably not showing up on the price that's shown to you. But there is usually a difference between what they pay and what they receive, and that's the margin.

DR. DeBUSK: Okay. This may come up again, but that's good. Thank you.

DR. CROSSON: All right. Pat.

MS. WANG: I think Brian's last question just underscored the complexity that everybody has been talking about because we've been talking about the complexity of PBMs. We haven't even talked about the complexity of GPOs, which is another way that people purchase drugs.

I am with Warner's comment about, you know, it's important to ask these questions, consider them carefully,

but not lose sight of the fact that we're already like into the process of trying to figure out -- nothing that -- you know, I mean, and I'm not saying I'm opposed to making recommendations around PBMs. That is not going to change the cost of a specialty drug from $100,000 a year to $10,000 a year. They cost too much at the start, brand and generic. I just really want to say that. That is the problem.

So, you know, once you get into the PBMs, yes, hugely complex. I'm a plan sponsor. I don't understand how all of this flows. But I will tell you in response to your three specific questions here, as far as exclusive networks are concerned from my perspective -- and maybe I'm really shortsighted -- right now I see that as a solution because I'm relying on my PBM to be able to drive, you know, higher rebates, lower costs to the plan because at least right now they have the ability to do that with the way that they are structuring their specialty networks.

Transparency requirement, I think that we get the DIR information. I can understand why consultants might want a more granular level and, candidly, if that helps them do market checks for me, you know, I'm all for that.

But as far as me as a plan sponsor is concerned, I think we get quite a lot of information right now from our PBM. The notion of allowing plans to manage Part B drugs, specialty drugs under the medical benefit and somehow kind of combine that is really interesting. I think that that's really -- I've got to assume that there's complexity there because these are sort of clinician-initiated sort of decisions and so forth. But you could see some benefits of sort of unified formulary management and so on. So I think that's very worthy of additional exploration.

I'll just leave it at that. Thanks.

DR. CROSSON: Okay. So hands for further comments. Paul and Kathy, I think.

DR. GINSBURG: Yeah, I just want to speak in favor of looking into this Part B, Part D issue. My takeaway from the work we did in the last cycle on Part B drugs was that we were trying to create something like Part D that could work in Part B. It's not easy to do that. And to the degree to which we could have some influence in moving drugs from B to D, that could really be an accomplishment.

I don't know who decides whether a drug is a Part

B or a Part D drug. I think that's where the source of the issues comes. I even know from personal experience getting flu shots that, you know, some commercial plans sort the drugs differently into their medical and pharmacy benefits. I don't know what's behind that. So I regret not having asked some of these things in the first round, and, you know, maybe you know or maybe you don't. But I think that's a potentially very fruitful area, even if it's just in Medicare Advantage with Part D, MA-PD, but perhaps more broadly.

DR. CROSSON: Kathy, last word.

MS. BUTO: Yeah. So I go back to kind of the way I look at this is, you know, our major concern is about the cost and, frankly, the growth in the use of specialty drugs. I think you all have made a major contribution to looking at structural changes in Part D that could begin to address some of the distortions in the way the benefit's being administered right now.

I like the idea of, you know, the medical and pharmacy benefit being managed as one rather than -- and I'd like to see it more broadly done through ACOs and otherwise.

I guess the question I came away -- the two questions I came away from this paper with were: First, how big a difference given the complexity do PBMs make and do specialty pharmacies make in the value, in the reduction in that overall cost? And I think I kind of agree with Pat's instinct. Probably not a huge amount. It's probably the manufacturer cost. It's probably the utilization. I don't know what it is, but I'm not sure it's a huge deal.

I gather from the paper that we're trying to get at the extent to which DIR is gameable or could be shifted to other cost centers so that it sort of disappears. And since DIR determines what Medicare is going to pay, it's n important question that we need to get an answer to. But I feel most comfortable with this whole set of issue if we frame it in the way that you all have approached the issue as part of a much bigger structural set of changes that need to be looked at, because we dive into the details and then pretty soon we're down the rabbit hole, and it's real easy to get lost in terminology and stuff like that. But we probably need to look at other ways beyond what you've already started, especially the medical-pharmacy benefit nexus that we could begin to look at this, because I don't

think we're going to see any diminishment of specialty drug utilization. So, you know, yes, it's important to make sure there isn't gameability, but really what should we be looking at next beyond the structural changes that you've already begun to outline for us?

DR. CROSSON: Okay. Dana has a last phrase.

DR. SAFRAN: Just to reflect that it makes me really nervous, this idea of potentially combining the medical and pharmacy benefit, because the distinction between them has been how they get administered, and I fear that we could get on to a slippery slope of suddenly a lot of pharmacy products that have to be -- can only be administered by a provider and, therefore, becomes cost escalating if we combine these when, you know, part of -- when that has been predominantly medicines are things patients can take for themselves. So I just want to flag that worry that I have about combining them.

DR. CROSSON: Okay. Good discussion.

MS. BRICKER: On that point, you should be able to find information on how specialty pharmacies hiring nurses for administration compared to -- exact same drug compared to administered through physician office. So to

get at that point, you should be able to find that.

DR. CROSSON: Okay. This has been a very excellent discussion on a really difficult topic. We will come back to it, and it will be much simpler.

[Laughter.]

DR. CROSSON: How's that?

Okay. Last presentation of the day.

So we have an issue, and you've read the paper, and it has to do with this issue of I think a common interest here, which is to have Medicare beneficiaries who are being discharged from a hospital find their way into the best possible post-acute care setting. And there are some regulatory obstacles to that at the moment and I think that's perhaps something we can do about. So, Evan, you are going to take us through that.

MR. CHRISTMAN: Thank you. Good afternoon. Next we're going to examine the use of high-quality PAC providers by Medicare beneficiaries.

This slide is a brief overview of the presentation. First we will review the cost and quality of care associated with PAC and the Medicare program. Then we will examine some of the challenges patients face in

selecting PAC providers and how Medicare tries to address these issues in the hospital discharge planning process. Next we will look at how the quality of PAC provider beneficiaries selected compared to other nearby options that could have been available. And finally, we will look at options for change that could help beneficiaries select high-quality providers more easily.

This slide is a reminder of what post-acute care looks like and it's likely familiar to many of you. Post-acute care is delivered through four sites: skilled nursing facilities, home health agencies, and patient rehabilitation facilities, and long-term acute care hospitals. About 40 percent of hospital discharges use one or more of these services and the total spending in 2015 was almost $60 billion. SNF and home health accounted for about 60 percent of this spending.

The supply of providers for SNF and home health is relatively high, with most beneficiaries living in an area with multiple providers participating in Medicare. IRF and LTCH supply is lower and generally concentrated in more urban areas. Though there is variation in supply across the country, there are often numerous PAC providers

available in many markets. This is particularly true for the SNF and home health services, the two most common PAC sites. For these two silos, the supply can be substantial. For example, in 2015, we found that 98 percent of beneficiaries had two or more home health agencies operating in their ZIP code and 86 percent had five or more.

PAC providers also vary widely in the quality they provide. For example, the rate of rehospitalization doubles between SNFs in the bottom quartile of performance and SNFs at the top. We have observed this variation on many quality measure in each of the different PAC silos.

This variation in performance and the large supply of providers suggests the PAC provider a beneficiary selects can have important consequences for their health and their program. Hospitals are already accountable for the outcomes of PAC, through programs such as the Hospital Readmission Reduction Program and Value-Based Purchasing. Also, some of the reform demonstrations such as ACOs and the inpatient bundling programs include incentives of penalties tied to readmission from PAC. Ensuring Medicare's policies help patients identify better PAC

providers has the potential to improve care and lower program expenditures.

Many factors suggest that beneficiaries being discharged from the hospital will need assistance in selecting a PAC provider. For example, acute stays can be disorienting and patients may be focused on the inpatient course of treatment and not thinking about the need for post-hospital care. Beneficiaries and their caregivers are often not familiar with PAC services and may not understand what to look for in their options. Discharge can arrive with limited notice, and one study found that 30 percent of inpatients had less than a day's notice about their discharge. Finally, beneficiaries may need assistance understanding how the availability and capability of facilities may affect their options, given their unique needs.

To assist beneficiaries in this period, Medicare has released provider-level quality data for SNFs and home health agencies. This data is available through Medicare.gov and it's designed to allow consumers to compare the quality of providers in their local area. However, the data has its limitations. The measures

include broad categories of patients and do not report results for specific conditions. For example, the SNF data report quality for short-stay patients on nine measures, but these measures include all clinical conditions and do not indicate how patients with specific diagnoses fared.

