

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, April 6, 2017
9:01 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
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

B&B Reporters
4520 Church Road
Hampstead, Maryland 21074
410-374-3340

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P R O C E E D I N G S

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[9:01 a.m.]

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DR. CROSSON: Okay. I think we can be seated and

The first agenda item for this morning is a return to the discussion of Medicare Part B drug payment policy issues, and we have got Kim and Nancy here. Kim, it looks like you are ready -- no, Nancy is starting. Sorry.

MS. RAY: Good morning. Today Kim and I will walk you through a draft recommendation aimed at improving the current ASP payment system in the short term while developing the Drug Value Program, the DVP, an alternative, voluntary program in which providers could choose to enroll instead of remaining in the buy-and-bill system. We have discussed issues related to Part B drugs for a couple of cycles and have developed the draft recommendation over the last several meetings.

Here is an outline of today's presentation. Before beginning, I want to point out that the draft chapter has been revised to reflect your questions and comments from the March meeting as outlined in the attached memo. For example:

1 Warner and Jack, we added a section on the
2 broader context for Part B drug spending which includes the
3 financial performance of drug manufacturers.

4 Bruce, we have added discussion about improving
5 the quality of the ASP data that manufacturers report.

6 On the inflation rebate policy, Bill Gradison, we
7 included a discussion of an exception process for high-cost
8 drugs in shortage on a case-by-case basis. And, Paul, we
9 have added more discussion on the rationale for the
10 inflation rebate policy.

11 Some of the changes to the DVP section include:

12 In respond to David and several other
13 Commissioners, we expanded discussion on shared savings
14 opportunities for providers in the DVP.

15 Several Commissioners -- Craig, Pat, Brian, Amy -
16 - we added the discussion about providers' incentive to
17 join the DVP.

18 In response to Pat and Craig, we have added
19 discussion about the potential for providers to purchase
20 drugs at the DVP rate for their MA patients.

21 And in response to several Commissioners, we have
22 expanded the discussion on the design elements in the

1 binding arbitration that could be used in the DVP.

2 In terms of background, the information is not
3 new to the Commission, so I'm going to move fast on this
4 slide.

5 Medicare spending for Part B drugs is
6 substantial, totaling \$26 billion in 2015.

7 The Commission's interest in reforming the Part B
8 drug payment structure over the last several years has been
9 driven by concerns that include the rapid growth in the
10 prices of and expenditures for Part B drugs.

11 Since 2009, Part B drug spending has been growing
12 at a high annual rate of growth, and between 2009 to 2013,
13 half of the growth in expenditures was driven by price
14 growth, which reflects price increases for existing drugs
15 and a shift in the mix of drugs.

16 This slide gives broader context for how the
17 package of reforms fit together and the timing of the
18 reforms. As the figure shows, the first set of reforms is
19 aimed at improving the current ASP system and could be
20 implemented almost immediately.

21 The figure also shows the implementation in 2022
22 of the DVP. As part of the transition to the DVP, the

1 current ASP add-on of 6 percent would be reduced to give
2 providers an incentive to enroll in the DVP.

3 Now I will start walking through the short-term
4 policy reforms, beginning with improving ASP data
5 reporting.

6 As we discussed in March, only manufacturers with
7 Medicaid rebate agreements are required to report their ASP
8 data. Some entities, such as repackagers, do not have
9 Medicaid rebate agreements and are, therefore, not required
10 to submit ASP data. Also, some manufacturers who are
11 required to report ASP data fail to do so in a timely
12 manner.

13 This policy reform would require manufacturers to
14 report ASP data for all Part B drugs and increase the civil
15 monetary penalties for failing to report the data in a
16 timely manner.

17 We discuss in the text giving the Secretary the
18 authority to exempt special cases from reporting. For
19 example, repackagers could be excluded from reporting to
20 ensure drugs are not double counted.

21 Our second policy reform concerns drugs that are
22 paid solely based on manufacturers' list prices, which is

1 referred to as the wholesale acquisition cost, or WAC.

2 New single-source drugs and the first biosimilar
3 are typically paid at WAC+6 percent for nearly three
4 quarters because of the lag in ASP data reporting. WAC-
5 based prices do not incorporate discounts that
6 manufacturers commonly provide.

7 We found that for a subset of new, high
8 expenditure drugs, small discounts were common while the
9 drugs were WAC-priced. Consequently, Medicare currently
10 pays more for the same drug when it is WAC-priced compared
11 to when it is ASP-priced.

12 To bring WAC-based prices and ASP-based prices
13 for the same drug closer together, this policy reform would
14 reduce the WAC add-on by three percentage points, roughly
15 the high end of the discounts we observed.

16 In addition, to maintain parity to ASP-priced
17 drugs in the future, the WAC add-on could be further
18 reduced when the ASP add-on is reduced to encourage
19 enrollment in the DVP.

20 So let's move to the third short-term policy
21 reform. Growth in the ASP payment rates are driven by
22 manufacturer pricing decisions. There is no statutory

1 limit on how much Medicare's ASP payment for a product can
2 increase over time.

3 This policy reform would require manufacturers to
4 pay Medicare a rebate when ASP growth exceeds an inflation
5 benchmark. The savings from rebates would be shared with
6 the beneficiary by basing cost sharing on the lower
7 inflation-adjusted ASP. The provider add-on payment would
8 also be based on the inflation-adjusted ASP.

9 To address the concern about CMS administrative
10 resources to implement a rebate, low-cost drugs could be
11 excluded from the policy. On a case-by-case basis, high-
12 cost drugs under shortage could be excluded as well. Also,
13 duplicate discounts could be avoided meaning that the ASP
14 inflation rebate could exempt Medicare utilization already
15 subject to a 340B discount or Medicaid rebate.

16 An inflation benchmark would need to be chosen.
17 It could be CPI-U like the Medicaid inflation rebate, or an
18 alternative could be considered that results in a growth
19 rate no greater than provider fee-for-service updates.

20 Moving to the last of the short-term policy
21 reforms, under the current ASP system, we have not
22 maximized competition between the reference biologic and

1 its biosimilars because the reference product is assigned
2 to one billing code and all its biosimilars are assigned to
3 another separate billing code.

4 This policy reform would require the Secretary to
5 group the reference biologic and its biosimilars in the
6 same billing code. The Secretary would rely on the FDA
7 approval process for biosimilars that was established by
8 the Biologic and Price Competition and Innovation Act
9 determine which products to group together.

10 Under this policy, the clinician would continue
11 to have the choice to prescribe the product most
12 appropriate for the beneficiary, and Medicare's payment
13 could be based on the volume-weighted ASP of all products
14 assigned to the code. The Secretary could be given the
15 flexibility to implement a limited payment exception
16 process under which Medicare would reimburse the provider
17 based on the ASP of the higher-priced product. This would
18 address the concern that beneficiary access could be harmed
19 if some providers are unwilling to supply the higher-cost
20 product to a beneficiary who needs a particular product due
21 to clinical reasons.

22 Lastly, we discuss in the draft chapter that the

1 Secretary could study the use of a broader consolidated
2 billing code policy for groups of drugs with similar health
3 effects and for groups of biologics with similar health
4 effects.

5 Now Kim will discuss the DVP.

6 MS. NEUMAN: So next we'll talk about developing
7 a Drug Value Program, or DVP, which would be a voluntary
8 market-based alternative to the ASP system. This policy
9 would give the Secretary the authority to create a Part B
10 DVP that would use private vendors to negotiate prices and
11 offer providers shared savings opportunities.

12 The DVP would be informed by lessons learned from
13 the CAP program, but structured differently to increase
14 vendors' negotiating leverage and encourage provider
15 enrollment.

16 So let's review the key design elements of the
17 DVP. The DVP would be voluntary for physicians and
18 outpatient hospitals. Annually, these providers would
19 decide whether to enroll in the DVP or remain in the ASP
20 buy-and-bill system.

21 To encourage provider enrollment in the DVP, the
22 ASP add-on would be reduced gradually in the buy-and-bill

1 system. The reduction to the add-on would be timed to
2 coincide with the target date for operationalizing the DVP.
3 The add-on reduction could begin by that target date
4 regardless of whether the DVP is operational in order to
5 create pressure for the DVP to be implemented.

6 We envision that Medicare would contract with a
7 small number of private DVP vendors to negotiate Part B
8 drug prices. Having a small number of vendors would give
9 providers a choice of which vendor they wanted to work with
10 and would also consolidate volume among a small number of
11 entities to increase negotiating leverage.

12 DVP prices would not be public. Different from
13 the original CAP program, DVP vendors would not directly
14 ship product to beneficiaries. Instead, providers would
15 buy the drugs in the marketplace from distributors or
16 wholesalers and in some cases directly from manufacturers
17 at the DVP negotiated price.

18 In terms of payments and shared savings, here's
19 how we anticipate it would work.

20 The provider payment would include three
21 components. There would be payment for the drug, which
22 would be the DVP negotiated price with no add-on. There

1 would also be payment for drug administration services,
2 which would continue to be paid at an amount specified in
3 the physician fee schedule or the outpatient prospective
4 payment system.

5 In addition, providers would have the opportunity
6 to receive shared savings if the DVP program resulted in
7 lower total cost of Part B drugs.

8 Vendors would be compensated through an
9 administrative fee, which might be a fixed dollar fee or a
10 fee per enrolled provider, or a combination of these
11 approaches. Like providers, vendors would be eligible for
12 shared savings if the DVP resulted in lower total cost of
13 Part B drugs.

14 Beneficiaries would also share in savings because
15 they would pay lower cost sharing, and Medicare would share
16 in savings because the Medicare payment rate for the drugs
17 would be set at the DVP negotiated price.

18 The DVP would be designed to include several
19 tools to increase vendors' negotiating leverage.

20 First, DVP vendors would be permitted to operate
21 a formulary. We would expect that a formulary would spur
22 price competition among products with similar health

1 effects -- so, for example, when there are multiple brand
2 products in the same therapeutics class -- and this would
3 lead to lower prices for these products.

4 Second, prices under the DVP would be limited to
5 no more than 100 percent of ASP. This would ensure that
6 vendors can get at least typical market prices for all
7 drugs.

8 Third, vendors could be permitted to use
9 additional tools like step therapy and prior authorization.

10 Fourth, binding arbitration could be used in the
11 DVP program for expensive drugs without close substitutes.
12 I'm going to pause here and spend a little time talking
13 about a few of the principles we outlined in the draft
14 chapter for designing a binding arbitration process within
15 the DVP and provide clarification.

16 First, binding arbitration, when it occurs, would
17 be between manufacturers and DVP vendors, not CMS.

18 Second, we would anticipate that the process for
19 binding arbitration would be developed through rulemaking,
20 which would allow opportunities for public comment.

21 Third, we envision that DVP vendors would have
22 one opportunity to invoke binding arbitration for a product

1 in a given time period.

2 Fourth, as we've discussed, including binding
3 arbitration as a tool in the DVP might actually promote
4 more negotiations between manufacturers and DVP vendors as
5 they might prefer negotiating rather than entering
6 arbitration where they may risk the arbiter ruling for the
7 other party.

8 Fifth, the paper touches on other design issues
9 such as approaches for selecting arbiters and criteria that
10 the arbiter might use to make a decision, and we'd be happy
11 to discuss any aspects of this on question.

12 So now to finish on a couple other design
13 elements for the DVP: DVP prices would not be included in
14 the calculation of ASP in order to give vendors more
15 leverage with manufacturers. Finally, it will take time to
16 develop the DVP so it could be phased in beginning with a
17 subset of drugs where savings potential appears to be
18 greatest, such as drug classes that include multiple
19 products with similar health effects.

20 At the March meeting, a question came up about
21 what are providers' incentives to join the DVP, and there
22 are a couple different factors that create incentives for

1 DVP enrollment.

2 We expect that providers that are on the higher
3 end of the price distribution would have an incentive to
4 join the DVP because the buy-and-bill system is less likely
5 to be attractive to these providers.

6 As higher-priced purchasers move into the DVP,
7 this may lead to a reduction in future ASPs as these
8 purchasers' prices would no longer be reflected in the ASP
9 calculation. A reduction in future ASPs might lead more
10 providers to consider DVP enrollment.

11 Another incentive for DVP enrollment is the
12 reduction of the ASP add-on from 6 percent to 3 percent
13 over time. A lower add-on would lessen the attractiveness
14 of the buy-and-bill system and create broader incentives
15 for DVP enrollment.

16 Another element that may make the DVP more
17 attractive to providers would be the incorporation of
18 provider input into DVP tools, such as the formulary and
19 other management tools.

20 And, finally, shared savings opportunities
21 available through the DVP also create incentives for
22 enrollment. DVP savings would be expected to come from two

1 sources. First, we anticipate that DVP vendors' use of
2 tools like a formulary would yield lower prices on
3 individual products. Second, providers would have an
4 incentive to shift utilization toward lower-priced products
5 where clinically appropriate. To the extent that savings
6 are generated from these two dynamics, providers that
7 enroll in the DVP would share in those savings.

8 So next we are going to move to the Chairman's
9 draft recommendation, and before we do, we have the
10 overview slide that sort of shows how all the pieces put
11 together and the time frame for potential implementation.

12 So the draft recommendation reads:

13 The Congress should change Medicare's payment for
14 Part B drugs and biologicals as follows:

15 One, modify the average sales price system in
16 2018 to:

17 Require all manufacturers of products paid under
18 Part B to submit ASP data and impose penalties for failure
19 to report.

20 Reduce wholesale acquisition cost-based payment
21 to WAC+3 percent.

22 Require manufacturers to pay Medicare a rebate

1 when the ASP for their product exceeds an inflation
2 benchmark, and tie beneficiary cost sharing and the ASP
3 add-on to the inflation-adjusted ASP.

4 Require the Secretary to use a common billing
5 code to pay for a reference biologic and its biosimilars.

6 Two, no later than 2022, create and phase in a
7 voluntary Drug Value Program that must have the following
8 elements:

9 Medicare contracts with a small number of private
10 vendors to negotiate prices for Part B products.

11 Providers purchase all DVP products at the price
12 negotiated by their selected DVP vendor.

13 Medicare pays providers the DVP-negotiated price
14 and pays vendors an administrative fee, with opportunities
15 for shared savings.

16 Beneficiaries pay lower cost sharing.

17 Medicare payments under the DVP cannot exceed 100
18 percent of ASP.

19 Vendors use tools including a formulary and, for
20 products meeting selected criteria, binding arbitration.

21 Three, upon implementation of the DVP or no later
22 than 2022, reduce the ASP add-on under the ASP system.

1 In terms of implications, the draft
2 recommendation is estimated to decrease program spending
3 relative to current law by \$250 million to \$750 million
4 over one year and between \$1 billion and \$5 billion over
5 five years.

6 In terms of implications for beneficiaries and
7 providers, the draft recommendation would: generate
8 savings for beneficiaries through lower cost sharing, and
9 would not be expected to affect beneficiaries' access to
10 needed Part B drugs.

11 In terms of the effect on provider revenues:

12 For providers choosing to remain in the ASP
13 system, ASP add-on payments would be reduced, but the
14 effect on providers' net revenues would depend on how
15 manufacturers respond to the policy.

16 For providers that choose to enroll in the DVP
17 program, they would be paid the DVP price with no add-on
18 and would be eligible for shared savings opportunities.
19 Whether these providers' net revenues increase or decrease
20 would depend on whether the shared savings is bigger or
21 smaller than the net revenue they would have otherwise
22 earned on drugs with an add-on under the buy-and-bill

1 system.

2 Beyond the specific text of the draft
3 recommendation, we would intend to add in the June report
4 additional text to reflect more detail on certain issues or
5 to reflect conversations that occurred among Commissioners
6 about alternative approaches or other ideas.

7 For example, on the ASP inflation rebate, the
8 text would mention the exemption of low-cost drugs; the
9 case-by-case exceptions process for high-cost drugs in
10 shortage; avoidance of duplicate discounts; and the need
11 for policymakers to select an inflation benchmark. The
12 text will also mention that there is another way to
13 structure the ASP inflation limit.

14 On consolidated billing, the text would encourage
15 the Secretary to examine the potential for consolidated
16 billing more broadly beyond biosimilars and reference
17 biologics.

18 The text would also discuss the timing of
19 gradually reducing the ASP add-on from 6 percent to 3
20 percent and would make clear that the WAC add-on would be
21 reduced further as the ASP add-on is reduced.

22 In addition, as I mentioned already, the text

1 would provide more detail on principles for binding
2 arbitration under the DVP.

3 Finally, the text would encourage the Secretary
4 to take steps to ensure the quality of ASP data reported by
5 manufacturers.

6 So that concludes our presentation. We look
7 forward to your discussion and are happy to answer any
8 questions.

9 DR. CROSSON: Thank you, Kim and Nancy.

10 So we'll take clarifying questions. Can I see
11 hands? Let's start with Bill Gradison.

12 MR. GRADISON: I just want to make sure I
13 understand the role of pre-authorization or a formulary.
14 Am I correct that under Part B today there is no use in
15 traditional Medicare, fee-for-service Medicare, of either
16 formularies or pre-authorization?

17 MS. NEUMAN: So for Medicare Part B drugs, there
18 is currently not a formulary under Medicare fee-for-
19 service. I believe there might be some experimentation
20 with prior authorization in other types of services in fee-
21 for-service.

22 MR. GRADISON: I understand, but I'm just talking

1 about Part B.

2 MS. NEUMAN: For Part B, no.

3 MR. GRADISON: Okay. My initial reaction in
4 seeing that was a little bit of belt and suspenders here.
5 Then as I thought more about it -- and there is a question
6 behind this -- it occurred to me that the negotiations, the
7 way I had thought about them, and the ultimate arbitration
8 were focused on price, actually exclusively on price the
9 way I thought about it. But if prior authorization and
10 formularies become an element, as we recommend here, then I
11 could envision the negotiation and possibly arbitration
12 might include those provisions. In other words, part of
13 the deal might be if we negotiate such-and-such a price, it
14 would be in consideration for being at a top tier, or at
15 least not having to have pre-author -- I mean, that would
16 just be a subject for negotiation. I'm not suggesting how
17 it might come out.

18 So I'm just trying to -- I'm really asking for
19 your help because I have had a little trouble thinking this
20 through, the interrelationship between the price -- I guess
21 we ought to say the price-oriented negotiation and possible
22 arbitration along with these two additional tools. Thank

1 you.

2 MS. NEUMAN: Sure. So I would sort of look at it
3 in two pieces. There's sort of the general negotiations
4 that the DVP would have for the drugs that are in the DVP
5 program broadly. And then there's arbitration which might
6 apply to a subset of products that meet certain criteria.
7 So they're kind of in two separate camps.

8 In general, the idea of including a formulary was
9 to allow vendors where there are multiple products that
10 have similar health effects in the same therapeutic class
11 to be able to go to manufacturers and try to secure
12 discounts for placement on the formulary or for educating
13 providers on which product is less costly and likely to
14 generate savings and so forth. And so the idea was that
15 these management tools would help the vendors to secure
16 discounts from manufacturers where there is competition
17 among products.

18 With respect to arbitration, as we have said,
19 there would be specific criteria for a product to be even
20 eligible for arbitration, and that would be drugs that are
21 very expensive and that don't have close substitutes, so
22 that any of these tools that we just talked about wouldn't

1 really be very effective. And so in that situation, there
2 could be a process where it meets those criteria, the drug
3 then goes into an arbitration process, and there is a
4 determination made about an appropriate price through that
5 process. And so there's sort of those two aspects to the
6 design.

7 MR. GRADISON: I think I understand. Thank you
8 very much for your help [off microphone].

9 DR. CROSSON: Clarifying -- I'm sorry. Warner,
10 do you want to have a question?

11 MR. THOMAS: A couple of clarifying questions.

12 First of all, on the penalties for failure to
13 report, have you thought through what those penalties might
14 look like, or is that to be determined in the future? Is
15 there any recommendation on the penalties?