Studied have examined whether the SNF and home health data have shifted beneficiaries to higher-quality providers, and generally concluded they had little effect on referral patterns. For example, one study found that the highest performing SNFs might have had a volume increase of less than 1 percent after the release of the measures.

These findings are consistent with those of other studies that examined the efficacy of providing quality information to consumers and private markets for other health care settings. Generally, studies have found that these efforts have not shifted referral patterns to higher-performing plans or providers.

Medicare statute and regulation assign responsibility for discharge planning to hospitals. Hospital discharge planners are expected to assess the need for PAC, educate beneficiaries about their options, and

facilitate transfer to PAC when necessary. The BBA requires hospitals to provide beneficiaries with a list of nearby SNFs and home health agencies but the list is not required to have quality information. Medicare statute provides beneficiaries with the freedom to choose their PAC provider, and the law states that hospitals may not recommend providers.

The IMPACT Act created a new requirement that hospitals use quality data during the discharge planning process and provide it to beneficiaries, but this new requirement has not been implemented.

In practice, beneficiaries report relying on information from trusted sources like health care providers, family, or others that may have experience with PAC. These trusted intermediaries are often considered by beneficiaries to be more important sources of information than Medicare's publicly reported quality data.

Discharge planners may be equipped to address some beneficiary concerns but two factors can limit the assistance they provide. First, as I mentioned, they are prohibited from recommending PAC providers, and in practice, this means that they may shy away from even

identifying better providers when prompted by patients. Second, some research indicates that planners are not always aware of the variations in PAC quality in their community.

Challenges in the hospital discharge planning process are particularly troublesome for hospitals and health systems trying to lower readmissions from PAC. Most of Medicare's delivery system reform programs, such as ACOs or the BPCI hospital bundling program leave the existing discharge planning rules in place. Hospitals in these programs report using voluntary efforts to identify and encourage the use of higher-performing PAC providers.

Many hospitals have formed PAC networks, or collaboratives, where they solicit PAC providers to work with in quality improvement efforts. Hospitals then use patient education, or the offer of supplemental services like transitional care nurses, to encourage beneficiaries to use these favored providers. No assessment of the effectiveness of these efforts in shifting volume to better PAC providers has been completed.

The CJR program, the Comprehensive Care for Joint Replacement program, is the exception, and in this program

CMS has waived the standard rules and provided hospitals with explicit authority to recommend PAC providers that the hospital is working with in the program. However, the impact of this waiver is limited, as the CJR itself applies only to hip and knee replacement patients in specific areas. And again, though hospitals can recommend providers, beneficiaries retain their freedom of choice and are not obligated to use a preferred PAC provider.

Reviewing the quality of PAC providers used by beneficiaries is a way of assessing, in part, how often current practices result in beneficiaries using higher-performing providers. To assess this, we did an analysis and compared the quality of the provider a beneficiary actually used to the quality of providers that were nearby. We conducted this analysis for SNF and home health patients in 2014. For each patient, we determined how many providers with better performance on a composite measure were operating within 15 miles of the beneficiary's residence. While this analysis will indicate how many higher-quality options were nearby, it does not capture other important dimensions of PAC access, such as whether providers had available capacity or could meet any

specialized clinical needs a patient may have.

This table shows that most patients had better options nearby. For example, for SNF patients, about 85 percent of them had at least one better option, over 60 percent had three or more better options, and almost 47 percent had five or more. For home health patients the results were higher, with over 94 percent of home health patients having at least one higher-quality option nearby and almost 70 percent had five or more.

Beneficiaries in urban areas generally had a greater number of better options nearby compared to rural beneficiaries. The quality difference between the selected provider and the other options was tangible. For example, for beneficiaries in areas with one better SNF, the better SNF's rehospitalization rate averaged 3 percentage points lower than the SNF the beneficiary received service from.

All of these findings suggest that additional policies that encourage the use of higher-quality PAC would be beneficial. Medicare does not require the use of quality measures in discharge planning, and the efforts required by the IMPACT Act appear to have no certain implementation date. Beneficiaries often have better

providers nearby, suggesting an opportunity to improve the care they receive, and fewer readmissions from PAC would improve the health of beneficiaries and lower program spending.

With these points in mind, Medicare could consider several policies. One set of changes could focus on providing additional flexibility for hospitals and more information for beneficiaries under the discharge planning rules. One major change would be to allow hospitals to recommend PAC providers, similar to what is now in place in the CJR program. Commissioners have suggested this change as a possible direction for Medicare in the past, and this would align discharge planning with the accountability for post-hospital care that hospitals have under programs like the Hospital Readmissions Reduction Program or ACOs.

Other changes could strengthen existing requirements by recommending two IMPACT Act requirements, that hospitals use quality measures as a factor in discharge planning and that hospitals be required to provide this quality data to beneficiaries. These changes could be beneficial because they would provide tools to consumers to be better engaged when making a PAC selection.

Other options could expand the financial incentives for hospitals and PAC providers. The HRRP penalizes hospitals with high rates of readmissions for six conditions. Expanding the number of clinical conditions subject to the HRRP penalty, as we proposed in our 2013 report to Congress, would further encourage hospitals to scrutinize the quality of the PAC providers they refer patients to.

Another strategy could aim to increase the quality of PAC available by expanding Value-Based Purchasing programs. Currently, Medicare has a Value-Based Purchasing program for skilled nursing facilities and an experimental VBP program in nine states for HHAs. Medicare could expand the home health program nationwide and implement VBP programs for URFs and LTCHs.

We have reviewed some of the challenges beneficiaries and hospitals face in discharge planning. Options could focus on near-term changes that modify existing requirements and they could also include changes to the financial incentives for hospitals and providers. These options represent different choices about the speed and scope that is possible, and we are interested in

hearing your thoughts.

This concludes my presentation. We look forward to your discussion. Please let me know if you have any questions.

DR. CHRISTIANSON: So, as usual, clarification questions first and then we'll turn to David to lead the general discussion. Clarification?

DR. DeBUSK: If we could go back to Chart 12, I mean, first of all, congratulations on a nice chapter. I thought that it was really well done. But if we could go back to Chart 12, you know, it's obvious that you did a lot of interviews and talked to discharge planners during your -- during the development of this work. Under this "other factors" on that last bullet point, did you capture a way these informal networks that seem to spring up, where, you know, for example, you know, a discharge planner is under a lot of pressure to get a number of patients safely out of the hospital. What happens when these networks spring up where, for example, if I know I have a PAC provider who maybe will help me with an uninsured patient, or, you know, typically there's a personal relationship there that drives some of those activities. Did you see any of that, or

experience any of that in your interviews, and if that's there, is there a way to measure, or somehow manage that, because I don't know that that's necessarily a bad thing.

MR. CHRISTMAN: Well, I guess I would say a few things, and one is that when we speak with hospital discharge planners and post-acute care providers, you know, they will talk about the informal communication that occurs back and forth between them, and certainly the discharge planners observe what patients go where.

I think the most important thing that discharge planners can often bring to a conversation like that is they will understand finer-grain information about a facility's capabilities that generally won't be available, and those are things such as sometimes patients are looking for specific cultural competencies, they're looking for the facility that has, you know, a strong Spanish-speaking staff, for example, or they're looking for -- and then some of the more common ones might be, you know, they're looking for a facility that will take a ventilator patient or a patient that needs a certain demanding drug regimen. And that type of information, if you go to the nursing home compare or things like that, it's not going to be there.

You know, it's sort of the on-the-ground information that only the people who are referring patients are really going to know.

DR. CHRISTIANSON: Anything else? Yeah, Alice.

DR. COOMBS: So sticking to the Round 1 question, staying super focused, I have two questions to ask. First of all, Evan, when you went to do the surveys, or did you do site visits at all?

MR. CHRISTMAN: We did a lot of interviews.

DR. COOMBS: Okay. Okay. So one key thing is, did -- was there a PAC provider at the acute care hospital who was available to patients and patients' families?

MR. CHRISTMAN: That's not an issue I really understand very well --

DR. COOMBS: Okay. I'll come back to it in Round 2.

MR. CHRISTMAN: Okay. All right.

DR. COOMBS: The second one, did you consider standby capacity even within the PACs? For instance, some PACs, like some LTCHs, will actually give pressers so that they don't have to bounce back to the hospital for readmission for hypotension if they're treating them

transiently, for whatever reason. They will actually treat their hemodynamic instability for a short period to see if they get better with it, especially because a lot of these patients have urine sepsis. So standby capacity means that how much of the bells and whistles that you don't see with some of the quality parameters that they can actually handle, which makes them go out on a limb and say "we can take that patient despite what their rankings might be on hospital compare."

MR. CHRISTMAN: I mean, I guess I would just go back to maybe the answer I gave Brian, which is, yeah, it's definitely -- I think I agree with you in the sense that, you know, when we look at what people have said about the information provided to consumers, much of it measures things that should be important but it doesn't capture a lot of other dimensions that are going to matter.

DR. CHRISTIANSON: Other questions?

DR. GRABOWSKI: Yeah, I wanted to look at your table on Slide 13, which is fascinating. I guess I'm struggling, though, with how to interpret it. One story is that, well, people are behavior suboptimally. They are not choosing the highest-quality provider, yet Brian already

gave you some stories for why there may be an informal network. You said earlier in the presentation that beneficiaries value distance from home or family. They may have, you know, reputation effects and other informal measures of quality that are present.

So I don't know if you have any thoughts based on your interviews of how to think about this. I think it's really fascinating. It's something we should keep in mind. But I don't know that it's necessarily evidence that this market is failing or not working.

MR. CHRISTMAN: I mean, I don't -- I think one of the, you know, major caveats of this, of course, is the capacity issue. You know, there could be a bunch of beneficiaries -- 10,000 beneficiaries living in one ZIP code with two truly great SNFs, and so those 10,000 beneficiaries are going to show up here and they're going to show up 10,000 -- and the same SNF is going to show up 10,000 times, kind of that way. And so, to a certain extent, it does -- there is that.

But I guess the thing that I balance that with is I guess I was just struck by, in sort of the three different types of information we looked at, the scholarly

literature, a lot of it that has gone out in interviews, discharge planning specialists. In the interviews we did with the health systems we dealt with, you know, the difficulty -- the different difficulties I described in getting quality information to consumers in a way that they understand, I don't think anybody is really comfortable that they're taking action on it.

And so I appreciate that in some ways this might overstate things and in some ways it may understate things, but it certainly seems consistent with the picture we've heard from the other sources, that consumers seem to struggle to factor it into their decisions.

MR. PYENSON: Evan, thank you for a terrific report. My question is about Medicare Advantage. I've seen spending by Medicare Advantage plans in a PAC dramatically lower than in fee for service. And the question is, for this topic, is there a way to see if Medicare Advantage plans tend to favor higher-quality PAC sites?

MR. CHRISTMAN: We can definitely look at that. I think what I would just caution is that, as you're well aware, Medicare Advantage plans will manage the SNF benefit

very differently, and I think that, you know, from talking to some of those companies that have been involved in that work, it seems that squeezing SNF days out is where a lot of people are focused. But this issue of whether they are doing a better job of getting people to higher-quality SNFs is something we could look at.

DR. MILLER: Yeah, and I guess the only caveat there, although I don't think it changes your question, is whether you're getting a full reporting, in the MA plan, of what their PAC, because you've seen lower utilization but there's some questions of whether all the encounter data is coming through. But to the extent it's there, what does the quality of the provider look like? I think that question could be asked.

DR. CHRISTIANSON: Pat.

MS. WANG: You had noted, as one of the thoughts, sort of allowing discharge planners to have more ability to actually give advice to discharge patients. In your interviews, did you find that they would -- that they had strong opinions about quality providers, that if unshackled they could actually, you know, share?

MR. CHRISTMAN: I would simply -- I would channel

them and say yes. I mean, I think there were -- you know, there were planners who -- I think when we spoke with people in the hospital industry, in general, they said, one, you will find a different range of practices across hospitals as to how much advice they will provide, because some people feel that the line about where educating the beneficiary and recommending is fuzzy. That's a separate issue. And so they don't want to get -- accidentally cross over that line. But you asked, specifically, you know, do they think they know who they would recommend, and I think many of them said, you know, they express reservations. I think some of the most profound cases where were they said, "We knew clearly who we wished people weren't going to," and they felt like they couldn't say anything.

DR. SAFRAN: Just picking up on Bruce's idea, I wonder if we could expand it to look to see if there are quality differences in the PACs being used for beneficiaries whose provider is part of an ACO program versus not, because I know on the commercial side, I've definitely experienced PACs talking to us, saying, "How do we better market ourselves to hospitals so they know that

we're going to be a really good partner for them, now that they're accountable for readmissions, total cost of care, global budget, et cetera"?

So I think it would be really interesting to follow that up.

MR. CHRISTMAN: Yeah. There was one piece, the most recent McWilliams article on ACOs did a dive at this. I don't think they took a deep look at it, but one of their findings was that the use of higher -- they saw spending go down for SNF but they did not see the use of higher-quality SNFs increase.

DR. GRABOWSKI: I was actually a co-author on that. What we attributed it to was a SNFist [phonetic] and other sort of activities kind of going into these buildings from the ACS and hospital systems, not the kind of shifting patients to higher-quality SNFs. But that is one of the hypotheses out there, that it would be easier to move people across buildings than to go out and invest in care in those buildings.

DR. CHRISTIANSON: Despite that, we are going to call it the McWilliams article.

[Laughter.]

DR. CHRISTIANSON: And I want to make sure that Evans gets the metaphor, the unshackled discharge planner in the revision of the Chapter 3. I really liked that. Sue.

DR. MILLER: Can we count that as answering her question?

DR. CHRISTIANSON: No.

MS. THOMPSON: And this is also on the thread of Bruce's comment about quality and MA. Do you have any idea about the assumption that was behind choosing CJR for recommending PAC providers?

MR. CHRISTMAN: I would say that's a good mystery that all of us have -- we can get together for a drink later and exchange theories. I mean, I don't -

[Laughter.]

MR. CHRISTMAN: You know, this may be -- the only noticeable difference, obviously, is that the CJR program was mandatory, and most of the other programs are voluntary, and I don't know that that contributed to their decision, but I haven't been able to find anyone who could really answer that.

DR. GINSBURG: I don't know the answer -

MS. THOMPSON: My experience observing a bundled CJR, run by an orthopedic group, they tried to eliminate using post-acute care. So I would just think the size of the n would get pretty small, in terms of whether or not they're recommending high-quality SNFs. I mean, it's a byproduct of the fact they're in a bundle.

DR. CHRISTIANSON: Paul.

DR. GINSBURG: I was just going to say, I don't know the answer of that CJR, but it just seems logically so obvious that if you're going to put the bundled payment groups at risk, and post-acute care is a very important part of the bundle, how can you not give them more authority to steer patients? It seems as though it's part of the contract, if this group is going to deliver lower-cost and better-quality care.

DR. CHRISTIANSON: We may be in the process of moving onto the next set of questions, but, Craig, a clarification question?

DR. SAMITT: Yeah, I think it is clarification. So this discussion has prompted, for me, a question about which lever is going to have the greater influence on referrals to high-quality PACs. Is it providers who are

encouraging and have the authority to recommend, or it is patient preference? And so I think what I'd hate to do is pull the lever that says, all right, providers can now recommend, but patients ultimately trump what the providers would say and want to go to the nursing home closest to home, regardless of what the provider has to say.

Has your research gotten a sense, and maybe CJR can actually set an example. Have we seen a change where providers playing a role have truly instigated a shift in the types of PACs that are being used?

MR. CHRISTMAN: I would say that nobody has really published any results that have looked specifically at efforts to shift people to better PAC. I think we have heard things under the table that this has been a very tough process, because, you know, most people are doing it in the voluntary models where they are under the existing rules, so they feel limited in what they can do to encourage beneficiaries to do it, and so they're working from there.

I mean, the difficulty is that, at least in the set of options we have offered here, we have come back with the idea that if we -- you know, that the hospitals are in

charge of discharge planning. If we place them at some financial risk for the post-hospital care and we give them some new tools, that will help move the system towards, you know, higher-quality PAC providers.

Now you raised the specific issue that the beneficiary is the ultimate decider, and we're certainly not proposing to change that. But I think, you know, if you wanted the beneficiary to share in this decision, you know, one possible approach is, you know, their financial exposure. Right now the post-acute care cost-sharing really isn't arranged in a way that -- it hasn't changed much since 1967. Let me put it that way. And so, but if you wanted to put some pressure on them to follow this issue, that's one direction you could go.