16 MS. RAY: I think we envisioned that they should
17 be increased from what the current level of penalties are,
18 but we haven't thought of a specific number.

19 MR. THOMAS: Was there a consideration of if they
20 do not report, potentially not being able to sell to the
21 program?

22 MS. NEUMAN: As a condition of Medicare coverage,

1 they would be required to report this data, and so if they
2 don't report, they could be terminated from coverage
3 ultimately.

4 MR. THOMAS: Okay. And then on the inflator cap,
5 you had said in further text that will be kind of further
6 vetted, because I know you talked about potentially tying
7 it to provider increases, and then there's, you know, or
8 potentially some type of CPI. I guess my clarifying
9 question is: If it was tied to provider increases, what
10 would that be roughly? Do we have any idea in a range of
11 what that might look like? And if it was tied to the CPI
12 Medicaid number, what would that look like?

13 MS. NEUMAN: So I can tell you on CPI that we
14 have -- there's a table in the paper that looks at CPI
15 growth on an annual basis over the period that ASP has been
16 in effect, so since 2005. And CPI has been growing at an
17 average rate of about 2 percent per year. My sense is
18 that, in general, market baskets might be a little bit
19 higher than that.

20 DR. MILLER: I think that's right. I feel like
21 they're running these days above -- market baskets are
22 running about 2, 2-1/2 is sort of what's happening.

1 There's several of them out there, so it's a little hard to
2 answer.

3 I would say the other thing that we're trying to
4 say conceptually -- and I don't think we have, you know, an
5 index horse that we're trying to ride per se, and some of
6 what I'm about to say is based on comments that you've
7 made. You probably don't want an index that the price set
8 by the drug manufacturers drives the index because then you
9 have a bit of a circularity problem.

10 MR. THOMAS: Right.

11 DR. MILLER: You raised concerns that -- and
12 others, but I remember your voice in particular -- you
13 know, the inflator shouldn't be going up faster than what
14 the person who's purchasing the drug and delivering it to
15 the beneficiaries, that we're sort of saying don't tie
16 yourself to drug prices, be mindful of the fact that the
17 providers' payments are going up. And then within that, we
18 threw out a few indexes, and I think our thinking is that's
19 the guidelines that you want to think of in selecting an
20 index.

21 Does that all pass your review?

22 MR. THOMAS: And the last question. You said

1 there would be a few DVPs. Have you thought about what you
2 think the number might be or how they're selected or
3 anything like that?

4 MS. NEUMAN: So we haven't hit a specific number.
5 We're cognizant of if there are too many, then we sort of
6 water down any leverage that they have. And at the same
7 time, we would like providers to have a choice, and so you
8 would need at least several, I would think.

9 MR. THOMAS: Thank you.

10 MR. PYENSON: On this point?

11 DR. CROSSON: On this point, Brian and Bruce.

12 Okay. Brian on this point?

13 MR. PYENSON: Just on the earlier point of the
14 CPI index, I think just a question. Often people default
15 to consumer indices, and whether it makes sense to identify
16 a broader range, such as the producer price index,
17 wholesale medical, as another consideration, just to create
18 the full scope or span of possibilities that are out there.

19 DR. CROSSON: And I think we are open to adding
20 that as another example in the text.

21 DR. MILLER: And I think based on what we were
22 saying as kind of the guidelines that we are thinking

1 about, that does fit into that guideline.

2 DR. CROSSON: Okay. We are back to clarifying
3 questions. Coming up this way. Pat.

4 MS. WANG: Again, I apologize that I don't have a
5 voice. I hope you can hear me all right.

6 Can you say more about how you think shared
7 savings could be calculated? How would that work? What
8 would the benchmark be? How would the benchmark change?

9 MS. NEUMAN: Sure. So we have some in the paper
10 that talks about the calculation of shared savings, and we
11 have said a couple of things. One is that we would want to
12 look not just at price but at the total cost of Part B
13 drugs, so that we look at both the price and shifts in
14 utilization that might occur in what the overall spend is.
15 And then you would want to compare that to some kind of
16 benchmark, as you note. So perhaps providers that are not
17 enrolled in the DVP program would be one possibility.

18 And there are other shared savings approaches
19 that occur within other aspects of the Medicare program,
20 and so we could look to that. We haven't gone into detail
21 in saying do it this way or do it that way. We have sort
22 of been at the principle level.

1 And then another piece that we have in the paper
2 now is sort of shared savings could work by the government,
3 calculating it sort of like we do with some of these other
4 programs and sort of figuring out how much each provider
5 would get, or an alternative would be to identify how much
6 savings is the provider's and vendor's share and then
7 turning that money over to the vendor, who could then
8 allocate it among providers. So there's different ways to
9 sort of distribute it.

10 DR. CROSSON: David.

11 DR. NERENZ: Thank you.

12 Two questions. Both can be related to Slide 13,
13 if you can bring that up.

14 First one, top line. If you could just clarify -
15 13 -- high end of the price distribution. Can you just
16 talk in a little more detail? Distribution of what exactly
17 and price to whom exactly, what does that mean? I assume
18 it relates to ASP, but can you tell us what that is?

19 MS. NEUMAN: Right. So that refers to the
20 provider's acquisition price for the product. So they are
21 buying drugs right now in the market from distributors,
22 wholesalers, and so on at a certain price, and that price

1 is --

2 DR. NERENZ: Which could be higher or lower than
3 ASP? That's the point?

4 MS. NEUMAN: Right. Higher or lower than what
5 Medicare -- yeah -- the ASP Medicare uses to base the
6 payment rate. Yeah.

7 DR. NERENZ: Okay. That's fine. So if you are
8 on the high end of the distribution and you get paid ASP+6,
9 you still may be losing money on the simplified version,
10 but that's the point?

11 MS. NEUMAN: Right. Or you may not be making
12 money.

13 DR. NERENZ: Thank you. Okay. I just wanted to
14 make sure.

15 The second question, then, is the second bullet,
16 and then this comes up again. In earlier discussions on
17 this -- and I may have been just mistaken -- I thought we
18 were fundamentally talking about moving from ASP+6 to
19 WAC+3, but in the proposal, I see ASP+3 and I see WAC+3.
20 Can you just talk a little bit about the relationship
21 between those two things going forward? When is ASP
22 relevant? When is WAC relevant?

1 MS. NEUMAN: Okay. There's sort of two pieces.
2 The WAC is used, as Nancy said, when we don't have ASP
3 data. So it is for a very small number of products where
4 the product is really new and we don't have ASP data yet,
5 and right now, we are paying +6, and think that is not an
6 efficient price and we should move to +3.

7 And then the ASP is what's used the vast majority
8 of the time, and in this case, we are suggesting that in
9 2022, we start phasing that +6 down.

10 DR. NERENZ: Okay. So the presumption is that
11 even though another part of this is to require stronger ASP
12 reporting, there still will be specific drugs for which ASP
13 data do not exist, and therefore, WAC+3 -- that is when it
14 applies?

15 MS. NEUMAN: Right. By definition, new products
16 will always lack ASP --

17 DR. NERENZ: Yes. Thank you. Okay. Just being
18 sure.

19 DR. CROSSON: Amy.

20 MS. BRICKER: So you mentioned inflation or
21 highlighted that there has been a 9 percent growth in
22 spend, half of which was actually due to price, growth, or

1 inflation. Is that correct? How does that compare to --
2 so roughly 4 to 5 percent in inflation. How does that
3 compare to Part D? DO you know?

4 MS. NEUMAN: I am not sure. I can answer that.

5 DR. MILLER: Can we get one of the D folks up
6 here?

7 MS. NEUMAN: Yeah. And --

8 MS. RAY: And it would also be for a different
9 basket of drugs.

10 MS. BRICKER: I understand. It doesn't actually
11 seem egregious. When you see 9, that is shocking, but when
12 you realize that half of it is utilization, I think it is
13 going to come out to be much less than what we see in Part
14 D. But I just wanted to confirm that assumption.

15 DR. MILLER: All right.

16 MS. BRICKER: Do you have mix? Brand versus
17 generic?

18 MS. NEUMAN: On that? For Part B? Do you want
19 the percentage or the price change?

20 MS. BRICKER: The percentage of brand versus
21 generic.

22 MS. NEUMAN: Okay. So under Part B, only 25

1 percent of the spend is on drugs, and of that, about 15
2 percent are drugs that are single source and so have no
3 opportunities for competition.

4 The remaining 10 percent are for products where
5 there is competition between brand and generic, but we
6 don't know from our data how many units of generic are
7 being used versus brand. We only know that drugs with
8 generic competition account for 10 percent of total spend.

9 MS. BRICKER: I am trying to figure out, again,
10 in comparison to Part D space, is this predominantly
11 generic products that are being utilized here. So, as we
12 look at inflation in this case, we're looking at a very
13 small subset of manufacturers that are branded
14 manufacturers that are highlighted potentially on page 26
15 of our reading material that are driving that ultimate 4 to
16 5 percent inflation, or is that not the assumption? The
17 mix is generally similar, B and D, and therefore, the
18 inflation is being held at a lower rate compared to D for
19 some other reason. And that's where I'm headed. I need
20 some help with that, though.

21 MS. SUZUKI: So for the Part D program, including
22 the generic substitution, since 2006, the prices have grown

1 by about 8 percent, so this is cumulative. But when you
2 look at single-source drugs, it's grown by 240 percent,
3 according to our price index analysis.

4 MS. RAY: That's cumulative.

5 MS. SUZUKI: It's cumulative too.

6 MS. BRICKER: And you're saying just inflation,
7 not actual utilization?

8 MS. SUZUKI: Right. This is just price --

9 MS. BRICKER: So 8 percent versus 4 to 5 percent?
10 Is that right here?

11 MS. NEUMAN: It is, but it is a different time
12 period, and it's also a different mix of products. The 4
13 to 5 percent represents the whole portfolio under B.

14 MS. BRICKER: Okay. Thank you, Shinobu. I
15 didn't mean to start a fire drill.

16 You mention in the reading material that as a
17 DVP, the worst that a DVP vendor could do is ASP. Yeah.
18 Okay.

19 So then when you think about there's going to be
20 some -- you mentioned some add-on, a professional service
21 fee or some sort of add-on to the prescriber. If you
22 assume ASP as the backstop, how does ASP plus a

1 professional service fee compare to ASP+3 or 6 percent?

2 MS. NEUMAN: So that administrative service fee
3 would be paid to both people who are in the buy-and-bill
4 payment system and people who are in the DVP. It would be
5 the amount that is paid under the physician fee schedule or
6 outpatient prospective payment system.

7 Under the buy-and-bill, you would get ASP+3
8 eventually, and under the DVP, you'd get the DVP price,
9 which would be no higher than ASP, but it would be exactly
10 what you acquired the product for.

11 MS. BRICKER: There is no add-on?

12 MS. NEUMAN: There is no drug add-on. Correct.

13 MS. BRICKER: Fee add, like for the
14 administration?

15 MS. NEUMAN: There is this fee for drug
16 administration services under the fee schedules, and that
17 goes to providers, regardless of which system they are in.

18 MS. BRICKER: Okay. I didn't understand that.

19 So, in the buy-and-bill, you get ASP+6 plus the
20 administration fee?

21 DR. MILLER: Correct.

22 MS. BRICKER: Gotcha. Okay. So future, worst

1 case, ASP plus the administration fee. Gotcha.

2 DR. MILLER: Yeah. But if they can negotiate
3 something down below ASP, then they get that piece.

4 MS. BRICKER: Okay.

5 Last question. You mentioned on the savings -- I
6 was shocked that it's so small, 1 percent, \$250 million,
7 first year.

8 MS. NEUMAN: Okay. Mm-hmm.

9 MS. BRICKER: Is that just ASP reduction, or what
10 is that?

11 MS. NEUMAN: So the first year of the policy
12 would be the four ASP provisions that Nancy discussed.

13 MS. RAY: So it would be the consolidated
14 billing, the inflation rebate, the moving from WAC+6 to
15 WAC+3 and improved data reporting.

16 MS. BRICKER: I was just surprised that all of
17 that reform, we would just see a 1 percent savings in plan
18 year one. Am I missing something?

19 DR. CROSSON: Well, I think it is the fact that
20 the expectation is that it would take time to develop the
21 DVP, and that whole mechanism is further out in that 5-year
22 window. I think that's the issue.

1 MS. BRICKER: Yeah. All the other things, absent
2 DVP, I was just surprised it would only result in a 1
3 percent savings.

4 DR. MILLER: Well, the other thing I just want to
5 get across is that the numbers that are in the piece of
6 paper that you have in front of us are a range. We are
7 required to do that because we don't do point estimates.
8 CBO has to do the point estimates. So it could be higher
9 than the 250, which is the lower end of that range. But
10 you're right. It's not huge.

11 And I think some of it also is that the inflation
12 index is one of the components, and of course, that's
13 something that would play out over time. So when you look
14 at that first year, you're probably not getting much out of
15 that, would be my on-the-fly response, and so what you're
16 really probably looking at there is the WAC+3 and the
17 consolidated billing. And to the extent that that relates
18 to biosimilars, it's going to affect just that group of
19 drugs.

20 MS. BRICKER: One last thing. I just noticed on
21 our reading material, 6, the number one drug in spend took
22 zero inflation since its launch in '13. Is that right?

1 MS. NEUMAN: Yes.

2 MS. BRICKER: Thank you.

3 DR. CROSSON: Clarifying questions?

4 Jack.

5 DR. HOADLEY: So I have a couple that are kind of
6 down in the weeds. One was I was just struck by Amy's
7 comment. It seems like we discussed this once. The
8 inflation adjustment, are we basically going to only look
9 at -- proposing only to look at inflation from essentially
10 the enactment of this new policy forward, or is it sort of
11 retroactive to inflation that is historical?

12 MS. NEUMAN: It would largely be from the policy
13 going forward, although you might set it a couple quarters
14 back so that you avoid opportunities for gaming.

15 DR. HOADLEY: Yeah. Okay. Or even from
16 enactment of the law or something like that. So, I mean,
17 that would be part of why the savings wouldn't be as great,
18 as if we were sort of recapturing sort of historical
19 inflation.

20 In the reading materials on pages 36 and 37, this
21 may have been in previous rounds, but I missed it. This
22 one had to do with the footnote where you talk about what

1 happens to the consolidated billing code at the front end
2 when the new biosimilar enters the market, and you say
3 there that the payment rate, until there is an ASP for the
4 biosimilar, would be based solely on the ASP for the old
5 drug.

6 In looking at the two examples that we have in
7 the case of Zarxio, that will cost us a little bit in the
8 sense that Zarxio came in with a WAC that is below the
9 competing drug, but in the case of the Remicade and
10 Inflectra, the biosimilars come in 20 percent higher. I
11 guess I am just sort of wondering about -- would there be
12 other -- would it be worth sort of mentioning there might
13 be other ways to think about that, whether we would want to
14 sort of use the WAC for those first couple of quarters as
15 part of setting that consolidated billing code? And sort
16 of regardless of that, it does seem like probably that
17 should be -- that policy point should be more than just
18 showing up in the footnote because it seems like it's
19 actually potentially fairly important.

20 MS. RAY: We can reflect your comment in the
21 chapter. Yes.

22 DR. HOADLEY: And my other question comes up in

1 the reading material on the DVP arbitration, and it was
2 sort of triggered by Bill's comment, which is whether each
3 of the DVPs would do a separate arbitration.

4 I know in the material, you do sort of speak to
5 that as one of the questions to be resolved, but it sounds
6 like in the way that you phrased it there that you are sort
7 of concluding that the only logical way from sort of an
8 administrative point of view is to have them do it
9 collectively. I just wondered if you had any more to say.

10 With Bill's sort of idea that that could
11 potentially include some discussion over formulary
12 placement, that would be a reason why sort of separate
13 arbitrations could make sense. So I just wondered if you
14 had any more thinking about sort of separate versus
15 collective.

16 MS. NEUMAN: So from an administrative
17 perspective, what you said about anticipating just one
18 arbitration for a product in a time period was the
19 thinking, and the paper sort of discussed the arbitration
20 potentially being quite narrow, so just price or something
21 like that. And in that case, there wouldn't necessarily be
22 issues if a group of DVPs were represented by a single

1 arbitration. So you might have to narrow your scope to
2 sort of make it work.

3 DR. HOADLEY: So it might just be worth kind of
4 putting that elaboration in.

5 DR. CROSSON: Questions. Alice.

6 DR. COOMBS: So say a provider goes with a DVP
7 program. Admin costs before and after changes, or is it
8 fixed, and what percentage? The administrative costs.

9 MS. NEUMAN: Could you say a little more?

10 DR. COOMBS: So what is the baseline
11 administrative cost prior to the DVP program currently?

12 MS. NEUMAN: So how much are we spending on drug
13 administration? I'd have to look. We had it in our
14 chapter. Yeah, I think it's in a footnote. We can find
15 that for you.

16 DR. COOMBS: Okay.

17 DR. MILLER: But the fundamental answer, though,
18 to her question is -- and I think this came up in Amy's
19 question -- is what they get through the fee schedule for
20 the administration doesn't change if they're in the buy-
21 and-bill or in the DVP.

22 DR. COOMBS: Right, right. Okay.

1 DR. MILLER: So whatever the number is, it can
2 remain --

3 DR. COOMBS: Do going into the DVP does not
4 change that at all in the big picture?

5 DR. MILLER: No.

6 DR. COOMBS: Okay.

7 DR. MILLER: But I also don't want anybody to
8 miss this. What is changing is what is paid for the drug.

9 DR. COOMBS: Right.

10 DR. MILLER: You stay in the buy-and-bill. Buy-
11 and-bill starts to move to 103, and then if you go into the
12 DVP, it is the negotiated price. And then if you have
13 savings, you share in those savings, but the admin
14 underlying fee to the physician for the administration of
15 the drug stays constant between the two settings -- or I
16 mean two payment systems.

17 Dr. COOMBS: Right, right.

18 And have we thought anything about provider-owned
19 DVPs in terms of if that were to occur?

20 MS. NEUMAN: So that is not something that we
21 have contemplated.

22 DR. MILLER: I was going to say the direct answer

1 is no. I hadn't thought of it until this moment.

2 Do you have a concern or a set of issues there?

3 DR. COOMBS: Well, I would just encourage us to
4 kind of maybe spend some time thinking about it.

5 DR. CROSSON: Bill.

6 DR. HALL: Thank you.

7 The third or fourth time around, I think I am
8 starting to get this. I really appreciate the detail that
9 you have been able to provide.

10 I have just a question about the potential of
11 adding another way of payment. Very heavy on negotiation,
12 arbitration when necessary. There is very little mention
13 of the value, clinical value of the products that we are
14 talking about, and I think Alice is going to lead us into a
15 discussion about low-value products.

16 So I introduce a new drug into the marketplace.
17 The arbitration for pricing on that is based solely on
18 things that don't really relate to what we will know about
19 the drug 2 or 3 years later or maybe 10 years later, where
20 it has inherently low value. Is there any way that this
21 new system could be manipulated by manufacturers who put
22 kind of a bum product on the market? What level does that

1 take place, and can we get more value, clinical value in
2 addition to financial cost for a rectification?

3 MS. NEUMAN: So if a product comes on the market
4 and it doesn't have any clinically meaningful improvement
5 over other products that are already on the market --

6 DR. HALL: Yeah. All we know about it is it has
7 a different -mab at the end of its name.

8 MS. NEUMAN: And so --

9 [Laughter.]

10 MS. NEUMAN: So, in that case, if there is a
11 sense that the products are similar, that one is not better
12 than the other, then some of these tools that the DVP
13 vendor have would permit it to potentially secure discounts
14 through formulary and other kinds of management tools.