DR. CROSSON: Warner.

MR. THOMAS: You know, maybe I have a little bit of a different view on this, but I think going to a little bit of Sue's point, I mean, to me, a lot of this falls on the discharging provider, not the beneficiary. And, you know, I know just from our own perspective, we took a look at this several years ago and realized that we were discharging people to a lot of different facilities, and we

got much more strategic about looking at the quality measures, and ultimately it's the beneficiary's decision where they want to go. But we were very transparent about what the quality measures were and how the facilities lined up, and I wouldn't say that we're not steering people but we showed them the information, and we're very clear about it.

And I just get back to -- I just think the discharging facilities needs to have a significant role here to help guide the patient to a place that's going to be a higher-quality organization. I just think it's our role and responsibility to help that patient. And, frankly, we're more capable of mapping that data out, we're more capable of knowing what it is, and I think to say, to leave that up to a beneficiary is a very difficult thing to do, frankly.

DR. MILLER: Can I just ask one thing on that? Did you see the pattern shift?

MR. THOMAS: [Speaking off microphone.]

[Laughter.]

DR. MILLER: Thanks, Warren. I appreciate it. Did you see the pattern shift?

MR. THOMAS: Yeah. I mean --

DR. MILLER: Because I think that answers, I mean, some of the -

MR. THOMAS: Yes. I mean, I think we found --

DR. MILLER: -- down the line.

MR. THOMAS: -- I mean we found people would follow the lead, and once again, we weren't steering people to a certain facility but we were being very clear about, you know, hey, these are facilities. And we went through kind of a process to really evaluate facilities, look at their quality, and say, "Look, these are the facilities we like to refer to because they're quality." Now you can go to anybody you want. It's ultimately someone's choice. But we would lay out, these are the ones that we feel like we have a better relationship with, they have good quality measures, we communicate more. And, yeah, we did see a change, and I think people appreciated the fact that we were being transparent about it.

DR. MILLER: I just wanted to connect it to the question that preceded it. The question was, if you go through all this, will anyone change? Will anyone change their pattern?

MR. THOMAS: And I think people –

DR. MILLER: And I wanted to make sure you two –

MR. THOMAS: Yeah. People did -- I mean, people did listen to the discharge planners.

Now, getting discharge planners in the organization to buy into some of this was obviously -- or not obviously -- was a challenge, but as we looked at it we really felt like we had an obligation to our patients to be mindful about where they're going post discharge.

DR. CROSSON: Okay. It sounded a little bit like Round 1.8.

[Laughter.]

MR. THOMAS: It's late in the day, you know.

DR. CROSSON: I didn't say 1.9.

MR. THOMAS: That's all right. Kind of staying kind of between the lines.

DR. CROSSON: Right. So I think we're going to move on to Round 2 and we're going to -- no, it's not -- David, you're on.

DR. GRABOWSKI: Great. First, Evan, great job with the chapter and the presentation today.

This is an incredibly important issue and I'm

really excited that the Commission is taking it up and considering it. And I'm very much thinking about this tension between sort of who owns the discharges -- is it the discharge provider or the beneficiary? -- and I think the answer is both, and I think there's a strong role for both. So I was going to go through your options and kind of give some thoughts on all of them, starting with –

DR. CROSSON: Slide 17.

DR. GRABOWSKI: -- Slide 15, and I also wanted to add --

DR. CROSSON: Oh, okay.

DR. GRABOWSKI: -- an option as well.

DR. CROSSON: Sorry, yeah, but that is the topic on the floor.

DR. GRABOWSKI: Yeah. So in terms of modifying the discharge planning rules, I'm very much in favor of this. I think, historically, many resisted this because there was this belief that the discharge planner was not working in the best interest of the patient. I think with the emergence of alternative payment models and the readmission penalty, I think there's much greater alignment today. And so I think there's a lot less concern there and

I think there's a real demand. I was just saying to Sue, offline, that there's a real demand among beneficiaries to get more guidance. We hear that time and time again, that we would like more help here in choosing a provider. So I'm very much in favor of allowing the discharge planners to make a recommendation.

In terms of bullet points 2 and 3 here, I sort of would -- if I had my druthers, I would love to push them together and actually force hospitals and beneficiaries to work through sort of portal, making everybody go through Home Health Compare or Nursing Home Compare and actually make their choices much like somebody does in terms of choosing, you know, on the exchange, for the ACA.

I think we can make much better use here. Right now a lot of discharge planners are ignoring the information. A lot of beneficiaries are. Why can't we force them to sort of step through the tools that are out there?

If I was going to add a bullet point here it would really be around those tools, and I think we have a long way to go in terms of improving Hospital Compare, Nursing Home Compare, and Home Health Compare. A couple of

comments, and I think as they currently stand they're complicated, they're incomplete, and they're potentially misleading, and I think two comments I'll make. I could make a lot of comments but I'll only focus on two.

Nursing Home Compare, it's based on a five-star system. I'm certain you've talked about it in prior years. It bundles or combines long-stay quality with short-stay quality. And so it's not necessarily the case that a provider that's good at post-acute care is also good at long-stay chronic care. And so separating out those dimensions, where I go on that website -- are you looking for a short-stay, post-acute stay or are you looking for a long-stay care? -- and I'm able to choose, and then having separate five-star systems. I think that would go a long way towards helping beneficiaries choose the appropriate provider.

The other comment, and, Evan, you touched on this, there's a lot of missing elements on Nursing Home Compare and Home Health Compare. I often tell audiences, I think I could quickly, online, learn more about the hotels in this sort of 10-block radius than I could about the nursing homes. I could see pictures. I could learn the

amenities. I could get a lot of information. We get none of that on Nursing Home Compare. And so I would like to know, you know, in addition to whether or not I could have a private room, I would like to know the volume of SNF care that's delivered in the facility. I'd love to know some satisfaction data from beneficiaries. And even just -- we've talked a lot today about clinical services onsite. Is there a physician there, a nurse practitioner, more information about the clinical models.

In terms of shifting to Slide 16, I'm supportive of both of these recommendations. I'll caution that I don't think we want to just use readmissions in choosing a potential post-acute care provider. That's one measure but we've had a lot of discussions today about value, and if I was a hospital system only thinking about readmissions, I would be pushing to a higher-intensity setting, not a lower-intensity setting, if all I'm worried about is somebody coming back. Obviously, if I'm an ACO or a bundled payment, I have a different set of incentives.

Finally, I was one of the evaluators for CMS of the Nursing Home Value-Based demo. I think there's a lot of potential with Value-Based Purchasing, but that

potential is yet to be realized. So I think we should continue to innovate in that space, but I don't know that that alone is going to be the answer, because I think we have a long way to go in terms of really building the right models that are going to improve quality.

So, thanks.

DR. CROSSON: Thank you very much, David. Very complete and concise and very helpful. So 15 and 16, I want to hear support for, and David added another bullet point about improving the tools. We could add that on page 15. So let's hear support for the various ideas, and we'll start with Paul.

DR. GINSBURG: I just want to support all of David's comments and add something to one. You know, with the tools being limited, what Warner mentioned, relationships, experience of previous patients are very valuable information that the discharge planner might have, and you want them to be able to use that.

My approach to this is that, think in terms of integration, that we know that post-acute spending various enormously, geographically in Medicare, and that there's ACOs, bundled payment have a lot of potential to better

integrate post-acute care. But if we have a system where we're actually, with those approaches, in addition to readmission penalties, we're telling the hospital, "We want to you to integrate with the post-acute care facilities," but then we're also saying, "Oh, but you can't steer the patient at all," and I think we just have to face up to the fact that if we're going to put hospitals at risk and give them responsibilities for integrated care we have to give them, or allow them to pursue the tools to succeed.

So, anyway, I support doing more of this. I do have this caution that, as David said, I was thinking as I was reading this, a couple of days ago, that, you know, we're using the term "quality" so glibly, as if we have a perfect tool to measure it. But I don't think we're ever going to get that strong a tool so that we have to increase the -- you know, depend not only on ratings but on other information that can come more informally.

DR. CROSSON: Okay. Thank you. Bruce.

MR. PYENSON: For the reasons that Paul mentioned, it seems as though the approximately one hour that a discharge planner works with a patient might be the most valuable hour in the health care system, from the

standpoint of reducing cost and improving quality. So it's a puzzle why that hasn't been capitalized on more, especially within ACOs.