15 And if the product is not any better than other
16 things on the market, then it wouldn't necessarily be a
17 candidate for arbitration because those other tools that we
18 have been talking about would be put to use, and it
19 wouldn't probably meet the criteria for arbitration.

20 DR. HALL: Just a thought that as we modify and
21 develop this, this might be an added opportunity associated
22 with this new structure to take a look at value-added as

1 opposed to value-diminished when we introduce new products
2 that don't work.

3 DR. CROSSON: Clarifying questions?

4 Bruce.

5 MR. PYENSON: Thank you.

6 There's a footnote, Kim or Nancy, on page 8 on
7 how ASP is calculated, and there's some words there that
8 sound legalese, as though they're taken from a legal
9 document of what does not affect average sales price and
10 its bona fide service fees; for example, fees paid by the
11 manufacturer to entities such as wholesalers and so forth.
12 And I've got a couple of questions about that, which
13 perhaps you could help me with.

14 One is, are we talking about 3 percent, 5
15 percent, 50 percent? Is there any view of how big those
16 payments could be or are in the real world?

17 Another is that condition of what's characterized
18 as a bona fide service fee, is that fee -- there are some
19 conditions listed there. One is that the fee is not passed
20 on in whole or part to the customers of the entity, meaning
21 the customers of wholesalers. And how that's administered;
22 that is, is that a rule imposed on the manufacturer and not

1 -- it's not a rule imposed on the wholesaler, presumably,
2 or is the manufacturer required to have that -- those terms
3 in its contract with wholesalers? So how would that rule
4 be enforced downstream from the -- and I know this is
5 pretty esoteric, but if you could shed any light on that,
6 that would be great, or perhaps these are topics for
7 future.

8 MS. NEUMAN: So a couple of responses. The
9 definition that you have in that footnote is the definition
10 that CMS came up with through regulation, and that is what
11 they tell manufacturers is okay to exclude from the ASP
12 calculation. So it is legalese because that is sort of
13 what is in the regulation.

14 We ourselves don't have a good window on sort of
15 what the size of these fees are and sort of how they are
16 being implemented on the ground. We hear anecdotally that
17 there may be some vagueness to some of them, and there
18 could potentially be use for more guidance. And so we have
19 tried to reflect that. You brought it up in the last
20 meeting, and we've tried to reflect that in this draft,
21 this idea that there might be a role for more guidance to
22 sort of improve the quality and precision of the ASP data

1 that's reported.

2 MR. PYENSON: Thank you.

3 The other question I have is on the terms of the
4 fee not be passed on from the wholesaler to the
5 wholesaler's customer. How would a manufacturer know, or
6 how would a manufacturer enforce that?

7 MS. NEUMAN: I can't speak to that currently. We
8 could look into it further for you.

9 MR. PYENSON: Thank you.

10 DR. CROSSON: Kathy.

11 MS. BUTO: I wonder if you could help me
12 understand how the inflation rebate approach would be
13 updated each year. In other words, I can understand how it
14 would be applied the first year that a drug price rises
15 above -- or the increase rises above the inflation limit.
16 How would you, going forward, update that?

17 MS. NEUMAN: So we sort of borrowed here from the
18 concept that Medicaid uses, and they sort of a cumulative
19 approach. So they have some base period, and then they
20 look at how much the consumer price index for urban
21 consumers has increased between the current quarter that
22 they are looking at and that base period. And they look at

1 the cumulative change, and then they compare it to the
2 cumulative change in the reported price for the drug over
3 that same period. And so, in that way, as you continue
4 further quarter after quarter, you get a new cumulative
5 number, and that's how it gets updated.

6 MS. BUTO: Okay, okay.

7 Just a couple of sort of almost editorial
8 comments. On page 11, you discuss some of the non-Medicare
9 issues that affect drug pricing, including patent and data
10 exclusivity, and I think it's helpful for the reader to
11 explain the differences there and why you think -- why
12 those are related to price, that patent life really starts
13 are a much earlier stage, and then it depends on FDA
14 approval times, and then date exclusivity is a different
15 deal. But both of those have an impact, and I think it's
16 helpful, rather than just throwing them out, to explain
17 that a little bit more.

18 On page 43, I think you were giving some examples
19 of some drugs where -- really to talk about consolidated
20 billing codes, where price increase differences really
21 didn't seem to be affected. There wasn't effective
22 competition, if you will. And I found it -- the examples

1 were useful, but using percentage increases wasn't that
2 helpful. In one case, I think it was -- I can't remember
3 which one -- one of the examples you used, a combination of
4 actual absolute price for one drug in the two you were
5 comparing, and the other was the increase in prices
6 percentagewise for the other one. I mean, I think it would
7 be useful to have both the absolute prices and the
8 increases just for clarity, because I think it makes the
9 point more precisely.

10 And then the last point is really related to, I
11 think, what Bill Gradison and Jack have touched on, and it
12 has to do with the VBP and the use of arbitration. I
13 listened to the presentation, and when, Kim, you were
14 talking about it, you alluded to the fact that the binding
15 arbitration might serve as a propped -- or incentive for
16 manufacturers to sit down and negotiate. And I don't think
17 that these other options for single-source drugs or new
18 drugs comes across as well as it should. In other words,
19 arbitration is one tool, but it actually might provide
20 incentives for other arrangements that might achieve the
21 same goal, and that really gets to Jack's point of
22 different VBPs might have greater or lesser leverage in one

1 respect or another, including demanding better data on the
2 first years of a new drug, et cetera.

3 So I would just try to beef that up a little bit.
4 It's certainly implied in the write-up and in the
5 recommendation, but it comes across more as, you know,
6 binding arbitration is the way to deal with these. But I
7 think you meant there would be greater flexibility.

8 DR. CROSSON: Thank you.

9 Questions? Brian.

10 DR. CROSSON: Thank you. Questions? Brian.

11 DR. DeBUSK: I wanted to revisit the footnote
12 that Bruce mentioned back on page 8 on the ASP calculation.
13 I understand we need to dig a little bit more into, you
14 know, what is a bona fide fee paid from the manufacturer to
15 the GPO or to the distributor. But could you help me
16 understand how that would work within the context? Some of
17 these wholesaler agreements to the providers actually have
18 negative distribution margins. I mean, you will see a
19 pharmacy distribution contract at, say, cost minus 7.
20 Could you help me understand how that would work if you had
21 a negative distribution margin but then these other fees
22 were coming in? How would all that work to alter the ASP?

1 And, by the way, Bruce, to your question earlier
2 about would they know, yes, wholesalers do give sales
3 tracings, what they are called is "sales tracings," back to
4 who they sold those drugs to.

5 MS. NEUMAN: So I understand your question, and I
6 don't think I can speak to it at this point. I do think
7 it's something that we need to do a little bit more digging
8 on and think through and come back at a later time.

9 DR. MILLER: And the two questions that I've
10 heard come up on this is: Do we know what this number is?
11 And I'm worried that we're not going to have a lot of line
12 of sight on that, so just -- my job is always to lower
13 expectations. And then I think the second question which
14 maybe we could bring something to is: Well, if you were to
15 enforce this or how you would know, you know, either from a
16 manufacturer, a wholesaler, or program point of view, maybe
17 we can bring something to bear there. But I'm not
18 optimistic that we're going to be able to know what these
19 numbers are. I'm not sure how we would know.

20 DR. DeBUSK: If I could follow up on that, I
21 would just be curious to see how a negative distribution
22 markup would actually allow a higher price to be sold --

1 you know, the ASP recorded to the wholesaler would be
2 higher, but then you would provide it to the hospital or to
3 the provider at a negative -- say a minus 7 markup. But
4 then these other fees would come back in. I'm just trying
5 to figure -- it seems like that would artificially inflate
6 the ASP, you know, possibly double digits. So any work
7 there would be appreciated.

8 DR. MILLER: Yeah, and it might be that we could
9 put together a hypothetical example about how if somebody
10 were to do X, you know, how does it trace through to the
11 ASP as opposed to what's actually gone on, which I think we
12 would have a hard time getting into. But I think I see
13 your point. If I were to do X, how would that play through
14 to the rest of the ASP. We may be able to mock up
15 something like that. I guess.

16 [Laughter.]

17 DR. MILLER: I just got the look from Kim that
18 was like, "We're going to talk about this."

19 DR. CROSSON: Okay. Thank you. Good questions.

20 We're going to proceed to comments and then
21 proceed to the vote. What I thought I would do in terms of
22 starting the comment period is to make a few remarks, I

1 think which will be understood by the Commissioners, but I
2 think for the benefit of guests -- and we have a bunch here
3 today -- who have not been present over the last two years
4 or so as we have worked on this issue, to provide some
5 context.

6 The Commission has been working on this issue for
7 two years or so. Why? Because we felt that it is our
8 obligation to deal with the escalation of the cost of
9 drugs, including in this case those that are paid through
10 Medicare Part B, for the benefit of the long-term solvency
11 of the Medicare program and also for the growing cost
12 burden that is borne by Medicare beneficiaries, many of
13 whom are financially vulnerable. That is, in fact, those
14 two aspects -- solvency of the Medicare program and the
15 benefit of beneficiaries -- are our primary duties.

16 That said, this is and has been a complex
17 undertaking because, first of all, Medicare does not
18 directly pay drug manufacturers or distributors; and,
19 secondly, Medicare does not set the prices it will pay for
20 drugs either in Part B or Part D, but it does that for
21 almost everything else it pays for. So we fundamentally
22 have been dealing with a different situation than we do in

1 most areas of Medicare expenditures, which has added to the
2 complexity, really, of coming up with a set of
3 recommendations or a recommendation with multiple parts.

4 So that said, we have come up with a
5 recommendation, and it consists necessarily of a set of
6 parts which we believe are balanced in a number of ways.

7 First of all, we understand -- again, referencing
8 Part B Medicare drugs -- that physicians should not have to
9 be in the position of providing Part B drugs at a financial
10 loss. However, the current 6 percent add-on payment
11 overpays many physicians at institutions and is inherently
12 a cost-inefficient payment system for the Medicare program.
13 Therefore, an additional better option is needed both for
14 Medicare, for the beneficiaries, but also for physicians.

15 Second point: The problem of escalating Part B
16 drug costs consists of both very high priced single-source
17 drugs, including newly launched drugs, and an unsustainable
18 and seemingly inexorable annual price increase for many
19 other drugs, where in theory competitive market forces
20 should be more effective than they appear to be. Our
21 recommendation, we feel, addresses both of these cost
22 issues.

1 In summary, our recommendation contains elements
2 which are intended to do three things: to strengthen
3 market dynamics for Part B drugs by creating more
4 equilibrium between the buyer and the seller than currently
5 exists; to provide physicians who administer Part B drugs
6 with an alternative reimbursement system through which they
7 can more broadly participate in lowering overall drug costs
8 for their patients, while preserving quality and then share
9 with Medicare in the results of that success; and, lastly,
10 to ask Congress to provide the Secretary with certain
11 administrative tools designed to supplement market forces
12 where that's necessary.

13 So now we will proceed with comments and proceed
14 to a vote. Could I see hands for those who wish to make
15 comments? We'll start over here with Paul.

16 DR. GINSBURG: Sure. Well, you know, what guides
17 my thinking in this Part B drug area is thinking that
18 Medicare as a large third-party payer, you know, always
19 needs to take steps to make sure it's paying the right
20 amount, and usually what we guide ourselves is that the
21 right amount would be something like the outcome of a
22 market that we can't have because of third-party payments.

1 Now, when I look at these proposals, I am
2 particularly enthusiastic about the DVP proposal because
3 this proposal actually promises to create a competitive
4 market. It really is proposing to do something that is
5 analogous -- it's certainly not identical -- to what the
6 design of Medicare Part D has done of engaging private
7 plans to establish formularies and use other practices to
8 get closer to what a competitive solution would be. The
9 difference, of course, is that the decisionmakers in Part B
10 are much more the physicians than they are in Part D where
11 beneficiaries are going to pharmacies.

12 Now, it is not often the case that we have an
13 opportunity to actually foster competition in markets that
14 are important to Medicare. In that case, we tend to turn
15 to trying to simulate markets, and I think one of our
16 crudest things but I think an important thing is the
17 inflation cap. The inflation cap clearly is not a market
18 force. But I think the basis of the inflation cap is
19 saying that these price increases we're seeing are not the
20 true outcomes of a cost-driven marketplace, but really the
21 outcomes of a change in the demand side of the marketplace
22 that have made the equilibrium prices of drugs much higher

1 than they were before, and I've always seen these continual
2 price increases as an adjustment to a market that is far
3 more favorable to the manufacturers because of expansion of
4 insurance coverage than was the case before.

5 So for that reason, I think there is a good
6 rationale, even though it's crude, to have these inflation
7 caps.

8 DR. CROSSON: Kathy.

9 MS. BUTO: So I support the Chairman's
10 recommendations. I continue to -- let me start with the
11 WAC add-on. On that one, I would just suggest -- and I
12 think Bill Gradison actually suggested this last time --
13 that we may want to leave ourselves a little room to take a
14 rebate approach on this similar to the rebate approach
15 we're suggesting on the ASP inflation limit. In other
16 words, base the reduction on the actual drop in ASP after
17 the first two quarters. That has more of a feel, if you
18 will, of letting the market, you know, tell us what that
19 discount should be rather than an arbitrary just reduction.

20 I continue to see some asymmetry between the way
21 we're thinking about the inflation rebate approach and the
22 consolidated coding approach, which is that, if I

1 understand this correctly, the rebate approach requires CMS
2 to adjust the beneficiary co-pays down. The provider
3 payment actually has to go up to compensate for the lower
4 beneficiary co-pay. And the 6 percent add-on has to be
5 adjusted down. So a lot of adjustments to make this work.
6 And, in essence, the underlying thinking there is we don't
7 want the provider to have to bear the risk. We'd rather
8 have the manufacturer bear the risk of that limit.

9 On the other hand, with the consolidated coding
10 approach where we're consolidating, in the case of the
11 recommendation, biosimilars with the originator biologic,
12 there if the physician feels from a clinical perspective
13 that a drug that is higher priced than, say, the weighted
14 average payment rate, the provider has to bear that
15 entirely, that cost entirely. I think the beneficiary is
16 protected, as I recall.

17 But, anyway, to me there's a little bit of
18 asymmetry there in our thinking about wanting to be very
19 protective on the ASP inflation limit, protecting them from
20 price increases, while, you know, on a clinical
21 perspective, if there's a judgment there, they're really
22 kind of more exposed. So, again, I support the

1 recommendations, but I see that as a little bit of an
2 asymmetry in our thinking.

3 And as I mentioned in the prior round, I think
4 that to the extent you can elaborate more on the use of
5 arbitration and other alternatives, I think that's helpful
6 in thinking through something which has never really been
7 used in Medicare before, which is binding arbitration. I
8 just see it as a difficult thing to execute, but it might
9 be a helpful bit of leverage in order to get other things
10 done.

11 DR. CROSSON: Bruce.

12 MR. PYENSON: Thank you. I support the
13 Chairman's recommendation, and without going into a lot of
14 detail, I think the changes will have ripple beneficial
15 impact through the health care system, on the commercial
16 side as well. So I think there's a lot of richness in the
17 suggestions that will have other beneficial effects beyond
18 Medicare.

19 DR. CROSSON: Bill.

20 DR. HALL: I support the recommendations
21 enthusiastically. I think we're going to learn a lot from
22 this.

1 DR. CROSSON: Comments? Alice.

2 DR. COOMBS: I support the recommendations and,
3 first and foremost, I am happy to say that cost sharing for
4 the beneficiaries is one piece that has been addressed by
5 that.

6 In terms of the provider side, several things
7 have come up in my mind and others' regarding the providers
8 having changes that might occur in the midst of a contract
9 period with formulary changes, and that's one thing that I
10 think what we don't know is how that's going to impact
11 providers. I think providers that are in smaller practices
12 may be a little bit more fragile and susceptible to changes
13 within formularies, changes with the manufacturers, changes
14 in the price. So that's what we don't know in terms of how
15 a DVP might work in the setting of abrupt changes, whether
16 or not there is a product that is not included as a part of
17 the negotiations and may be required. How easy will that
18 be for the provider to acquire something that's not on
19 formulary in a timely fashion? So those are some concerns
20 I have.

21 What we don't know is eradicating the 6 percent
22 and is it going to be adequately replaced by the shared

1 savings? That's unclear. But I think the golden nugget of
2 this whole family of recommendations is the inflation
3 rebate, and I think that -- and I said this from the very
4 beginning, that all the other health care industries are
5 held to a very different type of benchmark in terms of rate
6 of increase, and I think that this should be internally
7 consistent with what we've done for the other health care
8 industries, such as hospitals and providers.

9 And so, going forward, my key concern would be
10 how providers will adjust to acute changes within the
11 manufacturer's price or the contract or the DVP program,
12 and whether or not the DVP program would have differential
13 negotiations with different groups. That may become
14 problematic as well.

15 So those are some of the issues that I think we
16 should kind of describe going forward in terms of these are
17 the things that we don't know in terms of how providers
18 will deal with it, but the cost savings that accrue to the
19 beneficiaries I think is a key part of this.

20 DR. CROSSON: Jack.

21 DR. HOADLEY: So to start with, I really want to
22 note how pleased I am with all the great staff work and

1 research that has gone into this over the two years of this
2 effort. Kim and Nancy and all the others have done a great
3 job in both explaining this stuff to us as well as bringing
4 us a lot of really relevant data. And I think our own
5 evolution from just raising this issue a couple years ago
6 to getting to the point where we now have a nice package of
7 recommendations, maybe we should pat ourselves on the back
8 for that as well.

9 Like many of us, I've got some parts of this that
10 I'm more optimistic about than others. I remain somewhat
11 skeptical about some aspects of the DVP. It has grown on
12 me a bit over the discussions, and I do think we've evolved
13 a good model for it, a big improvement over the old CAP,
14 and so it is definitely something that will be worth
15 trying.

16 I'm maybe more optimistic about some of the other
17 measures, including reducing the ASP add-on and even
18 thinking back to getting it away from the percentage add-on
19 that we talked about a year ago, the inflation adjustment,
20 the consolidated billing, which I think, you know, may be
21 very important towards -- movement towards biosimilars,
22 which, you know, right now is just a couple of drugs out

1 there on the market in the U.S. but is likely to be a lot
2 more over the next few years. And I continue to hear
3 others outside of this group who like this kind of a notion
4 of some kind of way to use a consolidated billing approach
5 to move us more quickly towards biosimilars.

6 And then the last thing I would say is just to
7 note that, as we have noted all along in these discussions,
8 there are other important steps that are outside of our
9 scope that I think are just important to point again to.
10 One is that the FDA's process of approving biosimilars as
11 well as some of the rules that they operate under mean that
12 we're much behind Europe in getting a lot of biosimilars
13 approved for the market, and hopefully that will change,
14 and we'll get more of these out of the FDA in the near
15 future. We're definitely going to need better
16 understanding about substitutions for biosimilars. Part of
17 that is getting the FDA to settle on its interchangeability
18 policy, but it goes beyond that. And, again, what can we
19 learn from the European experiences in where some of these
20 that are maybe not ending up deemed interchangeable by the
21 FDA, still are considered by the research record to be good
22 substitutes? And we just need to understand that more.

1 And then it goes beyond the biosimilars, you
2 know, and I think it's good that we're raising the issue of
3 continuing to look at the consolidated billing options
4 outside of the biosimilars. They will be more difficult
5 undoubtedly, and so part of that is the need to understand
6 better the comparative effectiveness and the cost
7 effectiveness of the competing products for rheumatoid
8 arthritis, for macular degeneration, for multiple
9 sclerosis, and a lot of these other conditions that have
10 very expensive drugs so that we can, you know, get the
11 system -- get Medicare to move to the less expensive
12 effective alternatives where that's possible.

13 Thank you.

14 DR. CROSSON: Comments? Amy.

15 MS. BRICKER: Again, thank you so much for all of
16 the work. These issues are so complex, and I would say
17 that I am in support of about 80 percent of the Chairman's
18 recommendation.

19 You know, three things have really been for me
20 hard to rationalize and support wildly, and those being --
21 and this is consistent with prior comments I've made, but I
22 would like to go back through it.

1 So consolidated billing. I understand why the
2 Commission wants to get in front of, you know, biosimilars
3 and biologics and the pricing associated. You know, the
4 comments that Shinobu made around novel products and
5 single-source branded products and the gross price
6 increases that the system has incurred, I mean, you would
7 want to then put something in place today so that you could
8 potentially head off, you know, a future path. I
9 understand that.

10 My concerns remain around biosimilars have so
11 much headwind. There has been so much regulation already
12 put before that's naming -- and in the chapter around Part
13 D, we go through this, right? So this is the least of my
14 concerns, but I could get there. I understand why we want
15 to do it. I just still fear, given the infancy of
16 biosimilars, why would we not encourage more manufacturers
17 to market. So that aside.

18 Inflation cap, I mentioned this, and the reason
19 for my questions around the inflation cap were really to
20 better understand what's driving the inflation. I am
21 concerned that if it's not generics, if generics are
22 actually deflating -- I don't know. That's just a

1 question. If generics are deflating and yet we encourage
2 an inflation cap, do we, in fact, cause the generic
3 deflation to reverse to inflation, if that's, in fact,
4 happen. I don't know.

5 I would encourage us to not have the government
6 set inflation protection. So in the Part D space, it's in
7 your Part D materials, too. This is very common for
8 private entities to negotiate with manufacturers around
9 inflation protection. But it is a matter of private
10 contract. And so if there's a way to do this as part of
11 the DVP, I would be more enthusiastic about it versus just
12 setting a blanket you're going to only inflate by X
13 percent.

14 Which brings me to my last point. So I was
15 really encouraged, like others have already mentioned,
16 around embracing more of what is working today in Part D
17 and in fostering a free market sort of approach. DVP,
18 while wildly complex, while creating an entity that does
19 not exist today, there are so many tentacles with respect
20 to how this will operate. I am in support of us attempting
21 to get there.

22 I am absolutely opposed to arbitration because

1 the message that the Commission is sending is that we
2 believe in free market, but then we don't. The free market
3 today would allow for many of the things that we're
4 attempting to do with the DVP. But then to say unless the
5 free market can't do it, then we have this other solution.

6 So the things I think are still worth
7 considering, and I fear we haven't had enough discussion
8 around what does arbitration do, how does it play out, is
9 that I go back to if -- and this is Part D, but just so --
10 because everyone is aware of what happened with hep C. But
11 if arbitration existed when hep C products came to market,
12 and the manufacturer said, "I want \$100,000," and the DVP
13 would say -- I'm just making this up -- \$75,000, how would
14 we have ever gotten to \$40,000, which is where we are
15 today? You have an outside entity that's saying, "I think
16 \$75,000 is fair."

17 So as competition comes to market and you have
18 more entrants, why would they go to 40? They would stick
19 at, "Okay, I'll got at 70, I'll go at 68." I don't think
20 that arbitration ultimately results in lowering the
21 pricing. I don't. I think the way also the DVPs are
22 structured, we have to solve for then how are they not

1 colluding. So I have a competitor, two, three, how am I
2 going to tell my competitor, "I can't get a deal done. Can
3 you?" "No." "Okay. Let's go to arbitration."

4 This is counter to the free market and in
5 fostering competition. So for me, it's a bridge too far.
6 I understand why, again, the Commission wants to do this,
7 because we see and we feel paralyzed by drug pricing and
8 practices, but there is a way for us, I believe, to foster
9 competition, to bring value to the market without adopting
10 something as drastic as this.

11 Thanks.

12 DR. CROSSON: Comments? David.

13 DR. NERENZ: Yeah, thanks. I do in general
14 support the package. I share some of the concerns that
15 others have raised, and I would just for my own part
16 emphasize again the need, as this rolls forward, if it
17 does, past our recommendation, to create the strongest
18 possible shared savings incentives in the DVP. I think we
19 have seen other examples in other CMS programs about shared
20 savings that are quite weak. In my judgment, they don't
21 affect provider behavior. They don't move the policy world
22 in a direction, and so I think particularly if we want that

1 to be the main pulling factor to get physicians or
2 physician groups into this, I just think -- but I think
3 we've made our statement here. It's then up to Congress
4 and CMS to act.

5 I would say in response to and respect for Amy's
6 concerns, I think also about process, you know, we've
7 arrived at this point. We have a recommendation on the
8 table. It's sort of a package. I will support it. But I
9 think also it's good to have those concerns on the record.
10 So as this does move forward, there may be room in the
11 regulatory space to do something more about arbitration.
12 So I do hear and respect those concerns.

13 DR. CROSSON: Comments? Rita.

14 DR. REDBERG: I just want to speak in support of
15 the Chairman's recommendation. I think a lot of the
16 Commissioners, Jack and Kathy, and certainly I think shared
17 savings is important, and I really appreciate the work that
18 Kim and Nancy and others put into this because it took --
19 you know, it was clearly a big issue, a big problem, when
20 we haven't really looked at except for the last few years,
21 and then it was really thoughtful, and I think a framework
22 that is very useful here and may be useful for other things

1 that we're going to talk about. So thank you.

2 DR. CROSSON: Comments? Warner.

3 DR. GINSBURG: I would like to make a comment
4 [off microphone].

5 DR. CROSSON: Do you want to make a comment on
6 that comment or a separate comment?

7 DR. GINSBURG: On Amy's comments [off
8 microphone].

9 DR. CROSSON: Okay. Go ahead, Paul.

10 DR. GINSBURG: I think Amy's concerns about
11 arbitration are well taken, particularly bringing up the
12 dynamic aspect of arbitration, that there may be no close
13 substitutes today for a drug, but there might be tomorrow.
14 And it really got me thinking about the fact that we
15 probably should include a mechanism where the ability to go
16 to arbitration about a price is withdrawn once substitutes
17 enter the market, should that happen, because I am
18 concerned about the dynamic of it that she mentioned. I
19 think we could probably design a way to address at least
20 some of that risk.

21 MR. GRADISON: On that point, may I?

22 DR. CROSSON: Can I just -- that is the

1 intention, Paul. I believe it's in the text. If it's not,
2 it should be. Bill.

3 MR. GRADISON: Exactly. I mean, my understanding
4 is the arbitration approach would only be used if there
5 were sole-source, and if you have a competitor, it's not
6 sole-source. It would fall down to the inflation category
7 and be considered under a different pricing mechanism.

8 MS. BRICKER: Just to clarify, if I may [off
9 microphone].

10 DR. CROSSON: Yeah.

11 MS. BRICKER: My concern isn't that you're going
12 to go to arbitration when there's competition. It's that
13 an arbitrator has essentially determine what is "the fair
14 price." And so you don't have leverage -- your leverage is
15 reduced in the future, I fear, that if an arbitration has
16 said the fair price is \$75,000, in my example, how do you
17 ever get to something far less? You have an outside force
18 that's already declaring it's been fair. So that's my
19 concern.

20 DR. CROSSON: I think, Amy, if I could respond
21 there, I think the intention -- and perhaps it's not laid
22 out exactly -- although I can't remember exactly, but the

1 intention here is that were arbitration actually to be
2 triggered -- and, again, I think we have heard the comments
3 that particularly based on the design of the arbitration,
4 it would be a very unusual phenomenon. But once it's
5 triggered and let's say the arbiter finds for a particular
6 price, that doesn't mean that that is the price forever.
7 What it means is that's the most that can be charged. And,
8 therefore, in the event that a second drug or a third drug
9 comes on the market and now we have a competitive dynamic
10 that we didn't have before, that negotiation process that
11 would take place based on that competitive dynamic could
12 very well drive the price lower.

13 MS. BUTO: But, Jay, I think Amy's earlier point,
14 which I really see, is that the shadow pricing that goes on
15 with the second and third and fourth drug, there will be --
16 there could be some sluggishness in price reductions
17 because there is an established price. In other words, the
18 willingness to go a lot below that may slow down, and I
19 think -- I'm trying to think of the example, but there have
20 been examples in Medicare where the regulated price really
21 can interfere with, if you will, market forces. So I think
22 that was the point I got from your comment, which I hadn't

1 thought about before but I think is worth at least noting
2 in the text, that this is a concern, and that's why you'd
3 want to use it rarely.

4 DR. CROSSON: Okay. Fair enough. Thank you.

5 DR. REDBERG: Can I just --

6 DR. CROSSON: I'm lost now. Where am I? You.

7 DR. REDBERG: I understand your concern, but I
8 don't actually share it, and I have not been impressed that
9 market forces work very well at all in drug pricing or that
10 arbitration could not work better than where we are now.

11 DR. CROSSON: Okay. I think we had Warner last.

12 MR. THOMAS: Thanks. First of all, I want to
13 applaud the work that has been done, and I think that this
14 is certainly a step in the right direction.

15 I guess my view is that, given the magnitude of
16 the issue, I still wish the Commission was going further
17 from a pricing perspective. I believe in the fair -- you
18 know, a competitive market, but I would agree with Rita
19 that I don't think that a competitive market has worked in
20 pharmaceutical pricing. I'm not big on setting pricing,
21 but we do it in every other area of Medicare, and that's
22 just the reality of how the system works today.

1 My preference would be seeing us move to more of
2 a price-setting model for pharmaceuticals given the
3 magnitude of them and given the fact that -- I mean, we
4 were just talking about Part D, which I believe is more of
5 a fair market model, that I think we heard is running a
6 price increase of 8 to 9 percent and a cumulative increase
7 of 200 percent over a pretty extended period of time. So
8 it would appear that that fair market model has not
9 necessarily worked to create the right pricing competition
10 and to control pricing over time.

11 With that being said, I think the inflator is a
12 good model to help control that going forward. I would
13 encourage us to look at the market basket for providers
14 less any sort of rollbacks or adjustments that are applied
15 to them, because I think that is applicable so that we get
16 a net amount of that.

17 I think the last comment I would make is that I
18 would hope -- I know the DVP would be put in place by 2022.
19 My hope would be that that could potentially be accelerated
20 given the magnitude of this issue. But once again, I would
21 like to see us go further given the seriousness of the cost
22 increase here.

1 I also would ask in the chapter if there could be
2 -- I know there was a paragraph put in related to the
3 profitability of this industry. I would ask to see more
4 information of what's available out there because, once
5 again, when we do this in other components of the programs,
6 inpatient, home health, physicians, et cetera, we have a
7 pretty robust discussion of this area. And I think that's
8 an important background context of how we set all this
9 policy going forward.

10 But, with that being said, I would applaud the
11 fact that there is information in there that I think is
12 helpful as we make this decision.

13 Thank you.

14 DR. CROSSON: Brian.

15 DR. DeBUSK: I enthusiastically support the
16 Chairman's recommendation as written. I think the Drug
17 Value Program has a lot of really good thinking that's been
18 placed in it, particularly around some of the agency issues
19 and the way that there are different tiers. You know, it's
20 a complete tool set for working with manufacturers.

21 I also want to take just a moment and comment on
22 the proposed improvements to the ASP system, because,

1 unfortunately, we've been saddled with a system
2 particularly for single-source drugs that is designed to
3 increase prices. I mean, if you look at a system where the
4 more you -- the more expensive it is, the more you make, I
5 mean, it's just -- I mean, the system's working as
6 intended. And I know in the text, particularly in the
7 introduction, you know, we talk about -- I think the word
8 we use is maybe "concerns" exist. Well, it's beyond
9 concerns. I mean, it's obvious, and that we've wired a
10 system to work a particular way, so we shouldn't act
11 surprised when it works the way we wired it to work.

12 So my comment on these improvements to the ASP
13 system, to me this is -- and I share Warner's concern. I
14 don't know that we've gone far enough. I mean, I would
15 describe what we're doing as a gentle tapping of the brakes
16 on a system that's designed to go faster and faster.

17 So I see these as very reasonable
18 recommendations, and, again, I enthusiastically support the
19 recommendation as written.

20 DR. CROSSON: Seeing no further -- seeing one
21 further comment.

22 MR. THOMAS: Sorry. And I do support the

1 recommendation, by the way. I think the other comment that
2 I would have, getting back to ASP, is that it still does
3 come back to essentially pharmaceutical companies setting
4 their own pricing. And I think the other thing that -- and
5 this may, you know, not be a popular view, but I think the
6 other thing is that this is a domestic price. It would be
7 interesting to see what ASP or the WAC looked like if you
8 looked at a global price versus a domestic price. I know
9 that that's probably outside of the realm of this, but I
10 think just from a competitor perspective, it could be an
11 interesting thing to look at, and it may reset people's
12 views of how they look at pricing overall.

13 So, anyway, with that being said, I'll end there,
14 Jay. Sorry.

15 DR. CROSSON: Okay. Thank you. And we have come
16 to an expiration of the time, so we'll proceed to the vote.
17 The recommendation is before you. Can I see the hands of
18 all Commissioners voting in favor of the recommendation?

19 [Show of hands.]

20 DR. CROSSON: Okay. Thank you. All those
21 opposed?

22 [No response.]

1 DR. CROSSON: All those abstaining from voting?

2 [No response.]

3 DR. CROSSON: Okay. We have reached an end of
4 this. Again, Kim, Nancy, thank you so much for so much
5 work and perseverance and imagination and helping us get
6 here.

7 Just for the record, we have one Commissioner, I
8 will say, who has been detained. We will record his vote
9 later in the day provided he is able to make the meeting
10 before we adjourn this evening.

11 [Pause.]

12 DR. CROSSON: Okay. I think we can sit down now
13 and get back to work.

14 Now I think we are going to move on to a much
15 easier issue.

16 [Laughter.]

17 DR. CROSSON: Eric, did we give you any medal or
18 formal recommendation -- or recognition for the chapter?

19 MR. ROLLINS: No.

20 DR. CROSSON: I can't remember. Okay. But you
21 do realize you have set a personal record here.

22 MR. ROLLINS: I can't take credit for myself.

1 This is a --

2 DR. CROSSON: A group effort. All right.

3 Seriously, we are proceeding to the construction
4 of a chapter on premium support, at least from the
5 perspective of were Congress to decide to go in this
6 direction, what it might do, and we are going to pick up, I
7 think, the last piece here, which has to do with, were this
8 to take place, how would we deal with the problem of low-
9 income beneficiaries, and Eric is going to take us through
10 that. And I hope I haven't given your intro again, but go
11 ahead.

12 MR. ROLLINS: Thank you. Good morning.

13 Today, I am going to summarize the work that the
14 Commission has done over the course of this meeting cycle
15 on using premium support in Medicare.

16 The Commission's work often focuses on improving
17 provider incentives, but beneficiary incentives can play an
18 important role as well, and the Commission has been
19 interested in premium support because it would give
20 beneficiaries an incentive to use lower-cost forms of
21 coverage.

22 Under a premium support model, Medicare would

1 make a fixed payment for each beneficiary's Part A and Part
2 B coverage, regardless of whether the beneficiary enrolls
3 in fee-for-service or a managed care plan.

4 The beneficiary premium for each coverage option
5 would reflect the difference between its total cost and the
6 Medicare contribution, which means that higher-cost plans
7 would have higher premiums and lower-cost plans would have
8 lower premiums.

9 I would like to begin by giving you a brief
10 overview of the presentation. I will start by summarizing
11 the main points of the draft chapter on premium support
12 that will appear in the Commission's June 2017 report to
13 the Congress. This chapter lays out some of the key issues
14 that would need to be addressed if policymakers chose to
15 use premium support in Medicare.

16 After that, I will review some new material that
17 we have included in the draft chapter on the issue of
18 providing premium subsidies to low-income beneficiaries. I
19 will then raise some possible topics for discussion. It
20 would be especially helpful for us if the discussion could
21 focus on the new material.

22 Moving now to Slide 3, the draft chapter is the

1 culmination of work that the Commission has been doing on
2 premium support since 2012. The Commission has included a
3 chapter dealing with some aspect of premium support in its
4 last four June reports and has devoted four sessions to
5 this issue over the course of the current meeting cycle.

6 Our work during this cycle has very much been a
7 team effort. In October, Ledia and Carlos discussed how
8 quality could be measured and rewarded in a premium support
9 environment.

10 In November, I gave a presentation that examined
11 how benchmarks and beneficiary premiums could be calculated
12 and explored how policymakers could mitigate large
13 increases in beneficiary premiums.

14 At last month's meeting, Carlos gave a
15 presentation on standardizing various elements of a premium
16 support system, while Amy, Scott, and I discussed the
17 potential effects that premium support might have on
18 beneficiaries and managed care plans.

19 The draft chapter that you received as part of
20 your mailing materials consolidates the material from these
21 sessions into a single document and reflects comments that
22 Commissioners made during their discussions.

1 I will now briefly review the main points from
2 those earlier sessions before turning to the new material
3 on premium subsidies.

4 The first key issue discussed in the draft
5 chapter is the role of the fee-for-service program, which
6 covers about 70 percent of beneficiaries. In the draft
7 chapter, we suggest that, under premium support, the fee-
8 for-service program should remain available and be treated
9 like a competing plan. Under this approach, fee-for-
10 service would operate much as it does now, but CMS would
11 develop a bid for the expected costs of fee-for-service
12 coverage, and this bid would be compared to the bids
13 submitted by managed care plans to determine how much
14 beneficiaries would pay for fee-for-service coverage.

15 This approach has several benefits, such as
16 ensuring that Medicare coverage is available in areas
17 without managed care plans and helping plans negotiate
18 payment rates with providers that are close to fee-for-
19 service levels.

20 Next, the draft chapter examines how much the
21 coverage options that would be available under premium
22 support should be standardized to make them easier for

1 beneficiaries to understand. We suggest that all plans
2 should be required to cover the same benefits as fee-for-
3 service, as they are now in the MA program.

4 Policymakers may also want to consider reforming
5 the fee-for-service benefit structure to make it more
6 similar to the benefit structures now used by MA plans, as
7 the Commission recommended in 2012. Managed care plans
8 would have the flexibility to use alternate forms of cost
9 sharing and offer extra benefits, although beneficiaries
10 would not be required to buy them, and those that do would
11 pay premiums that reflect their full incremental cost.

12 Beneficiaries would also need better decision
13 support tools to understand their coverage options and make
14 an informed choice about the coverage that best meets their
15 preferences.

16 Moving now to Slide 5, the draft chapter also
17 examines how benchmarks and beneficiary premiums should be
18 calculated under premium support. The benchmark would
19 serve as a reference point for the cost of providing Part A
20 and Part B benefits and would have two components: the
21 Medicare subsidy and a base beneficiary premium.

22 For any given coverage option, beneficiaries

1 would pay an amount that equals the base premium plus the
2 difference between the plan's bid and the benchmark.

3 Premium support proposals typically assume that
4 competitive bidding would be used to determine the
5 benchmarks. In the draft chapter, we discuss two possible
6 ways to do this. The first option would use the lower of
7 the fee-for-service bid or the median plan bid as the
8 benchmark, while the second would use the weighted average
9 of all bids. Both options are appealing because they would
10 produce benchmarks that fall somewhere in the middle of the
11 distribution of bids, instead of using something like the
12 lowest or second-lowest bid.

13 The bidding process should also use bidding areas
14 that reflect local health care markets. This would result
15 in benchmarks that vary across areas due to the geographic
16 variation in Medicare spending, and would provide some
17 protection against higher premiums to beneficiaries who
18 live in high-cost areas.

19 The base beneficiary premium should be similar to
20 the Part B premium and equal, about 13 percent of total
21 Part A and Part B costs.