And to get insight into that, I would suggest we can construct and exhibit, like the table we had in the March report on why there were incentives for high-cost, high-rebate drugs to be put on the formulary. And what I'd suggest is look at two scenarios, one where a hospital sends people to high-quality, post-acute care, doesn't get very many rebates -- readmissions --

[Laughter.]

MR. PYENSON: -- doesn't get many readmissions, but also doesn't get the referrals from the nursing home, from perhaps long-stay patients or others. And the other scenario where maybe they don't send their patients to high-quality, post-acute, they get more readmissions but they also get more of the admissions from the nursing home patients. And I think we could actually look at where the incentives are and perhaps understand why it is this one hour of relatively inexpensive time, which could be incredibly valuable, isn't being optimized.

Another issue which I think we had talked about

in the past to some extent is the captive IRF or the captive SNF, and to look at the extent that hospitals are, perhaps without directing the patient, have a very high rate of discharges to their own IRF, and whether that's the flip side of the phenomenon we're talking about.

So a couple of things there, but I think this is a really terrific piece, so thank you.

DR. CROSSON: Okay. Dana.

DR. SAFRAN: Yeah, I'll be really quick. So basically I just agree, first of all, that it was a great piece, but David's recommendations I thought were spot on. I've sat here for the last 40 minutes, or however long we've been discussing this, puzzling over why -- what the history is, and we can talk about it another time, maybe over drinks -- that allows physicians to recommend specialists but not hospitals to recommend post-acute care. You know, it just seems like, for one thing, we know that patients need guidance from those who have been caring for them. It just makes no sense. So we should move that ahead.

And I love David's image of, you know, tools that are enhanced, and maybe even having something on them that

show like the distance or, even better yet, time to travel from whatever residence you care most about, whether it's your daughter-in-law or whatever, along with other measures that somebody can help the patient step through.

And the last thing I'll say is I think there's nothing like that to not only help drive improvement in those measures, once they're being really used and publicly reported, but also to have that part of the industry help us invent better measures. So I think that would be an added thing to think about here.

DR. CROSSON: Jack.

DR. HOADLEY: So I'll also be brief. First of all, I think it was a really nicely written paper. Second, I also would like to sort of just ditto David's comments, including in particular the addenda you included on things like the web portal and so forth. I think those are really helpful ideas.

The only other point I would make is sort of concern about some of these financial entanglement kinds of issues, and I think as you said, they seem less of a worry here than in an lot of instances. But where there is kind of a direct ownership kind of thing, that's just part of

what you put in that portal. So you just say, okay, this is owned by -- and, you know, but we should definitely raise that issue and sort of continue to flag that. But I think it can be dealt with, and I think this is good.

DR. CROSSON: Kathy.

MS. BUTO: This just occurred to me, and it may not be for this paper, Evan, but having just gone through with a family member some post-acute care, the thing that I was struck by is how there is a lack of a feedback loop back to the hospital. So part of the process, I think, for discharge planners learning about which post-acute care providers they might want to consider recommending, it just strikes me that, you know, that would be an improvement. We ended up being the feedback loop to the hospital and so on, but it seemed like a simple thing in this day of electronic connectivity something that should be easily done.

DR. CROSSON: Sue.

MS. THOMPSON: Thank you for the paper. Great work. I agree with your comments, and I'll keep moving.

DR. CROSSON: David.

DR. NERENZ: This is great. Just to extend one

of David's comments, particularly about improving use of the measures on Nursing Home Compare or Home Health Compare. You know, I started thinking about this, Evan, when I read the thing and the interesting things you've done about who makes choices and are there better quality places. So I did the exercise myself, and I picked zip codes that either I lived in or -- and I said let me do it, I'm going to pick a nursing home. So I went to Nursing Home Compare, and I went through. It was really hard. Why is it hard? Well, there aren't just two measures? There are ten or so measures in the quality, even if you subdivide by the short stay/long stay. You can do that. At least I just did 15 minutes ago. But what you find then -- and, you know, I've done a formal study of this in the hospital area. The measures are uncorrelated. If I pick the nursing home that has the lowest readmission rate, I'm going to pick a nursing home that's bad on three other things. And I did that. I said, okay, I'm liking this one. Well, okay, if I'd chosen that one, I would not pick the home that had the lowest pressure ulcer rate, nor would I pick the one that had the best pain control rate. So how you use it depends on your values for which of these things

matter.

Now, you know, in your example, let's just take a hypothetical, that patients in the study you did were perfect, perfect informed choosers, but they valued pain control and pressure ulcers. The results you showed would follow, because the two measures you used are different measures.

So somehow -- and I think I'm supporting and extending your point. When people work through these measures, they have to apply their values in a weighting system to say I care about these three things and I'm going to pick largely on that, but maybe I'll apply lower weight. That can be done. I mean, there are tools for doing that. But we just need to keep that in mind.

And then I'd just caution us on the syntax. When you throw up a slide that's says higher performing, better quality, be careful. Please be careful. It depends how you weight things. It depends how you select. You can come up with any ranking you want based on how you choose the individual measures and how you weight them.

DR. GRABOWSKI: Quickly, I think you're exactly right that you could go into all the sub-domains and sort

of do the weighting. I don't think most people are doing that. I think they're looking at the overall five-star score and choosing based on that. That's a composite of the short stay and long stay, and that's what I think we need to separate out.

I do think there are some consumers that will want all the information in all the sub-domains. I think the majority that are using it -- and that's not everyone by any stretch -- are just using the overall global score.

DR. NERENZ: And I understand, but then the point follows. The five-star doesn't always beat the two-star in every single measure. You've got to be careful.

DR. GRABOWSKI: You're exactly right that all the sub-measures are not well correlated with one another.

DR. CROSSON: Alice.

DR. COOMBS: Thank you very much, and, David, thank you so much for summarizing so well.

I had an opportunity to recently -- four weeks ago, I went to an LTCH just to visit on behalf of a hospital to just assess whether or not there was a need to increase the relationship, and I'll tell you, just from my experience in the ICU, patients don't necessarily have the

flexibility nor the nimbleness to look up on the computer Nursing Compare or any of those things. To be honest with you, as an ICU doctor, I have encouraged patients that this facility is a great facility, and I even have a patient who's willing to talk to other patients. I didn't think that there was a problem with that.

The case manager can encourage people based on their experience. Hospitals know, if you get a bounceback in the ER that comes straight back to the ICU, they know. So I think that a lot of the information is well known. Hospitals that come back, you got a patient that's coming back with C. diff and, you know, MRSA, and all of these things. So I think that information is liquid there. I think it really is important for us to steer the patients, and I can't say that enough. It makes a difference whether or not there's the support staff there. And in terms of the feedback loop, as an ICU doctor, I'm calling to find out at this nursing home what's going on with this patient. How is she doing or how is he doing?

So I think it exists. I'm glad we're here, and, Evan, thank you so much. You did a great job.

DR. CROSSON: Craig.

DR. SAMITT: I agree with everything that David said. The only thing that I don't want to discount is the consumer's perspective in all this. I know we've referenced the term "steering," but I remember when we had conversation about, you know, should we narrow choices to the highest quality PAC providers a year or two ago, even. There was significant pushback that consumers want to have a voice in where they go for post-acute care more than we perhaps give credence to. And so I think a lot of this is going to be about striking a balance. If the incentives are so significant that we essentially say of 20 nursing homes, we're going to steer you to two, that's probably too aggressive a steering process than saying we're going to rank-order them and we're going to suggest the ones that we think are best, but ultimately you as the consumer, for all the reasons that you would decide, get to decide.

So I think the reality is we're going to have to come up with a blend of methodologies that really achieve that balance.

DR. CROSSON: Okay. Comments? Sorry. Rita.

DR. REDBERG: Thanks. I'll also congratulate you on this excellent chapter, Evan, and agree with David's

comments. And I appreciate, David, that you went through the quality measures because it was what kind of -- I don't think most patients do, but it does point out even if you were so sophisticated, it's very hard, and that there's a lot of reputational things. And, honestly, I think what matters most to patients besides word of mouth is what their out-of-pocket costs are going to be as well.

In terms of the suggestions, I do not favor expanding the hospital readmissions reduction program just because I -- it's not like the greatest quality measure ever, as you mentioned. It could be good on this and bad on other things that are also important. So I wouldn't favor that.