22 Some proposals to use premium support would limit

1 the growth of the Medicare subsidy over time to ensure that
2 the federal government saves money. The Commission
3 maintains that this type of limit would not be desirable
4 because beneficiaries would bear the risk of paying higher
5 premiums without being able to take actions that lower
6 their premiums in a meaningful way.

7 An alternate approach would be to have the
8 benchmark, Medicare subsidy, and base beneficiary premium
9 all grow in tandem with plan bids, as they do now in Part
10 D, and see if competition among managed care plans can
11 achieve savings.

12 Under premium support, some beneficiaries would
13 see the premiums for their existing coverage increase
14 significantly. The kinds of beneficiaries that would be
15 affected would vary across areas. In some areas, the
16 higher premiums would mainly affect fee-for-service
17 enrollees, while in other areas, they would mainly affect
18 managed care enrollees. Beneficiaries could avoid paying
19 higher premiums by switching to lower-cost forms of
20 coverage, but there would also be numerous ways for
21 policymakers to mitigate large increases in premiums, such
22 as phasing in the higher premiums over time.

1 The draft chapter also discusses how high-quality
2 care could be rewarded in a premium support system. To do
3 this, CMS would need to measure quality for both fee-for-
4 service and the managed care plans within each market area,
5 preferably using a limited number of outcomes measures.
6 Policymakers would require managed care plans to meet
7 minimum quality standards and would publicly report quality
8 data for both fee-for-service and plans.

9 High-quality plans, which could include fee-for-
10 service, could also be rewarded financially by increasing
11 their Medicare contribution, which would allow them to
12 charge lower beneficiary premiums.

13 Finally, the draft chapter discusses some
14 potential effects that premium support could have on
15 beneficiaries and plans. Premium support is based on the
16 notion that beneficiaries will be willing to switch plans
17 to lower their premiums. There is some evidence that this
18 type of switching occurs in MA, but it is difficult to know
19 how responsive beneficiaries would be under premium
20 support, where the changes in premiums could be much larger
21 than what we have seen in MA. In some areas, we would
22 likely see fee-for-service enrollees switching to managed

1 care plans, while in other areas, we would likely see
2 managed care enrollees switching to fee-for-service.

3 The effects on managed care plans are also
4 difficult to predict. Plans would need to reassess which
5 markets they serve, which could lead them to enter new
6 markets and exit existing markets. The greater focus on
7 price competition under premium support would also likely
8 encourage plans to submit somewhat lower bids than they do
9 now in MA. The overall effects of using premium support
10 would vary across areas and would depend heavily on the
11 specific features of the proposal.

12 Up to this point, I focused on reviewing the
13 issues that we have discussed during our earlier sessions
14 on premium support. Now I would like to switch gears and
15 discuss the new material in the draft chapter on premium
16 subsidies for low-income beneficiaries.

17 As I mentioned earlier, the Commission has been
18 interested in premium support as a way to encourage
19 beneficiaries to use lower-cost forms of coverage. At the
20 same time, though, policymakers would need to make sure
21 that low-income beneficiaries can afford to buy coverage.
22 Premium subsidies are a way to balance these competing

1 goals.

2 Medicare and Medicaid already provide significant
3 premium subsidies under current law. Medicaid covers Part
4 B premiums through what are known as the Medicare Savings
5 Programs, or MSPs, while Medicare covers Part D premiums
6 through the Part D low-income subsidy, or LIS.

7 Premium support would effectively change how the
8 Part B premium is calculated, so the MSPs would be a
9 logical starting point for providing premium subsidies.
10 However, under premium support, policymakers may want to
11 reassess the role of the MSPs, which could include
12 incorporating some features from the LIS, which I'll
13 discuss shortly.

14 As part of that reassessment, policymakers would
15 need address three major issues: first, which
16 beneficiaries would be eligible for subsidies; second, what
17 kind of subsidy they would receive; and third, how those
18 subsidies would be financed by the federal government and
19 the states.

20 We will now look at each issue in more detail.

21 Moving to Slide 8, we start with the eligibility
22 rules for premium subsidies. The MSPs and the LIS both

1 require beneficiaries to have low income and low assets to
2 qualify for benefits. The MSPs have somewhat lower
3 eligibility limits than the LIS. For example, the MSPs
4 limit eligibility to individuals with income below 135
5 percent of the poverty level, while the LIS has a limit of
6 150 percent.

7 In 2008, the Commission recommended aligning the
8 eligibility rules for the two programs by raising the MSP
9 limits to match the LIS.

10 Policymakers would need to weigh a number of
11 factors when setting the eligibility limits for premium
12 subsidies under a premium support system. For example,
13 they would need to consider the income distribution of the
14 Medicare population and the number of beneficiaries that
15 would qualify under various eligibility limits.

16 About 15 percent of Medicare beneficiaries are
17 enrolled in the MSPs, but the share that are eligible is
18 larger because not all of those who are eligible
19 participate.

20 Policymakers would also need to consider how much
21 beneficiaries at different income levels might spend on
22 premiums. The method for calculating the Medicare subsidy

1 and beneficiary premiums would be an important factor here.
2 For example, a premium support system with a lower Medicare
3 subsidy would have higher beneficiary premiums, which could
4 be an argument for using higher eligibility limits.
5 Conversely, the existing MSP limits might be considered
6 sufficient under a system that has a higher Medicare
7 subsidy and lower beneficiary premiums.

8 In addition to the eligibility rules themselves,
9 policymakers would also need to determine how people would
10 enroll in the subsidy. Policies such as automatic
11 enrollment for certain beneficiaries, like dual eligibles,
12 and allowing beneficiaries to enroll through the Social
13 Security Administration would likely result in higher
14 participation rates among those who are eligible.

15 In particular, allowing beneficiaries to enroll
16 through SSA would be consistent with a recommendation that
17 the Commission made in 2008 that would require SSA to
18 determine if LIS applicants were also eligible for the MSPs
19 and to enroll those who qualify.

20 The next issue to consider would be the amount of
21 the subsidy. The MSPs cover the entire Part B premium, but
22 this approach would not be desirable under a premium

1 support system, where premiums would vary based on their
2 underlying costs. If the subsidy covered the entire
3 premium, regardless of the coverage option, low-income
4 beneficiaries would not have an incentive to enroll in
5 lower-cost coverage.

6 Policymakers faced a similar issue when they
7 created the Part D program, which uses a premium support
8 model. Their solution was placing a dollar limit on the
9 LIS premium subsidy. Under this approach, the LIS covers
10 the entire premium for any plan that has a premium below
11 this limit, which is commonly known as a zero-premium plan.

12 Beneficiaries that enroll in more expensive plans
13 pay the difference between the plan's premium and the LIS
14 limit. For example, if the limit is \$30, an LIS
15 beneficiary who enrolls in a plan with a \$25 premium will
16 pay nothing, while an LIS beneficiary who enrolls in a plan
17 with a \$40 premium will pay \$10. This approach ensures
18 that LIS enrollees can enroll in some plans without paying
19 a premium but also gives them an incentive to avoid higher-
20 cost plans.

21 This approach could also be used in a premium
22 support system for Part A and Part B, but policymakers

1 would need to decide what the limit on the subsidy should
2 be. Higher limits would give the beneficiaries who receive
3 the subsidy a broader choice of zero-premium plans but
4 would also increase the costs of the premium subsidy.

5 Policymakers may also want to ensure that the
6 subsidy is large enough to ensure that a certain number of
7 zero-premium plans are always available. For example, the
8 LIS limit is determined using a formula that ensures at
9 least one zero-premium plan is always available. If
10 policymakers did put a dollar limit on the premium subsidy,
11 the fee-for-service program would probably not qualify as a
12 zero-premium plan in many areas because it would be one of
13 the more expensive options.

14 The last major issue to address is how the
15 premium subsidies would be financed by the federal
16 government and the states. Broadly speaking, the premium
17 subsidies could be part of either the Medicaid program,
18 like the MSPs, or the Medicare program, like the LIS.

19 The simplest way to provide premium subsidies
20 would likely be to build on the existing MSPs and modify
21 them as needed. Since the subsidies would be a Medicaid
22 benefit, their costs would be shared by the federal

1 government and the states.

2 The federal share for most Medicaid expenditures
3 is determined by a formula and varies from state to state
4 based on their per-capita income.

5 Across all states, the federal government
6 currently pays about 61 percent of the cost of the MSPs'
7 premium subsidies, with the states paying the rest.
8 However, policymakers could change the match rate for the
9 MSPs if they wanted the federal government to pay a larger
10 or smaller share of the costs under a premium support
11 system. This decision would have significant budgetary
12 implications for the federal government and the states.
13 For example, if the MSP eligibility limits were increased,
14 the federal government could pay a larger share of the
15 costs for the newly eligible population. This would be
16 similar to the approach that the Congress used in 1997 when
17 it last expanded eligibility for the MSPs.

18 Under premium support, if the premium subsidies
19 were a Medicaid benefit, states would naturally be
20 concerned about the potential for higher costs. However,
21 the overall impact on state Medicaid spending is difficult
22 to estimate because it would depend heavily on the type of

1 premium support that was used. For example, a system that
2 has both low benchmarks and generous premium subsidies
3 might be more likely to increase state costs, particularly
4 in states where a large share of MSP enrollees have fee-
5 for-service coverage.

6 Instead of a Medicaid-based approach,
7 policymakers could also consider replacing the MSPs with a
8 system of premium subsidies that are part of Medicare.
9 Since the states now pay part of the costs of the MSPs,
10 shifting this responsibility from Medicaid to Medicare
11 would ordinarily increase federal spending and reduce state
12 spending. However, the higher federal spending could be at
13 least partly offset if states were required to make
14 maintenance-of-effort payments that approximate what they
15 now spend on the MSPs. These payments would be similar in
16 nature to the so-called "clawback" payments that states now
17 make to the federal government as part of the Part D
18 program.

19 This presentation has focused on the MSPs' role
20 in covering the Part B premium, but they also cover Part A
21 and Part B cost sharing for many low-income beneficiaries.
22 If the MSPs' premium subsidies were converted into a

1 Medicare benefit, policymakers would need to decide if the
2 cost-sharing subsidies would be federalized as well, and if
3 so, how much of the cost sharing Medicare would pay. This
4 decision would have significant cost implications because
5 states are allowed to limit their spending on MSP cost
6 sharing, and almost all states do so.

7 Prior Commission research has estimated that
8 states only pay about 35 percent of the cost sharing for
9 eligible MSP beneficiaries. As a result, if Medicare
10 covered the full amount of the cost sharing, there would be
11 additional federal costs that could not be offset by state
12 maintenance-of-effort payments. Furthermore, full coverage
13 of cost sharing could create inequities across states
14 because the states that now spend the least on MSP cost
15 sharing would benefit the most.

16 Moving now to the last slide, I would like to
17 close with some potential topics for discussion. First, we
18 would like to know if you have any comments on portions of
19 the draft chapter that summarize our earlier sessions on
20 premium support.

21 Second, we would like to get your reactions to
22 the new material on low-income premium subsidies that we

1 have presented here today, focusing on the three key issues
2 of eligibility, the amount of the subsidy, and financing.

3 Finally, we would like to hear suggestions for
4 future Commission work on the topic of premium support.

5 That concludes my presentation. I will now be
6 happy to take your questions.

7 DR. CROSSON: Thank you, Eric.

8 So we will do clarifying questions. Can I see
9 hands for questions?

10 We will start over here with Brian.

11 DR. DeBUSK: I had a question, and I guess it is
12 derived from the footnote on page 76.

13 You know, it is very novel, the way you are
14 taking that LIPSA approach to low-income subsidies for
15 premium support, and in the footnote, you mention that in
16 Part D, once the plan's premium drops below the LIPSA,
17 basically there is no incremental benefit to the
18 beneficiary to choosing a plan that is even lower cost, and
19 that that somehow sets almost an artificial floor for how
20 plans would want to bid in D.

21 The text sort of talks around it, but have we
22 modeled or would we consider modeling what to do with that

1 extra money, maybe to set that money aside for some other
2 health care spending for the beneficiary? I mean, in
3 theory, would a negative premium, if the LIPSA exceeded the
4 premium -- could we model out other things to do with that
5 money that would be beneficial to the beneficiary?

6 MR. ROLLINS: By the extra money, do you mean the
7 difference between that amount and --

8 DR. DeBUSK: The LIPSA amount and the premium --

9 MR. ROLLINS: -- the premium that is lower than
10 that.

11 DR. DeBUSK: -- for plans that are below that.

12 MR. ROLLINS: It is not something that we have
13 modeled out. You could certainly think about strengthening
14 the incentive for beneficiaries to pick one of the cheaper
15 plans of the zero-premium ones that are available by saying
16 you will get some portion of this difference yourself.
17 That would be one option.

18 In the Part D world, one thing that is a factor
19 in affecting the behavior of plans not having an incentive
20 to go much below the low-income benchmark, is the fact that
21 of the plans that are zero premium, CMS auto-enrolls a lot
22 of low-income beneficiaries to Part D plans and does so

1 equally among the plans that are sort of below that
2 threshold.

3 So one concern that has been raised is that there
4 is no additional reward, as you know, but one option you
5 could at least consider is sort of changing the assignment
6 mechanism that is used for plans that are below that
7 threshold and saying the lower you bid, the more
8 beneficiaries you could expect to get.

9 DR. DeBUSK: That is a great idea too. Thank
10 you.

11 DR. CROSSON: Questions. Bruce.

12 MR. PYENSON: Thank you very much, Eric. This is
13 really very well done.

14 A question on page 83 of the material on
15 implications for beneficiaries. You identify experience,
16 looking for precedence, experiences in the movement of
17 consumers for MA plans and Part D premiums -- Part D
18 program experiences on the packet exchanges. I am
19 wondering if you think the experiences of mandatory managed
20 Medicaid, the implementation of that has lessons for
21 premium support. Under those programs, states rolled out
22 mandatory enrollment in a variety of different ways. Is

1 that something that might be helpful?

2 MR. ROLLINS: Potentially helpful, I think, in
3 certain respects, although Medicaid managed care is very
4 different, of course, because there is no premium for
5 beneficiaries. So it is a very different dynamic than what
6 you would have on a premium support system for Medicare.

7 But I think one area where you could think about
8 sort of drawing on the Medicaid experience is -- one option
9 that is sort of raised in the paper is one way that you
10 could mitigate the impact of higher premiums on
11 beneficiaries would be to sort of the default assignment in
12 a particular -- it could be whatever is the lower-cost
13 option in that area. So if fee-for-service is the cheaper
14 option in your area, the default option for new enrollment
15 would remain fee-for-service, which is what we have today.
16 But if you live in an area where managed care is cheaper,
17 your default assignment would be to a managed care plan,
18 and I think in that context, that is getting a little
19 closer to sort of what you see in Medicaid. And what
20 Medicaid typically does in those cases is, once you have
21 been sort of assigned to a plan, if you take no action,
22 they will send you a letter saying you are in Plan XYZ.

1 Beneficiaries usually have about a 60- or 90-day period
2 once they are enrolled in the plan to sort of then change
3 to another plan, and after that, they are sort of locked
4 into the plan until the next open enrollment window. So I
5 think that would be an element that you could think about
6 incorporating.

7 MR. PYENSON: A follow-on question. But the
8 auto, that kind of enrollment for dual eligibles, where
9 there would be no premium, would that be an analogy also to
10 the Medicaid mandatory managed care?

11 MR. ROLLINS: Potentially, yes. I mean, I think
12 that's what the low-income subsidy does in Part D is the
13 dual eligibles are sort of -- we don't want them to pay a
14 premium, and so they are default -- assigned into a zero-
15 premium plan.

16 DR. CROSSON: Kathy.

17 MS. BUTO: I have a couple of questions. One is,
18 since Part D is essentially a premium support model, are
19 there any lessons in terms of what LIS beneficiaries have
20 done? In other words, have they all migrated where they
21 auto-enrolled in the lowest-cost plans?

22 And then, secondly, what do we see in terms of

1 switching based on cost, switching behavior by
2 beneficiaries more generally? Do we have a sense of that
3 from Part D? Which actually I would think would be easier
4 to switch than a health care plan, but --

5 MR. ROLLINS: Right.

6 So in terms of the overall switching, we do have
7 some figures in there about the switching that we see in
8 the Part D world, and I think in the years we looked at,
9 roughly 15 percent of your non-LIS population switched from
10 one plan to another. And we had sort of broke out the LIS
11 population, looked at it separately from the non-LIS
12 because the dynamics are so different. The non-LIS
13 population is only going to move to another plan if they
14 affirmatively choose, "I don't want to be in Plan A. I
15 want to be in Plan B."

16 MS. BUTO: Right, right.

17 MR. ROLLINS: And within that subset, we see
18 roughly 15 percent of beneficiaries switching in a given
19 year.

20 MS. BUTO: Okay.

21 MR. ROLLINS: In the LIS segment, you have this
22 additional feature of -- Part D auto-assigns you --

1 MS. BUTO: Right.

2 MR. ROLLINS: -- to a plan when you first join,
3 and then if your plan's premium goes above this sort of
4 subsidy limit --

5 MS. BUTO: They auto-assign you again.

6 MR. ROLLINS: -- you are assigned to a new plan.
7 So you see a lot more switching in the LIS segment, but a
8 lot of that is a function of sort of --

9 MS. BUTO: The algorithm or --

10 MR. ROLLINS: -- the assignment that goes on.

11 MS. BUTO: Yeah. It's involuntary, not
12 voluntary.

13 MR. ROLLINS: Right.

14 But there is still a substantial segment, and
15 Jack has looked at this. A substantial segment of your LIS
16 population has picked a plan on their own. I think I want
17 to say it's something like 40 percent.

18 MS. BUTO: Okay. The second --

19 DR. CROSSON: Wait. Sorry.

20 MS. BUTO: Sorry.

21 DR. CROSSON: Shinobu, did you want to weigh in
22 or not?

1 DR. MILLER: I asked her to go because she --

2 MS. BUTO: She was his backup.

3 DR. CROSSON: Oh, okay.

4 DR. MILLER: -- made a run-in through with stuff
5 that she had done.

6 MS. BUTO: Okay.

7 DR. CROSSON: Sorry.

8 MS. BUTO: The other question I had was on page
9 9. I am puzzling through this. It is the first bullet on
10 -- if providers negotiated Medicare payment rates with
11 managed care plans that were comparable to commercial
12 payment rates, then costs for premium support could be
13 higher than, I guess, current law or current program. So
14 that caused me to think of two questions. One was provider
15 consolidation is affecting costs, anyway, right? Both in
16 fee-for-service and probably in managed care as well, so
17 that is one.

18 So does this somehow -- is this related to the
19 fact that we don't imagine managed care plans would be able
20 to default back to fee-for-service payment rates, like DRGs
21 and -- if they can't negotiate a better deal? What are we
22 thinking in terms of commercial rates affecting the overall

1 cost of the program?

2 MR. ROLLINS: So I think a lot of that is driven
3 by the feature that you have now in the MA program, which
4 is plans, when they are negotiating rates with the
5 providers, have by law the authority to say, "If you are
6 not in my network, I will pay you the fee-for-service
7 rate," and so that greatly strengthens the plan's leverage
8 in negotiating with providers. And the available research
9 suggests that MA plans pay providers rates that are roughly
10 similar to what you see in fee-for-service, and so I think
11 the concern would be if you created a premium support
12 system that doesn't have that requirement in there, the
13 plan's negotiating leverage would be a lot weaker than it
14 is today, and then sort of the dynamics that you're seeing
15 with provider consolidation could have more of an impact.

16 DR. MILLER: And just today, CBO came out with a
17 report where they did some analysis looking at it and sort
18 of arrived at the same point that we were making a while
19 back, that the managed care plans tend to end up paying
20 around fee-for-service, and it is something that we've
21 talked about repeatedly. What you wouldn't want to do is
22 import those prices that are the product of consolidation

1 into Medicare because you basically make premium support
2 make Medicare more expensive.

3 DR. CROSSON: Questions. Around the horn, are
4 there questions?

5 [No response.]

6 DR. CROSSON: Okay. So we will start with
7 comments, and I see Bill Gradison.

8 Oh, I'm sorry. I did it again. Jack is going to
9 kick it off.

10 DR. HOADLEY: Okay. So thank you, Eric. I think
11 this is a really important topic and it also raises some
12 concerning issues, in terms of sort of how the low-income
13 beneficiaries are going to fare should such a system go
14 forward. And I will talk about sort of each of the three
15 themes that you raised, in terms of the low-income
16 population, and I think most of these are points that
17 you've got but I want to sort of focus in on certain of
18 them.

19 So on the eligibility level, you know, I think
20 there's -- there are all the issues that you raised about
21 sort of what's the right level and sort of what are the
22 implications for spending, and some of that kind of stuff,

1 but I think -- and you raise this, but I think there are
2 major issues around sort of the complexity of eligibility
3 and the whole application process, and we've addressed some
4 of that in the past with the notion, and you raised it
5 again here, that Social Security Administration can be a
6 more natural place for people trying to get their
7 eligibility.

8 A couple of points. One is that it does seem,
9 and the literature seems to suggest that the asset test is
10 something that may discourage some people from applying,
11 not because they necessarily have a lot of assets but
12 because it makes the paperwork that they're required to go
13 through much more extensive. There's all these, you know,
14 issues of what's accepted, what are the exceptions to the
15 assets, and so forth, and it leads to the paperwork for
16 qualifying being more complex, and even raises some issues
17 for people about sort of a reluctance to have to disclose,
18 you know, the values of their assets. And so I think there
19 is evidence there that sort of raises that, and I think
20 that's something that we should, you know, at least raise
21 as an issue.

22 You talked some about take-up rates. I think

1 there might be worth sort of indicating some of the levels
2 of take-up that we have today for Medicaid Savings Program
3 and for the LIS, and I know those data are difficult to
4 have, you know, clean numbers on, and certainly on the LIS
5 side we have lacked the ability to say. But we do have a
6 sense that among the LIS they're not automatically enrolled
7 through being dual eligibles. The ones that have to go
8 through an application process, there's some suggestion
9 that more than half of those eligible are not enrolled, and
10 I think the evidence suggests it's even worse on the MSP
11 numbers. And so that's just part of the context, and I
12 think that becomes more important here because the
13 consequences of not getting the subsidy that you're
14 entitled to, I think, will be greater in this system than
15 under the current system.

16 There are some studies out there. There was an
17 analysis a few years ago, a Health Affairs article that, in
18 particular, the Hispanic population has lower Part D
19 enrollment attributed to lower take-up of the subsidies
20 there. So again, there may be some factors that suggest
21 some of the ways that we could improve it, and I think it
22 would be useful to try to raise some of those issues.

1 So turning to the amount of the premium subsidy,
2 you know, I think this discussion sometimes takes a -- when
3 people talk about this, sometimes get into almost a sense
4 of blaming low-income people for not being better shoppers,
5 because of how we've structured incentives, and they end up
6 sounding like they're at fault for not saving the
7 government money, and I think we really need to dig deeper
8 into sort of what's going on for this population.

9 You know I was looking at -- well, two points.
10 One is that the choice of plan under a premium support
11 model, the choice of Medicaid Advantage versus traditional
12 Medicare, is probably going to be a much bigger deal than
13 in the Part D world, where, you know, it's pretty much just
14 all a financial transaction. Most pharmacies are in most
15 networks. You know, there are some potential issues there.
16 But for the most part you go, you pay, you get the
17 copayment that you're entitled to. And so if you switch
18 from one plan to another, it may have financial
19 implications but for the most part we are shielding the
20 low-income beneficiaries from some of those.

21 In the Part C world, in the Medicare Advantage
22 world, there's a lot bigger issues about provider networks,

1 and I think, you know, if we're going to have the kind of
2 situation where we're creating either strong incentives or
3 automatic assignment of low-income folks into Medicare
4 Advantage plans, we better make sure that we're looking at
5 whether those Medicare Advantage plans have networks that
6 serve the communities the low-income people live in
7 adequately, and that they're open and available to those
8 kinds of folks, before we start looking at that as
9 something that either is the only way you can get Medicare
10 without paying a premium, or whether it's something where
11 you're being automatically assigned.

12 And then the other piece of it is the amounts,
13 and I was looking at some of the charts you had in the
14 mailing materials, and in some of your hypotheticals there,
15 it would be something like a \$120 premium, even after the
16 subsidy, for somebody who wants to either stay in
17 traditional Medicare or perhaps pick some of the particular
18 MA plans in their given market.

19 And sort of looking at that next to the table on
20 the income levels that we're talking about, we're talking
21 about something that is, you know, 10 percent of the
22 person's income, and, in fact, since the income levels for

1 people at the federal poverty level, and since those income
2 levels are lower for couples but the premiums aren't, if
3 two people in a family are both trying to sign up for
4 traditional Medicare in an area where it's \$120 a month,
5 it's going to be 15 percent of their combined income, if
6 they're at the federal poverty level.

7 And I think we really need to think hard about
8 what that means, if we're in a kind of situation where the
9 networks and the way the particular Medicare Advantage
10 plans are organized, are not going to be satisfactory for
11 those kinds of people, and they really do need to be in
12 traditional Medicare, we're asking them to pay a pretty
13 large percentage of their income, which is probably not
14 affordable.

15 One option around this might be to think about,
16 effectively, what's been done in some parts of Part D,
17 where, you know, it's not just that the dollar value -- and
18 you pay the entire extra amount -- but maybe we scale down
19 the add-on for low-income populations, so that they still
20 face the financial differential but it's not that full
21 differential that gets up to levels where you're dealing
22 with an amount of income that's prohibitive.

1 So what we are really saying to somebody who's a
2 middle-income person, okay, you have financial incentives
3 to pick among the various options, we've tried to change
4 the way those are structured to encourage you to do certain
5 things, but they're all things you can afford to do. You
6 can choose not to do them, but if you want the advantages
7 of traditional Medicare, it's affordable to you. For this
8 population, we're putting that at a price that basically is
9 unaffordable, and I think we really need to think about
10 what that means.

11 And then, on the third -- oh, and there are other
12 issues, and I don't want to take too much more time around
13 the sort of passive enrollment and reassignment issues that
14 we've seen. You know, you talked about some of the Part D
15 evidence where a lot of people now are paying premiums they
16 shouldn't have to because they don't switch. You know,
17 it's fine to sort of think of the first year going into
18 this, and you sort of get everybody put in something that
19 works, but as things change, you know, sort of what are we
20 going to be doing? And there is -- and Bruce mentioned the
21 experiences in Medicaid managed care there's some good
22 experiences there but there's some pretty bad experiences

1 there, that haven't worked well.

2 But going on to the third issue in your list of
3 topics, how the Federal Government and the states would
4 finance the subsidies, I'm increasingly concerned about
5 keeping the financing of the support for Medicare in the
6 Medicaid program, and as the policy discussions in
7 Washington go a lot more towards -- on the Medicaid side,
8 go a lot more towards per capita caps or block grants, I
9 think the funding for the Medicare part of Medicaid, the
10 support for the dual eligibles, the support for the
11 Medicare Savings Program, could be subject to significant
12 rollbacks by states who were put in those situations, or
13 we're going to put them in situations where they're trading
14 off the interest of our Medicaid population, where those of
15 us who are sitting on a commission like this worried about
16 Medicare aren't part of that conversation, or the other
17 Medicare policy folks, this becomes -- we turn this over to
18 the states to make decisions.

19 And so I think we either have to think about,
20 pretty seriously, about moving the financing of this to the
21 Medicare side, with all the implications you raise, or if
22 we want to leave it on the Medicaid side, thinking about

1 provisions that would protect Medicare beneficiaries from
2 decisions that states make, should policy on the Medicaid
3 side shift in some of the directions that have been talked
4 about lately, and maybe that's -- you know, again, since
5 all of that is subject to new law, there's really not
6 anything we can do to permanently sort of protect that.
7 So, to me, it makes sense to really think hard about
8 bringing the financing of this back into the Medicare side.

9 Thank you.

10 DR. CROSSON: Thank you. Jack, go ahead.

11 DR. MILLER: So this is your second point, okay,
12 and you made your point about, you know, if you're going to
13 set up plans that the LIS are encouraged to go into, you
14 should be really sure that the provider networks are
15 complete. I'm with you on that. So assume, for the
16 moment, that you have accomplished that. Did I also hear
17 you saying, though, in the end of your comment, but the
18 person should have the option of going into fee-for-
19 service, even if it ended up -- even if it wasn't the
20 lower-cost option?

21

22 DR. HOADLEY: So, I mean, personally, that's

1 where I would go. I would like to preserve for these
2 beneficiaries a good traditional Medicare option. Within
3 the framework of the kinds of structure we're talking
4 about, what I'm trying to think about is to make it a -- so
5 to make it a choice that does cost them something different
6 but not with the size of the differential that results. So
7 basically, in Eric's table, in one of the examples it's
8 zero dollars in MA versus \$120 in traditional Medicare.
9 Obviously there are other examples and other situations.

10 But, you know, that dollar difference, which, to
11 me, is a choice I can opt to make and I can afford to make
12 it, to this person who is at exactly the poverty level,
13 where we're talking about 10, or for a couple, up to 15
14 percent of their income, it seems like we just made that a
15 non-viable option, and I want to, at the very least, keep
16 it a viable option by figuring out a way to scale back that
17 differential. So maybe we say there's a differential.
18 It's not 0 versus 120. It's 0 versus 30, or 0 -- you know,
19 something. I haven't thought through what the numbers
20 would be.

21 I would be happy to keep it in a situation where
22 we guarantee that person has access to traditional Medicare

1 without additional cost, but, you know, there's less
2 interest in that approach, so I'm trying to offer something
3 that's within more of the context that we're raising here
4 for this -- and again, we're not making recommendations, so
5 it's options.

6 DR. MILLER: But just to make sure I follow your
7 thinking, above whatever the income level was, you wouldn't
8 do that.

9 DR. HOADLEY: Again, personally, I would like to
10 set benchmarks for the broader premium support system to
11 maintain better access to traditional Medicare than a lot
12 of our examples do, but here I'm particularly focusing on
13 the low income.

14 DR. CROSSON: Well, and maybe I wasn't -- so you
15 would not -- having just said that then, you would not be
16 looking at some sort of graduated payment scale, for this
17 population, but you might be looking at a graduated payment
18 scale for a larger population.

19 DR. HOADLEY: Well, I mean, the premium support -
20 - so I'm working from the framework that we're laying out
21 here, and so what we've laid out is something that would,
22 depending on the cost in a particular geographic area --

1 and again, the tables, they're not on a slide so you can't
2 pull them up here -- would say, for the non-low-income
3 beneficiary you're going to pay these various amounts if
4 you want to stay in fee-for-service, and you're in an area
5 where that's the most expensive option you're going to pay
6 more.

7 What I'm suggesting is potentially, rather than
8 just put in a fixed sort of premium subsidy is create that
9 kind of a graduated system for the low-income, if we are
10 otherwise doing what we're talking about in this proposal.

11 DR. CROSSON: Right. So it would be --

12 DR. HOADLEY: Do something that's more graduated,
13 yes.

14 DR. CROSSON: Okay. So let's go back to comments
15 -- I'm sorry -- comments. Bill Gradison.

16 MR. GRADISON: First off, I think this is
17 extremely valuable. I look forward to the time when it can
18 be transmitted through one of our future reports, maybe in
19 June, because I think it would be very helpful to people
20 who have been thinking about premium support, because it
21 gives them an analytical framework at a depth that they may
22 not have had the benefit of in the past.

1 I also, however, wanted to say that I think that
2 this represents, potentially -- and I know we're not making
3 a recommendation. I've got that. But this whole concept
4 really goes to the heart of the deal that was struck in
5 1965, which, in my simplistic view, was we'd have a uniform
6 national program for the elderly, and later the disabled
7 were added, and for others of low income there would be
8 variation from state to state, which is kind of what we
9 have today.

10 Now I appreciate the Medicare program is not as
11 uniform as perhaps it was originally intended, and I'm --
12 it's where, I guess, anybody around the table -- of some of
13 the variations. But this would go a lot further, in terms
14 of changing what that deal was, because of the reality
15 that, in a sense it would take away the option that's
16 always been there, to stay with fee-for-service medicine if
17 that's what you want to do, which is what 70 percent still
18 do. So it's not exactly like it's a minority.

19 I don't -- what I'm going to say now is not an
20 analytical point, and I know that, but I don't think it's
21 just a political point either. I think it's more a
22 question of trying to decide what we mean by fairness. How

1 do you explain to somebody who moves from, say, Minneapolis
2 to Miami. They're going to have to pay a very substantial
3 amount just to have the same kind of arrangement they had
4 back home, for reasons they can't control at all. That is
5 the environment. The prices are not the same. The cost of
6 living is not the same in Manhattan and Mississippi. I
7 mean, there are variations around this country.

8 So the paper is great, but I think the
9 fundamental issue here is one that we have to, I think,
10 really make sure that we highlight effectively. I don't
11 want to simply close by saying that this very same issue is
12 being discussed -- I don't know how seriously discussed --
13 but in terms of a potential replacement for the ACA.

14 And there are a lot of changes there, but one of
15 the fundamental changes would be to move from a subsidy
16 that's based on income, related to what the premiums would
17 be -- in other words, a subsidy adequate regardless of
18 income, to permit you to buy something at the second-lowest
19 silver plan level or whatever, to a plan, which some have
20 recommended, which would be based upon using the income tax
21 system on a subsidy that's based upon age. But it's not
22 related to what it costs to buy the insurance, and would

1 mean that in some parts of the country, it would be quite
2 adequate to some, or someplace, I guess, to buy a plan.
3 For others it would be totally out of the question.

4 And so I think there's a very direct parallel
5 between those two issues, the fundamental one that's
6 underlying here, which is are you going to be able to
7 continue to get a fee-for-service plan without paying a
8 premium for it, in some parts of the country, and the
9 question of, in the case of the ACA, is not only should
10 there be a subsidy but how should that subsidy relate to
11 what it costs to buy insurance.

12 DR. CROSSON: Thank you, Bill.

13 Comments? Coming up this way. Pat.

14 MS. WANG: I just want to commend you for the
15 amount of work and thought that went into this. It's
16 phenomenally complicated, and as you concluded the chapter,
17 if people want to really consider this seriously they have
18 a lot of really complicated decisions to work through.

19 I just want to focus on the notion of auto-
20 assignment based on lowest cost option. I think that that
21 is a very dangerous and not desirable principle, if there
22 is going to be some sort of direction for folks with LIS

1 and SP, because low cost -- and I echo some of the comments
2 that have been made, Part D is one benefit. It's one
3 benefit. It's just drugs. Parts A, B, and C, it's your
4 doctor, it's your specialist. You might be in the middle
5 of a care plan. It's far more complicated and there's much
6 more at stake. There might be a reason that a plan is low
7 cost, because they've got a really skinny network, or
8 they've really put together their package of benefits in a
9 different way. In the Medicaid managed care space those
10 tend to be -- really, they're just sort of identical
11 benefits, you know, very strict regulation of networks,
12 administered pricing that is determined by the state. I
13 don't know exactly how it works in states that bid, but
14 there's much more uniformity, I think, in the benefits
15 package and also the way that the network looks. So I
16 wouldn't use that as a complete sort of template example,
17 precedent for the wisdom here.

18 Personally, I think that there are other
19 approaches to encourage enrollment in the best option, but
20 it might not be the lowest cost option. So, for example,
21 for duals who -- I mean, most Medicaid folks these days are
22 in some sort of mandatory managed care program and as they

1 age in and seamless enrollment, if that plan has a Medicare
2 option within an opt-out, it might be a first step that is
3 better because they're in that network and they're in that
4 sort of care plan, care management environment. Beyond
5 that, though, I really think that we have to be very
6 careful about this idea of going to the "efficient plan,"
7 because there could be very significant differences for
8 beneficiaries in what that means.

9 One of the things that I wondered was whether it
10 would make any sense to take a closer look at the
11 experience of some of the duals demos, which did try to do
12 some sort of passive enrollment, I think, in some cases,
13 more effectively than others, and sort of reasons for the
14 opt-out rates, which I think would underscore the issue
15 about mismatch and provider networks and so forth, and how
16 important that is.

17 To Jack's point about the sensitivity of the
18 population, the LIS population, to small amounts of money,
19 I can attest. You know, a lot of these folks are just --
20 they've just got a few bucks more income than somebody who
21 qualifies to be a full dual, and, candidly, even just, you
22 know, ensuring med adherence for somebody who's got a \$3

1 copay is very, very hard. The sensitivity, the income
2 sensitivity of the population is tremendous and I don't
3 think we should kind of underestimate that.

4 The final thing is that I realize I should have
5 raised this during the question period, but I just wonder
6 whether, Eric, you've kind of thought about sort of the
7 next phase, in the thinking about Medicare potentially
8 taking over MSP, et cetera, what are the implications of
9 that for integrated care? And when you start getting into
10 the long-term care benefit or behavioral health benefits
11 and those kinds of wraparounds, you know, it might be
12 something to think about, because I think it's a very
13 important policy goal for the country to get to, to have a
14 better system of integrated care for folks with Medicaid
15 and Medicare who need long-term care services. So I'm not
16 really quite sure how premium support would interact with
17 that.

18 DR. CROSSON: Comments? David.

19 DR. MILLER: Can I ask just --

20 DR. CROSSON: Oh.

21 DR. MILLER: In the midst of that, Eric, we are
22 going to be going back out to the dual eligible

1 demonstrations again. Did you want to say anything about
2 the middle part of her question there and what we're going
3 to be looking at?

4 MR. ROLLINS: So we have been doing a series of -
5 - so we did an initial round of site visits to the duals
6 demonstrations, sort of the year before you came onto the
7 Commission, and we had a chapter on the demonstrations in
8 last June's report, but we have sort of a second round
9 going on now. We've gone to Massachusetts and California
10 and we're going to go to Ohio at the end of the month.

11 So the use of passive enrollment and how people
12 are getting assigned to plans and how that's working out is
13 definitely an issue that we have focused on.

14 DR. CROSSON: David.

15 DR. NERENZ: Just a couple of things. A little
16 bit off of the low-income part, but in the chapter. It's
17 interesting, by page count, to me, that of the 100-and-so
18 pages we've identified I think there 2 about quality
19 measures and sort of the role of quality in consumer
20 choice. That's probably not a bad reflection, actually, of
21 the way it works now, meaning that, you know, in a lot of
22 studies publicly reported quality measures don't drive

1 choice very much, and I don't know that anything we're
2 envisioning here is going to change that very much. But
3 that's an observation.

4 But then from that, I'm curious, Eric, what your
5 thoughts are about, then, the neighbor concept of narrow
6 networks. If consumers are going to make choice,
7 beneficiaries make choice, they're going to make choice on
8 something. Now, clearly the premium, or their total
9 payment requirements would be one. But in almost all areas
10 of plan choice, whether it's Medicare Advantage,
11 commercial, or whatever, the question is, is my doctor in
12 this plan? Can I see my doctor?

13 I'm thinking that a lot of what we have here will
14 create a set of dynamics that push, perhaps, even more
15 strongly in the direction of narrow networks. A plan can
16 become more attractive through the bid and the premium
17 process by having a tight network. It's sort of where the
18 networks come from now.

19 I don't think that's necessarily bad, but as I
20 look at the diagram that's on page 60, that's really
21 illustrating a quality choice, or actually it's an
22 additional payment dynamic, I was trying to think, what

1 does this look like in practice? If I choose a plan, am I
2 also essentially choosing a distinct provider network, or
3 am I just choosing a plan as one of several means of
4 getting to the provider I want to see anyway? I don't know
5 if there's a right or wrong answer.