And the last thing I wanted to add on, on the McWilliams-Grabowski paper, I was the editor for that paper.

[Laughter.]

DR. CROSSON: Okay. Coming up this way, I see Brian.

DR. DeBUSK: First of all, again, I think it's a great chapter. I completely agree with David's comments. Bruce, I still love your comment about the most important

hour in care coordination for discharge planning.

The one comment that I would like to add, I think for elective procedures, we ought to go back and just lift all the work that's been done in BPCI because I continue to be impressed. They have the discharge planning worked out, but these big conveners even have templates that they give the participants. They have these things worked out. Not only do you pick your SNF, you talk about pre-hab, you talk about your expected length of stay in the SNF, you talk about the patient's obligations. I couldn't get a hold of the MOU for today's meeting, but I have everything else. I've seen practices that actually have memorandums of understanding where the patient, the PAC coordinator, and the physician actually sign off.

Now, I'm sure it's not binding, but it really is an expectation setting, and it translates to a form letter that they just hand the discharge planner that says this is -- I expect to go to this SNF, I expect to stay this long, and these are the -- this is what I expect. And I think for elective procedures, I think that's a best practice across the board.

DR. CROSSON: Okay. Good discussion. Evan, nice

formulation, well put together. I think we're very close to consensus, at least on most of the pieces. And so that is the end of this discussion, the end of today almost.

Now we have an opportunity for public comment. If any members of audience guests who would like to come up and make a comment on what we've discussed this afternoon, please do so.

MS. TRUJILLO: Thank you. In the interest of brevity, I will be --

DR. CROSSON: I'm sorry. Just one second. Please identify who you are, any organization affiliation, and you have 2 minutes to comment. And if this light goes back on, the two minutes is over. Thanks very much.

MS. TRUJILLO: Got it. Thank you very much. My name is Sylvia Trujillo, and I'm with the American Medical Association and my comments are specifically concerning the telehealth discussion today. I just wanted to underscore that the AMA did submit some extensive input and comments for your consideration. It includes in-depth interviews that were conducted over the course of this year with health systems that are utilizing different modalities of telehealth. And I do want to emphasize telehealth is not

one service. It's the delivery of existing services using technology to enable it.

We had very similar questions to the ones that you all were raising in your discussions today, so the AMA, at the beginning of this year, assembled a group of overwhelmingly physicians who deliver telehealth services as well as a complement of physicians who do not but are very involved in issues around coding, coverage, valuation, to look at issues around utilization, and very specifically, one of their charges was to generate data for consideration by MedPAC and by the Congressional Budget Office. And so the submissions that you hopefully will all have received either earlier or later on include information about utilization and appropriate services.

And just one last caveat. The Medicare program does define what telehealth services are covered and makes a case-by-case determination based on clinical evidence. And so just like the AMA, being very judicious and relying on evidence, there is a mechanism to make sure that when the most onerous restrictions which are around originating site and geographic are lifted, the services that would be delivered, in our opinion, and that should be delivered,

irrespective of those restrictions are ones that have been validated clinically and for which there's an evidence base not just for the delivery of the services in person or virtually, but that they've been validated as a virtual modality.

Thank you very much.

DR. CROSSON: Okay. Thank you. And we are adjourned until 10:00 tomorrow morning.

[Whereupon, at 5:31 p.m., the meeting was recessed, to reconvene at 10:00 a.m. on Friday, September 8, 2017.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

Friday, September 8, 2017
10:03 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
ALICE COOMBS, MD
BRIAN DeBUSK, PhD
PAUL GINSBURG, PhD
DAVID GRABOWSKI, PhD
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
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AGENDA PAGE

P R O C E E D I N G S

[10:03 a.m.]

DR. CROSSON: Okay. I think we can begin this morning's working session. We're going to take on the question of physician supervision requirements. Ledia and Jeff are here to present, and, Ledia, it looks like you're going first.

MS. TABOR: Good morning. Today we will discuss CMS physician supervision requirements for outpatient therapeutic services.

CMS requires outpatient services like chemotherapy and cardiac rehabilitation to be directly supervised by a physician, meaning that they are immediately available but not necessarily in the room.

CMS has specifically not enforced the supervision requirement for critical access and small rural hospitals, and this presentation will review how enforcing the supervision requirement could impact beneficiaries in rural hospitals.

We'll review our mandate, CMS definitions of physician supervision levels, and then the regulatory and legislative history of the physician supervision

requirements for hospital outpatient services.

We'll next discuss our findings based on discussions with several rural hospitals and CMS about the effects of the supervision requirements on Medicare beneficiary access to and quality of care, as well as economic impacts on the hospitals and their staffing needs.

Finally, you will discuss potential guidance to CMS on the physician supervision requirements.

The 21st Century Cures Act instructs CMS not to enforce physician supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2016. The Commission has been asked to analyze the effects of enforcement instruction on Medicare beneficiaries' access to and quality of care, as well as the economic impact on hospitals. Today's presentation provides the draft material for the report, which we will submit to the Congress by December 13th.

As I previously mentioned, CMS requires direct supervision for hospital outpatient therapeutic services unless they make an assignment of another supervision level. Because outpatient services have varying complexity, CMS has four different levels of physician

supervision:

First, a procedure requiring general supervision is furnished under the physician or non-physician providers, or NPP, such as a physician assistant or nurse practitioners, overall direction and control, but their presence is not required during the performance of the procedure. An example of this is a blood transfusion service.

Second, for a procedure requiring direct supervision, the physician or NPP must be immediately available to furnish assistance and direction throughout the performance of the procedure, but they do not have to be present in the room. An example of this type of service is chemotherapy intravenous infusion.

Through rulemaking, CMS has clarified that "immediately available" means the physician must have a physical presence, meaning not on call, though CMS has not defined a distance or a time interval in which the physician must be adviser. Hospitalists or ED physicians can provide direct supervision if they are interruptible, licensed, and have hospital privileges to furnish the services.

These two other levels of supervision require a hybrid of direct and general supervision or in-person supervision. They are included here for completeness, but I won't go into detail on them.

We'll now discuss the regulatory history of the physician supervision requirement in outpatient settings. During the calendar year 2009 Medicare Hospital Outpatient Prospective Payment System rulemaking process, CMS restated and clarified the agency's policy in place since 2001 that outpatient therapeutic services for Medicare beneficiaries delivered in a hospital must be directly supervised by an appropriate physician or NPP.

Over the years, CMS has added flexibility an partial clarification on the direct physician supervision level definition. For example, as described on an earlier slide, adding that ED physicians can provide direct supervision if they are interruptible.

In 2012, CMS implemented an independent review process to assign each outpatient therapeutic service as requiring one of the four levels of supervision. CMS receives advice from the Hospital Outpatient Payment Panel, or HOPP, on the appropriate supervision level for each

hospital outpatient therapeutic service that will ensure quality and safety during the delivery of the service.

The HOPP consists of a total of 15 members who are selected by the Secretary of Health and Human Services or the CMS Administrator among the fields of hospital payment, provider billing, and accounting systems. Panel members are full-time employees of hospitals, hospital systems, or other Medicare providers. Currently, ten of the panel members are clinicians and two of the panel members are employed at critical access hospitals.

In determining the appropriate supervision level for an outpatient therapeutic service, the panel uses evaluation criteria such as the complexity of the service and probability of an unexpected or adverse patient event. The panel makes recommendations to inform preliminary agency decisions, but CMS makes the final decision on the supervision level appropriate for each service.

Based on input from the HOPP, since 2012 CMS has reduced the level of supervision for about 50 services from direct to general supervision.

We'll now discuss the enforcement of the physician supervision requirements in critical access and

small rural hospital outpatient settings.

Since the calendar year 2009 rulemaking, hospitals have expressed concern to CMS that small rural hospitals have insufficient staff available to furnish direct supervision, and they have difficulty recruiting physician and non-physician practitioners to practice in rural areas.

In response to these concerns, CMS instructed all Medicare administrative contractors not to evaluate or enforce the supervision requirements for therapeutic services in CAHs and rural hospitals with 100 or fewer beds during calendar year 2010. CMS regulatorily extended this notice of non-enforcement as an interim measure for 2011 and again for 2012 and '13.

Congress then used legislative action to extend non-enforcement of the direct supervision of hospital outpatient therapeutic services in 2014. The latest legislative action extended non-enforcement until December 31, 2016.

In July 2017, CMS stated in the 2018 OPPS proposed rules that it proposes to continue not to enforce the direct supervision requirement in CAHs and small rural

hospitals during 2018 and '19.

We spoke with several CAHs in multiple states and CMS about direct supervision requirements. We organized what we learned into three categories listed in our mandate: access, quality, and economic impact. Before diving in, we want to note that during our conversations, hospitals most frequently discussed how they provide chemotherapy and cardiac rehabilitation services, which both require direct supervision. Note that CR specifically requires a physician and not other advanced practice clinicians to supervise.

Around access, the CAHs we spoke with did not express that the direct supervision requirements for outpatient therapeutic services are limiting the types of services they provide. If the hospital can work with appropriate specialists and have the necessary volume of patients, they offer the patients chemotherapy infusions and CR.

CAHs have implemented various processes that they believe address CMS' direct supervision requirements as well as offer appropriate access to care. CAHs are using ED or family physicians in the same building or nearby in

an attempt to address supervision requirements when the specialists are not available. One CAH schedules their few chemotherapy infusion appointments on the one to two days of the week the oncologist is present at the CAH due to the specialist preference.

In our conversations with CMS, they noted that there have been no patient safety concerns raised to them about hospitals, whether rural or urban, using inappropriate physician supervision for outpatient therapeutic services. CMS also noted that there's currently no way to monitor this requirement through administrative data, so it is a more challenging requirement to enforce. A whistleblower would likely be how the Medicare program would learn of any patient safety concerns due to inappropriate supervision levels.

All the CAHs we spoke with explained that they have physicians or NPPs available, whether it's an ED or family physician, to respond to adverse events during therapeutic services.

We also heard that the specialists working with the hospital take patient safety into account. For example, one hospital said that their oncologist will refer

high-acuity patients to begin chemotherapy in a large hospital more adept to handle complications, and if no complications arise with initial treatment, then the patient can receive subsequent treatment in their local CAH.

The CAHs described processes that they have put in place with current staff to offer what they believe to be the appropriate level of supervision, but they are unclear on whether what they have done will meet CMS requirements. We did not hear from the CAHs we spoke with that the supervision requirements would cause a significant economic burden and that they do not have sufficient staff to furnish direct supervision for therapeutic services.

For chemotherapy and CR, hospitals we spoke with are using their ED or family practice physicians or NPPs in the same building or nearby to address physician supervision requirements if an oncologist or cardiologist is not available. One CAH explained that during CR a cardiologist is personally present for some aspects of the care -- for example, during a stress test -- and that a nurse does much of the exercise supervision and education components of the program with an ED or family physician

always available in a short amount of time.

In summary, we did not hear from CAHs that enforcement of the physician supervision requirements in rural areas would cause meaningful access, quality, or economic impacts. Based on our conversations with CAHs, we have some direction that we can share with CMS about refining the physician supervision requirements to limit the need for hospitals to interpret the definitions.

In the June 2012 report to the Congress, the Commission defined a set of principles designed to guide expectations and policies with respect to rural patients' access, rural providers' quality of care, and the Medicare program's payment to rural providers. One principle is that expectations for quality of care in rural and urban areas should be equal for non-emergency services rural providers choose to deliver. That is, if a provider has made a discretionary decision to provide a service, that provider should be held to a common standard of quality for that service, i.e., physician supervision standards, whether it's provided in an urban or a rural location.

The Commission also believes that determining the supervision needed for these discretionary services is a

clinical decision about the appropriate level of quality needed for safely delivering the service to each beneficiary.

CMS should continue to use their clinical judgment regarding the patient safety when deciding the most appropriate supervision level for these and other therapeutic services and that their clinical decision should apply to both urban and rural hospitals.

CMS can also offer more clarity on the definition of "immediately available" and "interruptible" in the direct supervision requirement by providing a minimum time required for a physician to arrive on site if needed during the therapeutic services.

Although this guidance is particularly relevant for rural hospitals that face physician shortage issues, clarification of the supervision requirements can benefit all hospitals.

After discussing any clarifying questions, we would like to discuss your comments about our findings of the analysis and the proposed guidance to CMS. We'll incorporate those comments into the report to the Congress we deliver by December 13th.

Thank you, and I look forward to the discussion.

DR. CROSSON: Thank you, Ledia.

Okay. We're open for clarifying questions. Jack.

DR. HOADLEY: Yeah, I had two questions. You said on Slide 11 that some of the hospitals indicated they were unsure about exactly what applies, and I'm trying to get a sense of what it is that they're unsure about. You talk I guess in the next slide about the sort of notions of the immediacy and the interruptibility concepts. Is that the main thing that they're concerned about? Or are there also issues around whether the FP or the ED doc or the nurse practitioner are the appropriate supervisor? I mean, what's the scope of what's unclear?

MS. TABOR: We heard from the hospital executives all of the above.

DR. HOADLEY: Okay.

MS. TABOR: But I think what we found to be kind of the biggest hole is the interruptible and immediately available.

DR. HOADLEY: Okay.

DR. MILLER: That's what I feel like I heard on

the calls most.

DR. HOADLEY: And then my second question I guess has to do with timing. You talked about CMS has in their proposed rule an extension of the current non-enforcement for the next two years. Our report is due in December. The hospital rule goes final -- when is it?

MS. TABOR: November 1st.

DR. HOADLEY: November. So that policy decision will already be made. So, I mean, obviously we will just say what we say in our report, but sort of the next opportunity, at least from a regulatory perspective, to make a change in the policy would be -- I guess they could restate the 2019 policy next year or they could act for 2020. Is that roughly right?

MS. TABOR: That sounds right.

DR. HOADLEY: Thank you.

DR. MILLER: The other thing that would go on is that we communicate with the agency all the time about what we're doing. They are aware of this. We've already communicated with them about it once. And depending on this conversation, we would do that again, even though the report will officially be public.

DR. CROSSON: Alice, did I see your hand?

DR. COOMBS: So, Ledia, you mentioned this in the paper about the whole notion of the expertise to cover -- whether or not the NPP or physician had the expertise to cover some of the services that they were speaking to. I would think that that would make a difference if there was this whole component of time as well. Was there any clarification as to what level of expertise they were lacking? Was it just mainly cardiology?

MS. TABOR: And oncology, but I will say that we did hear from the hospitals that they were confident that the specialist was talking to the family physician or the ED doctor about the cases, so kind of that they would both feel comfortable about the level of complexity. But as far as kind of having the expertise, you know, that can also be another area for CMS to provide more guidance.

DR. COOMBS: And there wasn't like an outcry from beneficiaries saying, you know, we're demanding access or anything like that?

MS. TABOR: No. It seemed like the biggest issues were really around did they have access to the specialist to provide the service and also the volume of

patients.

DR. CROSSON: Yes, Kathy.

MS. BUTO: Ledia, I'm just curious. I see that, you know, there have been a number of extensions of the non-enforcement approach as regards CAHs. Does CMS actually enforce the supervision requirements for urban hospitals and other hospitals that you know of? I mean, I don't think of that as a heavily regulated or enforcement area for the agency. I didn't know that --

MS. TABOR: We heard that it wasn't a high priority, also because no issues have been raised in either or rural hospitals.

MS. BUTO: Right. Okay.

DR. CROSSON: Alice.

DR. COOMBS: So there are two things at work here, and I think that may make a difference in alluding to what Kathy has said here, and that is that hospitals within urban settings commonly have by-laws and regulations within the framework of the institution. So that actually is a higher bar to fulfill rather than the bar that's been set for the rural. So they may have adjusted -- it might be possible that they have adjusted some of the hospital by-

laws and regulations to their needs in their given community.

DR. CROSSON: Okay. I'm not seeing any other hand for questions, so I think the business -- go ahead and put on the next slide. I'm sorry, 12. Yeah. So the guidance to CMS. Have we got this right? Are there any suggestions for changes in emphasis or wording, or do we support the guidance pretty much as written? So, Warner.

MR. THOMAS: My only comment on this --

DR. CROSSON: Did I miss Sue?

DR. MILLER: Sue was going to --

DR. CROSSON: Oh, I'm sorry. Sorry. I did it again. Sorry, Warner. We had -- Sue, sorry.

MS. THOMPSON: No problem.

DR. MILLER: I really just wanted to cut off Warner.

[Laughter.]

DR. MILLER: That's all I was doing.

MR. THOMAS: Watch it or I'll do the thing with the microphone again.

[Laughter.]

DR. CROSSON: Sorry, Sue. Go ahead.