6 I think, Pat -- and there's an empirical question
7 underneath that might be, to what extent are providers
8 currently tightly aligned, say, with just one plan, or in a
9 given area, are providers typically contracting with all
10 plans and working in fee-for-service so that you can get to
11 the provider through any of these means?

12 MR. ROLLINS: One element in particular to
13 comment on, the idea of narrow networks. We do see that,
14 obviously, in sectors like the ACA exchanges. It's a
15 little unclear to me how much of that would go on in a
16 premium support system for Medicare because a lot of the
17 negotiations in other sectors are driven by a tradeoff of
18 volume for getting a better price.

19 And what I was talking about earlier with Cathy,
20 that is sort of this backstop on MA plans that, you know,
21 they're able to essentially get fee-for-service rates, to
22 some extent that's a double-edged sword. The providers are

1 also able to make sure they don't get less than fee-for-
2 service.

3 So it's unclear that plans in this context would
4 be able to sort of strike that same kind of bargain that
5 you see in other sectors, so I don't know if we would have
6 quite the same dynamic that we do now. There could still
7 be -- you know, when we work more closely with specific
8 providers we think quality is better, or outcomes, or
9 things like that, but I think the dynamic would be a little
10 bit different than what we've seen in some other programs.

11 DR. NERENZ: Just to clarify, that feature that
12 you just mentioned, the ability to trade off, say, a lower
13 per unit reimbursement against volume, that's not part of
14 what's being put on the table here, at least not
15 explicitly.

16 MR. ROLLINS: No, not explicitly.

17 DR. NERENZ: Is it forbidden?

18 MR. ROLLINS: I'm sorry?

19 DR. NERENZ: Is it forbidden?

20 MR. ROLLINS: You mean is it open for discussion?

21 DR. NERENZ: Well, I --

22 MR. ROLLINS: I mean --

1 DR. NERENZ: -- I mean, it's too late in the
2 game. I'm not trying to open this up, and I'll --

3 MR. ROLLINS: I mean, that would be one of the
4 things to consider in a larger discussion of, you know, to
5 what extent are you going to sort of let plans use fee-for-
6 service rates as a backstop.

7 DR. CROSSON: Jon.

8 DR. CHRISTIANSON: I just want to go on the
9 record as saying I think it's okay we went over 100 pages
10 for a proposal that turns the Medicare program on its ear,
11 like Bill was saying. And I also think what you've done
12 here is really important. As the data that you provided
13 and other data that we've seen underscores, we've got
14 almost half the Medicare population that's below 200
15 percent of the poverty level, in terms of income. I don't
16 know what you want to call low income, but that's low
17 income in my book.

18 So we are talking about half of the
19 beneficiaries, that this discussion applies to, at least.
20 So if we want to add even more pages, I think we need to
21 continue to develop and address a lot of the details and
22 issues that Jack has brought up, because it affects so much

1 of the program and so many beneficiaries. So I think I
2 would encourage anything you could do to continue to
3 address some of these issues. I know, again, as David
4 said, it's kind of late in the game for the June chapter,
5 but --

6 And the other thing I would comment on is I
7 haven't seen a discussion as structured and detailed -- and
8 Jack, maybe you would know more about this -- around how
9 low-income people are going to be addressed in a premium
10 support system. So that, alone, is going to be a major and
11 very important contribution to the ongoing policy
12 discussion. So I'm really, really pleased that you tackled
13 this topic because I think it's so important for premium
14 support.

15 DR. CROSSON: Comments? Bruce.

16 MR. PYENSON: Just a couple of comments or
17 suggestions. One, it seems as though we should consider
18 having a roll-out of premium support initially for dual
19 eligibles as a manageable -- potentially more manageable
20 approach to the concept of premium support, rather than
21 having it roll out for everybody, at least initially.

22 In terms of the issue that Pat correctly raised

1 about how instability, in effect, in bids could result in
2 shifting enrollment from one plan to another plan for a
3 vulnerable population, I am thinking that having multi-year
4 bids or rate guarantees would be a way to help manage that
5 issue. It's also a way to help manage other issues in the
6 MAPD world. The annual bid cycle is taxing and the short-
7 term basis of that is a -- there's potentially better ways
8 to do that, rather than an annual cycle.

9 And, finally, in terms of the impact of the
10 states, you know, states with the Part B buy-in, in effect,
11 I've heard that explained as a state is paying roughly 25
12 percent of the cost of Part B and in exchange for that the
13 state's community, the state's local economy gets 100
14 percent of Part B back, a net of 75.

15 And I'm wondering how that might change states'
16 motivations here. One way that MA plans are less expensive
17 than fee-for-service is that they pay less for Parts A and
18 Part B, for those services. So, in effect, states may not
19 just be saving what it's buy-in is but have an impact on
20 the revenue coming to a community of providers in the
21 state.

22 So I think there might be something -- some

1 useful thinking or modeling around that issue.

2 DR. MILLER: Can I just get two sentences on why
3 you would think the rollout first to dual eligibles?

4 MR. PYENSON: It's not everybody. It's easier to
5 do this in pieces. But it's also potentially a savings to
6 states whose, as I understand, contribution for the Part B
7 buy-in would be less expensive for -- in a couple of ways.
8 One is that to the extent MA plans are lower priced and
9 more efficient, if a state is paying for cost sharing, for
10 the Part A deductible, Part B coinsurance, those would
11 presumably be less expensive for the state. And the other
12 reason is that the state's buy-in would be less expensive
13 than it currently is.

14 DR. CROSSON: Okay. Kathy and then Paul and then
15 Brian.

16 MS. BUTO: I think that would complicate the
17 rollout enormously. I guess I'm thinking from a plan
18 perspective when you're bidding, only to be bidding to
19 cover the dual eligibles just seems to me to be really
20 complicating the rollout and actually making it maybe less
21 attractive.

22 But my concern -- and I think this goes to --

1 this does go to supporting Jack's concern about
2 beneficiaries' ability to absorb costs, is I worry about
3 Medicare becoming too much of an income-related program,
4 which would undermine the whole point to me of social
5 insurance at some level when you -- if we create a
6 situation where low-income beneficiaries can really just
7 afford to go to the lowest-cost plan or something very low
8 on the spectrum and don't have the same choices because of
9 cost, we sort of create -- we are creating a two-tiered
10 system in Medicare that we will -- we've started down that
11 road already, but I worry that this will make it even more
12 of an issue. And I think leaving cost-sharing subsidies in
13 Medicaid also exacerbates that issue.

14 So as we go into the next go-round, I hope we'll
15 really think about, you know, what's the tipping point for
16 creating a situation that's really pretty untenable for the
17 lowest-income populations.

18 DR. GINSBURG: I just wanted to mention that I
19 think the work that has been done this year, that Eric has
20 presented, and the work that MedPAC has done in prior years
21 on this premium support issue I think has been so valuable
22 because so far the way that Congress has approached this

1 topic has been with poorly thought out proposals. It has
2 been very ideological. It has become a "toxic" that some
3 people aren't allowed to advocate it, and I don't know when
4 the situation will change. But I think that if Congress
5 ever does, you know, address this in a more serious way
6 than it has before, I think MedPAC's contribution will
7 really make for much better policymaking.

8 DR. DeBUSK: First of all, I want to thank you
9 for a very well written chapter. Don't let anyone give you
10 a hard time of the length. Write as much as you want.
11 We'll read it all. This is very important work, and,
12 again, I really do appreciate the time and the effort and
13 the thinking that you've put into this.

14 You know, I had been concerned that when we
15 started talking about how to deal with low-income people,
16 that we were going to hit a wall. And to see what you did
17 with the LIPSA-derived approach, I think that's a wonderful
18 place to start. So, again, thank you.

19 The other thing I noticed, a couple times we
20 talked about, you know, how do you get to the benchmark?
21 Do you do bids? Do you do weighted averages? I hope we
22 could give weighted averages a lot of consideration just

1 because I think by weighting it on the number of enrollees,
2 you're going to get an inherent stabilization over time,
3 because populations only shift at a certain rate, so you'll
4 -- I think that will have an inherent stabilizing effect on
5 local markets.

6 And then the final thing I wanted to touch on was
7 something Pat said earlier, which I -- you know, as soon as
8 you said it, I thought this is a fantastic idea. You were
9 talking about people who were in Medicaid aging into
10 Medicare. If you're already in a managed Medicaid program,
11 if we could reach out to those plans and say if you will
12 build a compatible dual MA plan so that these people could
13 seamlessly move into this new plan, you could do some auto-
14 enrollment and provide some individuals to create this
15 seamless on ramp for Medicaid into a dual-eligible MA plan.
16 And I could get excited about that because that's really
17 pre-premium support. You know, that would be a nice way to
18 test some of these ideas, and it would be a test in a way
19 that would err to the side of the beneficiary, because
20 these would be the doctors and the networks that they're
21 used to and, you know, the EOBs would look the same. You
22 know, it would have that continuous feel.

1 So, again, Pat, I think that is a wonderful idea,
2 and I like the fact that we could do something like that on
3 a fairly short term.

4 DR. MILLER: On that point, I'm looking for an MA
5 person, and seeing none, I think I might be -- oh, there he
6 is. Okay. Because I was going to be free to operate
7 entirely without facts.

8 This issue of, you know, kind of rolling a
9 patient -- or, sorry, a beneficiary over, you know, if
10 they're in a commercial managed care plan and then they
11 come up to eligibility, and then you were saying but if
12 they are in Medicaid managed care, this issue has come up
13 in our conversations multiple times, and there is something
14 on the books that allows this. But my sense is it doesn't
15 go on as much as you might guess given -- and I would
16 suspect that some people may have views on this, and I
17 wonder if this is an issue we should unpack separately,
18 even just as it relates to MA, as it relates to premium
19 support, continuity for the beneficiary, just almost on a
20 stand-alone basis and make sure -- because I don't feel
21 like I understand exactly what is allowable and isn't and
22 why things don't go on more than they do, because on its

1 face -- all right. I'll stop.

2 MR. ROLLINS: So the option in Medicare Advantage
3 is sometimes referred to as "seamless conversion," where
4 you can go from -- you're not in Medicare yet, but you're
5 in a Medicaid plan or an ACA plan or just commercial
6 insurance, and you're given 60 days' advance notice that,
7 you know, unless you take action, you'll be enrolled in
8 this company's MA product when you reach 65.

9 The use had been very limited, and CMS for a long
10 time had not put out much information at all about to what
11 extent this was getting used. And then they finally did
12 put out some information -- I want to say at the end of
13 2015? -- but they've also put sort of a hold on sort of new
14 applications to do this. There was starting to be a lot of
15 interest from insurers offering ACA plans in terms of using
16 this, and I think there was some uncertainty about -- CMS
17 has rules saying you need to do this equally for people who
18 are disabled coming into Medicare and aged coming into
19 Medicare, and it was unclear that they were able to
20 implement it uniformly given that it is hard to know when
21 the disabled are going to qualify for Medicare.

22 But one point that is worth flagging is you do

1 see this used in a few limited cases with Medicaid managed
2 care. For example, the State of Arizona, which has done a
3 lot of work to integrate Medicaid and Medicare using D-SNPs
4 as a requirement for all of its D-SNPs -- I'm sorry, for
5 its Medicaid managed care products, that they have to offer
6 a D-SNP, and they have to get permission from CMS to use
7 this seamless conversion so that this situation of somebody
8 who's Medicaid only and then graduates into becoming a dual
9 sort of can stay in the same sort of environment.

10 DR. MILLER: So what I heard is you volunteering
11 to take this --

12 [Laughter.]

13 MR. ROLLINS: I was volunteering Carlos and
14 Scott.

15 DR. MILLER: Oh, Carlos, okay. For the record
16 then, Carlos.

17 DR. CROSSON: Yes, Pat, do you want to elaborate?

18 MS. WANG: So they described the current state
19 very clearly. The point that I do think is important to
20 make, though, the seamless conversion might not be the
21 lowest-cost option in a premium support. That was the
22 point that I was trying to make from, I think -- I'm a

1 little biased here, but I think from a member/beneficiary
2 perspective, it's like a pretty good option because they're
3 already in the plan, they're already using those providers.
4 They're actually in the Part D, you know, like the pharmacy
5 benefit part of it. But it might -- so from that
6 perspective, it might be a good thing for the person with
7 an opt-out, but it might not be the lowest-cost option.

8 DR. CROSSON: Okay. Very good discussion. Jack?

9 DR. HOADLEY: On this point, I know there are
10 some issues from the beneficiary advocacy community on some
11 of the seamless conversion, so I can connect to people that
12 they can provide more of that.

13 I just want to make sort of a last comment since
14 I focused my initial comments kind of narrowly on this new
15 section of the chapter and tried to think about how within
16 the context of our chapter and the proposals that we lay
17 out there, how we could address the low-income issues in
18 some different ways.

19 But I also want to come back to the broader focus
20 of this chapter. I think to me the discussion over low-
21 income just highlights and emphasizes some of the broader
22 concerns I have, and some of those came out in the exchange

1 I had with Mark about some of the consequences. And I'm
2 really taken, for example, by John's point, which I hadn't
3 quite thought of this way, but the point that 50 percent of
4 Medicare beneficiaries are under 200 percent of the poverty
5 level is really something we should keep in mind, that, you
6 know, we're focusing on low-income help at, you know, 100
7 or 135 or 150 typically; 200 isn't very far away from that.
8 They would be fully exposed as sort of the rules are laid
9 out now to some of these financial consequences and ones
10 that they wouldn't be able to afford.

11 And to Bill's initial comment about really, you
12 know, how fundamentally this goes back to change the
13 initial premise of Medicare, and Kathy's comment about, you
14 know, changing the social insurance nature of this program,
15 I think, you know, one of the real strengths of Medicare
16 over the years that it's been social insurance available to
17 everybody, regardless of income, that has been its source
18 of political support, that has been its source of just
19 broad societal support. And the more we sort of mess
20 around with that premise and we turn this into something --
21 obviously, we want to be able to find ways to help the low-
22 income people to be able to afford the same things that

1 everybody else can. But we've got to make sure we're doing
2 that in a way that really doesn't turn this into a much
3 more income-related program.

4 And so I think this whole exercise with the
5 chapter, the work on it has been terrific. It does help to
6 frame -- you know, as Paul noted, it helps to frame the
7 issues in a way that people can see some of the
8 complexities, the issues, and in my mind some of the
9 liabilities of going down this path. So I think, you know,
10 this chapter is going to be of real service, but, you know,
11 from a policy perspective, I'm concerned about some of the
12 directions for those who want to really go in this kind of
13 policy.

14 DR. CROSSON: So just a couple of closing
15 comments.

16 First of all, Eric, thank you and those who have
17 helped you. Just to reinforce the comments that have
18 already been made, this is a tremendous piece of work, well
19 thought through, well presented as well.

20 I would also suggest that you never let anybody,
21 particularly the Chairman, kid you about the length of the
22 chapter because I realize that you've just set a new bar,

1 and it's one that we will work with, no question about it.

2 Also, I think just a comment for the public to
3 reinforce some other comments that have been made here,
4 because not everybody who is sitting here may have been
5 participating in all of our conversations on this topic.

6 What we have done here -- and this has been a
7 year's or so worth of work, perhaps more thinking well
8 before that -- is to try to provide guidance and advice and
9 facts when they're available to those who are thinking
10 about premium support or something like that as a model for
11 Medicare for the future.

12 Going in that direction is not the position of
13 the Commission. We simply have attempted to say, based on
14 the fact that others have been thinking about this and that
15 our responsibility is to provide facts and advice when we
16 can, that we would do that service. But we have not taken
17 a position on the Commission either for or against moving
18 from traditional Medicare to this model or a combination of
19 the models.

20 So, with that, thank you, Eric, and we will now
21 open to public comment. Those of you who are interested in
22 making public comment, I'd ask you to please come to the

1 microphone.

2 Seeing then none -- oh, I'm sorry. Got you
3 there. What I would like to say is I'm going to ask you to
4 identify yourself and your organization. Limit your
5 comment to two minutes. When this light, which I will turn
6 off, goes back on, that is the two minutes. And just to
7 re-emphasize that there are other ways to provide input to
8 the Commission through the staff. But you're free to make
9 comments right now. Go right ahead.

10 DR. DUPREE: Great. Thanks. My name is Jim
11 Dupree. I'm a urologist with the American Urological
12 Association. I thank everyone for the very engaging
13 discussion this morning, especially about the Part D
14 spending. I have one quick question for consideration as
15 the report goes out and then one comment, if I may.

16 The question is just to add some clarification
17 about how the Drug Value Program would interact with
18 alternative payment models like the oncology care model
19 that already exists and in which there's a lot of Part B
20 spending and in which there are already shared savings
21 incentives. Just for some clarification on how those two
22 programs would interact.

1 The comment, also about the Drug Value Program,
2 actually reflects back to the first clarifying question
3 that was asked about the precedent of having prior
4 authorizations and other managerial tools in a Part B
5 program. As a practicing clinician, I don't actually
6 prescribe Part B drugs ever, but I do interact with
7 patients often who are faced with the patient side, the
8 beneficiary side, of many of those managerial tools. And
9 as we put forward a report that recommends some of those
10 tools in Part B, I would just ask that a lot of
11 consideration be given for the beneficiary's perspective on
12 what it's like to experience care when there are prior
13 authorizations, limited formularies, and other managerial
14 tools in place.

15 I think, you know, from my experience caring for
16 patients, it is often at times a frustrating experience for
17 them having to deal with those sort of tools, and I would
18 just ask for careful consideration, informed by what we
19 know from the commercial market, informed by what we may
20 know from Part B, about what it's like for a beneficiary to
21 face those types of managerial tools.

22 Thanks very much.

1 DR. CROSSON: Thank you.

2 We are now adjourned until 1 o'clock, so we'll be
3 back at 1 o'clock for a busy afternoon. Thanks very much.

4 [Whereupon, at 12:05 p.m., the meeting was
5 recessed, to reconvene at 1:00 p.m. this same day.]

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1 [No response.]

2 DR. SAMITT: Abstentions?

3 [No response.]

4 DR. CROSSON: All right. Thank you very much.

5 DR. SAMITT: I noticed you didn't give me the
6 opportunity to comment.

7 DR. CROSSON: Right.

8 [Laughter.]

9 DR. SAMITT: But I vote in favor of the
10 recommendation.

11 DR. CROSSON: All right. For the record, the
12 vote on Point B is completed.

13 Now we'll turn to a final discussion, maybe,
14 final discussion on unified PAC for post-acute care, a
15 unified payment system for post-acute care.

16 Carol Carter is back with us. All yours.

17 DR. CARTER: Okay. Good afternoon.

18 Last month, we reviewed the Commission's past
19 work on a prospective payment system to span the four post-
20 acute care settings -- skilled nursing facilities,
21 inpatient rehab facilities, long-term care hospitals, and
22 home health agencies -- and discussed implementation issues

1 that will be a chapter in this year's June report. This
2 month's presentation will be brief, but the complete
3 analysis is in the paper.

4 For new folks in the audience, Medicare pays for
5 post-acute care using four separate payment systems that
6 can result in considerably different payments for similar
7 patients. The idea of a PAC PPS is to have one payment
8 system to establish payments for patients treated in any
9 one of the four PAC settings, basing payments on patient
10 characteristics rather than the setting where they were
11 treated.

12 The Commission's initial design would eliminate
13 the existing biases in the home health and SNF payment
14 systems that favor treating some types of cases over
15 others.

16 Although the IMPACT Act of 2014 requires reports
17 on a PAC PPS, including the mandated report the Commission
18 completed last summer, it does not require implementing a
19 unified payment system. The timetable for these reports
20 makes it unlikely that a PAC PPS would be proposed before
21 2024 for implementation sometime later.