MS. THOMPSON: No problem. Thank you to both Ledia and Jeff on the research you've done. You've spoken with a lot of critical access hospitals and I, too, had the opportunity, when this chapter appeared, to visit with a number of critical access hospital leaders that I'm familiar with or work closely with, and to a question, my findings were similar to yours.

I think this is a slippery slope. I think the question that's on the table is clearly around standard of care, and I think it's important. It's paramount to take a very strong position on behalf of MedPAC for the Medicare consumer.

The standard of care, whether urban or rural, must be consistent, and yet, at the same time, what I did hear from those leaders was a plea for some clarity around the definition, because just like you outlined in your chapter, they do live in some uncertainty about what does it mean, what does "interruptible" mean, what does "immediately available" mean. So I do believe the call for clarity around these definitions would be met with great welcome by these organizations, likewise the minimum amount of time for responding.

So you've outlined that well. I believe what's summarized on this screen is quite consistent with what I believe to be important for MedPAC in terms of how we outline our comment to this question.

DR. CROSSON: Thank you, Sue. Warner?

MR. THOMAS: Just to add on to Sue's comment, I just would encourage us to perhaps provide some guidance to allow flexibility here, because one of the things I worry about is that we are too specific with some of these. I mean, we've got to be specific so people know what they need to do, but I think we also understand that a lot of these hospitals are challenged providing services and having the right coverage. So I think if it's too stringent what we may find is it could have the reverse impact of organizations not being able to provide certain services.

I also wonder is there a role for telemedicine here, and I don't know. I mean, I just think it's a question, something that maybe ought to be considered is the -- we had a good discussion about that yesterday, and could telemedicine play a role here, and what role would it play in being immediately available to a critical access

hospital in helping to provide some of these services.

So I didn't really see that necessarily contemplated but given today's world I think we ought to think about whether that plays a role in the definition.

DR. CROSSON: Craig.

DR. SAMITT: My only added comment, I'm completely comfortable with the guidance as written. This was well done. It's about this notion of enforcement in consequence management and that pertains to several of the discussions that we have, including the one yesterday where we suggested perhaps we should assure that systems are putting forth recommendations for high-quality nursing homes and home health agencies. To put in policy without any consequences or reinforcement of those policies, it feels as if it's -- it will not have a favorable impact in the absence of that consequence management process. So I don't fully appreciate how that works with CMS but I wonder if we need to think a bit more about that.

DR. CROSSON: So on that point, is there any requirement for example for a hospital to submit to CMS annually their policy or their plan or how they go about doing this?

MS. TABOR: There's not now.

DR. CROSSON: Is that consonant with what you're saying, something like that?

DR. SAMITT: Well, I mean, I think it could be reporting, which would certainly be one way to go. You know, not necessarily referencing this but referencing even the discussion we had yesterday about nursing home, you could envision that Medicare could survey beneficiaries, specifically to ask, "Were you given a prioritized list of referral options for post-acute care?" as a way to assure accountability and looking for non-adherence to the policies as written. So I don't presume to know all the levers that would be possible. The question is if you have policies without any methodology whatsoever to assure that the policy is being followed, why would we envision that there would be adherence or compliance?

DR. CROSSON: Pat. Pat, Alice.

MS. WANG: Actually, this is just a question for things like supervision requirements. Would this be included in a JCAHO accreditation survey? Do they look at things like this?

MS. TABOR: I don't know offhand but I can look.

MS. WANG: Because that might be --

MS. TABOR: They do.

MS. WANG: Yeah. And actually related to that question, is this policy of supervision embodied in the conditions of participation? I mean, where does it -- what -- because if it is, then JCAHO is the natural enforcement mechanism for that, the surveys that are done.

MS. TABOR: I will look in reference to that.

DR. CROSSON: Okay. Good. So, Alice.

DR. COOMBS: I support these and I support what Sue has said, and I think an easy way to do this is, it is in the conditions of participation, so whatever is in the urban -- and the paper does a great job, you guys did a great job -- outlining that the paper says let's keep the standards the same as in the urban setting, the same this is true. I wouldn't require there be anything done differently from the urban setting. So whatever is done in the urban, for the rural, in terms of seeking compliance or whatever is necessary for that.

DR. CROSSON: Jack.

DR. HOADLEY: So I really like the work you did on this to really find out what things look like out there

in practice, and I think -- and I definitely agree with the guidance that you've outlined here. I mean, I think -- and I'm sure you'll be doing this -- in reporting on this, I think, you know, one of the values is we've got those research findings to say, you know, we're basing this view on some sense of what the experience out there is, and I think, you know, it's the opportunity to raise some of these other issues to say, you know, if there's a telemedicine option or we have some ideas about it. I mean, we don't have to completely wrap our arms around any one particular idea, but the more we can sort of lay this out, that gives people on the Hill and in the agency the foundation there, and I think that's the value, you know, given that we have this mandate of being able to put those items on the record and put that case together. And I think that's where we can take this request and really provide good service in responding to it. So nice job.

DR. CROSSON: Okay. I see no other comments. This is very good feedback. Ledia and Jeff, terrific work. Oh, did I see another hand? I'm sorry. Kathy.

MS. BUTO: I just have a question, actually, about the Committee. Do we envision, as part of our

finding, that the Committee would continue to do its work as part of the process? I mean, what role do you see for them, and are we pretty satisfied with the process they were using, or is there room for some improvement there?

MS. TABOR: I think that we believe that CMS should continue to use clinical judgment as the main source and that the HOPP can kind of continue to provide advice more of like how do hospitals actually function, because I think that is really their role. If they are more specialists in payment, they happen to also be clinicians. But I think that their clinical judgment overall at CMS should rule.

DR. CROSSON: And presumably no procedures come online over time, there are changes in technology and things of that nature.

MS. TABOR: Yeah, and they do -- the HOPP, when they do -- for example, they just met in August and they did have a call for any new -- any requested changes to any of the different therapeutic services, but they didn't actually do any discussions because there wasn't enough kind of change in guidelines.

MS. BUTO: You might just want to add something

about the Committee's role and the fact that we think it's fine and appropriate, but something, since they do have something to do with the issue.

DR. MILLER: I also just want to follow up on something that Warner said. We are definitely trying to --

COURT REPORTER: Turn your mic on.

[Laughter.]

DR. MILLER: You know, I'm not going to say it now.

[Laughter.]

DR. MILLER: I'm a little bit hurt.

MR. THOMAS: I'm fine with that.

[Laughter.]

DR. MILLER: Nicely done, Warner.

[Laughter.]

DR. MILLER: Nicely done. We are -- in a sense, we are really trying to not be real prescriptive about how they meet these things, but they want a bright line so that they know if somebody comes behind them that they are meeting them. And if you have these conversations, in a way it's really interesting. They have all these different ways they're meeting this requirement. You know, we grab

the physician out of clinic or we -- you know, our physician happens to live five minutes from the -- and so we definitely don't want to leave you or anyone else with the impression that we're going to articulate specific ways -- you know, it's more, okay, if you can get the person there in five minutes, you can get the -- then you're okay. But you have to just show how you would do that in five minutes, or in response to a question. Because I do want to say that we're not trying to be highly prescriptive about, you know, the mechanisms.

DR. CROSSON: David.

DR. NERENZ: I just wanted to briefly support Warner's comment about telemedicine. I was surprised in reading the chapter and the presentation that it wasn't mentioned. It just seems like a natural application of that class of technology. I think we could defer to the HOPP in terms of specifically under what circumstances, what technologies.

But in the wording of the charge to us, to talk about economic impact, it seems like it matters a great deal that if a critical access hospital has to hire a full-time physician that has one impact. If it can use a

telemedicine technology to get appropriate supervision through a larger hospital serving the region, that's a different impact. So it seems like it's got to be on the table somewhere, and I think it would be on a table in a positive way.

DR. CROSSON: Okay. Good discussion. Not seeing any other hands I think we are done. I suspect that you've gotten the input that you're looking, and so we look forward to the final letter.

And that then concludes the September meeting of MedPAC, except for the public comment period. So we have an opportunity now for our guests, if they wish to make a public comment, to do so. If you are interested please come up to the microphone so we can see who you are.

[Pause.]

DR. CROSSON: Not seeing anyone, we are adjourned then until the October meeting.

Safe travels, everybody. Thank you very much.

[Whereupon, at 10:34 a.m., the meeting was concluded.]