22 MedPAC's conclusions. In its mandated report,

1 the Commission concluded that a PAC PPS was feasible using
2 currently available data and therefore could be implemented
3 sooner than the timetable laid out in the IMPACT ACT.
4 Functional assessment information should be included in the
5 risk adjustment when these data become available. To
6 create a level playing field for providers, the Secretary
7 would need to begin to align the setting-specific
8 regulatory requirements.

9 In terms of impacts, the Commission's design
10 would redistribute payments from stays with high amounts of
11 therapy that are unrelated to patient characteristics to
12 medical stays. With that redistribution, the equity of
13 payments would increase across different clinical
14 conditions, by narrowing the differences in their relative
15 profitability. As a result, compared to current policy,
16 providers would be less likely to prefer to treat some
17 types of patients over others.

18 The Commission has discussed three implementation
19 issues. The first is whether to include a transition when
20 implementing the new payment system. A transition would
21 blend new and current setting-specific rates, thereby
22 dampening changes to payments during the phase-in period.

1 It would extend the current inequities in the home health
2 and SNF payment systems but would give providers time to
3 adjust their costs and mix of patients.

4 The size and the variation in the changes in
5 payments suggest the need for only a short transition.
6 Providers could be given the option to bypass the
7 transition and move directly to PAC PPS rates.

8 The second issue is whether the level of payments
9 should be lowered when the PAC PPS is implemented. We
10 estimated that in 2017, the average payment is 14 percent
11 higher than the average cost of stays.

12 Given the Commission's long-standing update
13 recommendations for PAC, the level of PAC spending should
14 be lowered when the PAC PPS is implemented, if Congress has
15 not already done so. Because MA and Medicare payment
16 reforms are based on fee-for-service, a PAC PPS and its
17 level of payments will also influence these payments.

18 We found that even with 5 percent reduction, the
19 average payment across all stays would remain 9 percent
20 higher than the average cost of stays.

21 And for most of the 30 patient groups we
22 examined, the average payments would be in the 7 to 9

1 percent range, higher than average cost of stays.

2 The last implementation issue that we will be
3 discussing is the required maintenance of any payment
4 system. As with prior payment policy changes, we expect
5 providers to change their costs, their patient mix, and
6 practice patterns to maintain or increase their
7 profitability. Therefore, the Secretary will need to
8 periodically refine the payment system to keep payments
9 aligned with the cost of care. These refinements include
10 revising the relative payments across different types of
11 stays and rebasing the level of payments for all stays.

12 Both types of refinements are part of any ongoing
13 maintenance system, and the Secretary will need the
14 authority to do both.

15 We conclude that a PAC PPS could be implemented
16 as soon as 2021. When uniform assessment data, functional
17 assessment data becomes available, it should be
18 incorporated into the risk adjustment method.

19 The implementation should include a short
20 transition.

21 The level of PAC spending should be lowered, and
22 concurrent with the implementation of the PAC PPS, the

1 Secretary will need to begin the process of aligning
2 setting-specific regulatory requirements and will need the
3 authority to do so. The Secretary will also need the
4 authority to revise and rebase payments.

5 This leads us to the draft recommendation, which
6 is identical to the one you discussed in March with one
7 exception. At the March meeting, there was a consensus to
8 lower the spending by 5 percent when the PPS is
9 implemented. The recommendation reads: "The Congress
10 should direct the Secretary to implement a prospective
11 payment system for post-acute care beginning in 2021 with a
12 three-year transition; lower aggregate payments by 5
13 percent, absent prior reductions to the level of payments;
14 concurrently, begin to align setting-specific regulatory
15 requirements; and periodically revise and rebase payments,
16 as needed, to keep payments aligned with the cost of care."

17 The text below the recommendation would note that
18 if the Congress has already lowered payments to PAC
19 providers, the Congress should compare the reduction it has
20 already taken with this recommended amount and make an
21 additional reduction if necessary to reach the 5 percent.

22 We would also state that providers could be

1 allowed to bypass the transition, and thus the reduction
2 should be applied once at the beginning of the transition.
3 We would also note that by law, MedPAC will continue to
4 evaluate the PPS every year as part of its update work and
5 continue to monitor beneficiary access to care and provider
6 performance and make subsequent recommendations if
7 necessary.

8 In terms of implications, for the one-year
9 spending, there will be no change relative to current law.
10 This is because the recommendation does not apply until
11 2021, which is year four. Over five years, the spending
12 will be lower by between 5- and \$10 billion. This score
13 assumes no behavioral changes by providers. We expect
14 provider behavior to change, and I will talk about that in
15 a minute. Savings will depend, in part, on whether
16 providers are allowed to bypass the transition, and if so,
17 how many elect this option.

18 We expect providers to respond to this major
19 change in payment policy, just as they have done in the
20 past. By rebalancing the financial incentives, the PAC PPS
21 will correct the current inequities in the SNF and home
22 health PPS that favor some types of patients and providers

1 over others.

2 For beneficiaries, providers will be more willing
3 to treat all types of patients, and therefore, there should
4 be less selection among different types of patients.
5 Therefore, patients with complex medical care needs should
6 be easier to place at discharge from the hospital.

7 For providers, the PAC PPS will redistribute
8 payments across providers. The impacts will depend on
9 provider responses and will vary widely depending on each
10 provider's cost, their mix of patients, and their current
11 treatment practices. The changes in payments will result
12 in more equitable payments across different types of
13 patients because the differences in profitability will
14 narrow.

15 For more than a year, the Commission has
16 discussed that the PAC PPS is within reach and should be
17 implemented sooner than the approach laid out in statute.
18 The recommendation reflects the Commission's concern that
19 payment reforms in PAC settings have been too slow.

20 Over the coming year, the Commission will
21 continue to work on a PAC PPS, turning its attention to the
22 regulatory alignments across PAC settings.

1 And with that, I will put up the draft
2 recommendation and turn the discussion back to Jay.

3 DR. CROSSON: Thank you, Carol.

4 We are open for clarifying questions.

5 Jack.

6 DR. HOADLEY: So I just have one. In the text,
7 you talk a little bit or you elaborate a little more on the
8 regulatory relief aspects. One of the comments there was
9 that in some settings, in some situations, there might be
10 more stringent requirements, and I was trying to make sure
11 I understood. And it looked to me like an example of that
12 would be where there would be patient-specific standards as
13 opposed to setting base standards for things like the need
14 for ventilator care, and so that might turn out to be more
15 stringent in some settings because they don't exist now or
16 because there is less to them. Is that what --

17 DR. CARTER: Right. So what we had talked about
18 was sort of a short-term and a long-term strategy. The
19 short-term strategy would be to identify when a uniform
20 payment -- when the payments begin to be uniform, which
21 regulatory requirements need to be waived. And then a
22 longer-term process would be aligning the conditions of

1 participation for, if you will, sort of the institutional
2 PAC provider and probably something slightly different for
3 home health providers.

4 We had talked about in the paper a longer-term
5 approach would be to develop conditions that are based on
6 patients rather than setting, and so there could be a core
7 set of requirements that every PAC provider would have to
8 meet. And then there would be additional requirements if a
9 provider opts to treat special types of cases; for example,
10 severe wound care or ventilator care. And so those would
11 be focused on special patient populations that we know
12 require both different staffing and equipment, for example.

13 DR. HOADLEY: And so with some of those latter
14 ones that lead to being more stringent in particular type
15 of provider, if they are going to see a particular type of
16 patient?

17 DR. CARTER: They would just be additional.

18 So, for example, if you are going to opt to treat
19 ventilator patients, you obviously need the equipment. You
20 need staff that have been trained to do that, to wean
21 patients, and to manage that kind of care.

22 So I guess the word "more restrictive" or "more

1 stringent" --

2 DR. HOADLEY: Stringent.

3 DR. CARTER: It is really -- I think of it as
4 being more targeted to the types of patients that providers
5 would --

6 DR. HOADLEY: And when you use the term "waive"
7 in terms of the short-term strategy, are there some where
8 the Secretary would actually be able to waive a requirement
9 in statute, or does it look like most of those would
10 require --

11 DR. CARTER: It's a mix. It's a mix.

12 DR. HOADLEY: It's a mix. Okay.

13 DR. CARTER: So, for example, the intensive
14 therapy requirement for IRFs is something that CMS has
15 defined. The 25-day length of stay for LTCHs is in
16 statute, so it is a mix.

17 DR. HOADLEY: And there is no waiver authority,
18 the way you might have in some others, like in a demo
19 situation where the Secretary could waive requirements for
20 purpose of a demo? There wouldn't be any ability to waive
21 even for a temporary basis for --

22 DR. CARTER: I wouldn't think so, but I haven't

1 looked at that.

2 DR. HOADLEY: Yeah. That's what I was thinking
3 too.

4 DR. CARTER: Yeah.

5 DR. CROSSON: Pat.

6 MS. WANG: Can you talk a little bit more about
7 the spending estimate on page 10? No change in year one
8 recommendation does not start until year four.

9 DR. CARTER: Right.

10 MS. WANG: So the five-year spending, does that
11 mean year two of implementation?

12 DR. CARTER: Yes. Right.

13 MS. WANG: Okay.

14 DR. CARTER: So when we talk about a one-year and
15 a five-year, that's starting with next year.

16 MS. WANG: Okay.

17 DR. CARTER: And so the five-year window only
18 extends into the second year.

19 MS. WANG: Okay. That's helpful. Thank you.

20 And so the 5 percent overall reduction that's
21 being recommended in the aggregate funding level accounts
22 for three-plus-billion of this, I assume, \$60 billion

1 program? I am trying to figure out the derivation of the
2 estimate of savings, 5- to \$10 billion. A good chunk of
3 that probably is just implementation of the reduction of
4 aggregate payments by 5 percentage points?

5 DR. CARTER: Right. Yes, yes.

6 MS. WANG: Okay. Then so the balance of it --

7 DR. CARTER: That would be all. I guess I am
8 sort of missing your question.

9 MS. WANG: Okay. I was trying to figure out what
10 --

11 DR. CARTER: Yes. All the reduction to the level
12 of payments.

13 MS. WANG: From the overall --

14 DR. CARTER: Right, the 5 percent --

15 MS. WANG: Okay.

16 DR. CARTER: -- aggregate spending, lowering of
17 that.

18 MS. WANG: And everything else is just re-
19 distributional?

20 DR. CARTER: Right.

21 MS. WANG: Got it. Thank you.

22 DR. CROSSON: Clarifying questions?

1 Bill.

2 DR. HALL: So I am very excited about this whole
3 concept, Carol.

4 I have one kind of visualization problem. I
5 agree that health care providers will adapt to incentives.
6 One of the best examples, probably, is 30-day readmissions,
7 which have shown a very substantial drop, and the main
8 reason is that the providers are no different, but there
9 are penalties involved. And the change occurred very
10 rapidly and universally across the country.

11 So the visualization issue, I am sure you thought
12 about. It's let's take the average American -- well, no.
13 An American hospital, a general hospital that sees -- maybe
14 has 300 beds. Let's put it that way -- or larger. In one
15 way or another, usually those hospitals are providing or
16 contracting out for each of these services for their
17 patient population. The incentive is to make sure that we
18 don't readmit patients over and over again. This gets you
19 in trouble with quality, financially, and all the rest.

20 But the hospital has to provide these services in
21 one way or the other. So while I am sure there are some
22 issues of people who are trying to take advantage of the

1 system and are motivated by different payment streams and
2 which will benefit them more, I think the major problem
3 from at least a practical point that I see is that you have
4 to have these services.

5 They aren't the same very often. So contracting
6 for home health agency, intensive rehab, they require
7 infrastructure somewhere within the hospital system. So
8 what would the hospital -- as you think about this, what
9 would the hospital look like? I wondered if maybe somebody
10 here who has to deal with this, like Warner, would comment
11 on that. How is this going to work in a practical way?

12 DR. CARTER: So I'm a little confused because
13 what we're talking about is sort of a more uniform PAC
14 provider, and is that what your -- right. This isn't about
15 hospitals, per se.

16 DR. HALL: Well, they are services that really
17 have to be provided to run a modern hospital, and
18 strategies have developed that end up with patients being
19 put in various different venues, where it is assumed the
20 service will be provided in a more efficient way,
21 particularly to keep the hospital going. That is where I
22 am having a little bit of trouble understanding from a

1 practical standpoint how this is going to work.

2 DR. CARTER: So do --

3 DR. MILLER: Do you want me to try it, or do you
4 want it? You've got a momentum. Go.

5 DR. CARTER: Well, so the thing that wouldn't
6 change for a hospital is they still have to have discharge
7 planning staff. That's a requirement to be a hospital, and
8 those requirements wouldn't change, and we're not talking
9 about sort of the hospitals.

10 If you're talking about an integrated hospital
11 system that has these other entities, is that what you're
12 talking about? Because we are talking about a more uniform
13 PAC provider, and so --

14 DR. MILLER: I would take this in pieces.

15 DR. CARTER: Okay. Good.

16 DR. MILLER: I would start it right -- I would
17 have started right where you did start, which is the first
18 thing I would say is let's say there is a hospital that
19 actually has a relationship with IRFs, has a relationship
20 with SNFs, has a relationship with home health. It would
21 be point of discharge. They would do their normal
22 discharge planning activities, and in a sense, as the

1 patient hits one of those settings, on the basis of their
2 patient characteristics, all that would have changed. And
3 I don't mean to say that as simple, but just from a
4 perspective of the hospital. All that would have changed
5 as the payment rate and then the regulatory environment
6 that we have been talking about a bit. So the hospital, in
7 a sense, would be conducting its business as business as
8 usual.

9 Then my mind, as you spoke, went to her second
10 scenario of were you asking about what if the IRF is inside
11 the hospital, what happens there, and there again, the main
12 thing that's changed or the two main things are changing is
13 that the payment rate may go up or down, depending on what
14 kind of patient we're talking about, and the regulatory
15 environment may get somewhat leveled, if you will, across
16 different settings. So if the IRF had a very aggressive
17 regulatory or has this many regulations -- this is a
18 scientific graph -- and that was more leveled down to have
19 more of a common standard across the institutional
20 providers, there may be some change in the regulatory
21 environment for that hospital and say you don't have to
22 have these types of people on your staff.

1 DR. CARTER: And so for that hospital, if they
2 have an IRF, they would have the flexibility to take
3 patients who currently don't meet IRF requirements for
4 intensive therapy.

5 DR. HALL: I understand that part.

6 DR. CARTER: Okay.

7 DR. MILLER: But was that your question? Is that
8 where you were going?

9 DR. HALL: No. I mean, the point is there's a
10 lot of shoehorning that goes on now. This patient doesn't
11 really need intensive rehabilitative services, but we need
12 to move him out of the acute hospital setting, and so
13 sometimes that causes probably unnecessary care.

14 DR. CARTER: I have heard hospitals give talks
15 about their discharge planning tools that help them decide
16 does this patient need it to go to a SNF level of care,
17 does this patient need to go to an IRF level of care. And
18 those decision-making tools under this scenario, where a
19 provider has much broader flexibility about where they send
20 patients, I guess hospitals would then have a broader
21 flexibility to send patients to providers kind of without
22 the label on the front of the building, if you will.

1 But they still may opt -- I mean, we're reading
2 this in the trade press, that hospitals are much more --
3 and you started your comment with this -- much more focused
4 on contracting or directing their patients to high-quality
5 providers, and so that would still remain in place, that
6 they would be looking for high-quality providers. It might
7 just not be IRF or SNF, but now would be a PAC provider.

8 DR. HALL: Okay. I will come back if we have a
9 Round 2.

10 DR. CROSSON: We are still on questions.

11 Warner.

12 MR. THOMAS: I am just going to make a comment to
13 Bill's question. I think the mental model I use on this is
14 just as an acute care hospital, you have an ICU. You have
15 med-surg. You have step-down units. I think the same
16 scenario is here. I mean, you are going to have people who
17 go to a post-acute facility that have -- some are going to
18 have more intensive rehab needs. Some are going to have
19 more -- some may be on vents because more of an LTCH.

20 I think we have been programmed to think, well,
21 they can only go to a rehab or they can only go to an LTCH
22 or they can only go to a SNF versus they need to go post-

1 acute. Let's determine the right place for them versus --
2 and I think if there can be the right regulatory relief and
3 also I think if there can be the right regulatory relief
4 for hospitals to repurpose some of their existing capacity,
5 this could actually be a step-down within a hospital --

6 DR. HALL: Right.

7 MR. THOMAS: -- which would actually facilitate
8 this and make it a lot easier, quite frankly, because, you
9 know, with unused capacity, maybe you could have a post-
10 acute entity right in a hospital, so it becomes another
11 component to the step-down versus having to go find -- if I
12 have to find a rehab because of the regulatory issues, this
13 person has to go to a rehab.

14 Once again, I think this can work. We can't just
15 change the payment model, though. We have to change the
16 regulatory issues to allow people to move amongst the right
17 components, and I think if that's done appropriately, along
18 with a payment model, I think this actually probably works
19 pretty well for folks.

20 DR. CROSSON: Very well said, Warner.

21 Does that help answer your question as well,
22 Bill?

1 DR. HALL: Yeah, it certainly does. I mean, I
2 think we're going in the right direction.

3 But I see this as an opportunity to improve the
4 quality of care provided to people when they leave the
5 hospital, and I think the systems will be invented enough
6 to do this, but it might take some time.

7 So when we think about the amount of time we were
8 going to give for transition to this system on the payment
9 side, we probably ought to give the hospitals a little bit
10 more time, rather than less time, to let this creativity
11 actually work.

12 DR. CROSSON: Okay. Further questions?

13 [No response.]

14 DR. CROSSON: Not seeing any, we will move to
15 Commission comments, discussion period.

16 I will be brief. I would just like to once again
17 congratulate Carol for an outstanding body of work. It
18 started with a very complex analytical process and then
19 into policy development, and it really has helped lead this
20 Commission forward to, first of all, a complete or
21 reasonably complete understanding of the issues, and then
22 you've managed to engender broad support from the

1 Commission as well.

2 I would also like to congratulate the
3 Commissioners, many of whom -- I think, Kathy, I would
4 start with -- who have taken this topic to heart, as well
5 as with respect to their intellect, and understood that
6 this is a big deal for Medicare. It's a big deal for
7 beneficiaries, and that these changes, both in terms of the
8 prospective payment system as well as the amount of money
9 that Medicare pays, these changes should occur as quickly
10 as possible. So I think we have, again, a very well-
11 executed piece of policy development and a very good coming
12 together as a Commission, moving things aggressively in the
13 right direction. So thank you for that.

14 So let's take Commissioner comments, other
15 discussion.

16 Jack.

17 DR. HOADLEY: I just really want to second what
18 you just said. I think back to the discussions we were
19 having a year ago in response to the congressional mandate,
20 and as we learned the process, it seems like we really sort
21 of developed this notion of being able to move forward on a
22 more rapid time table, and this has just been a great job

1 of getting us to that point.

2 So I am obviously going to support this, and it's
3 an enthusiastic "yes" vote.

4 DR. CROSSON: Alice.

5 DR. COOMBS: Thank you very much, and thank you,
6 Carol, for such great work over the past years.

7 I honestly think that we have gotten to a better
8 place on this, addressing all the concerns. I support the
9 recommendations.

10 DR. CROSSON: Thank you.

11 Kathy.

12 MS. BUTO: I think this is great work. I think
13 we can all be proud of it, but especially, Carol, you and
14 your team.

15 And I support going forward with it. I'm very
16 excited about the accelerated time frame, and even though
17 it's hard to do some of the other things, like regulatory
18 changes and conditions of participation, it's doable. And
19 having an open-ended implementation with no specific date
20 will only mean this may never get done. So I think it's
21 terrific.

22 I think all of us need to just be aware of the

1 fact that as it goes along, we want to keep our eye on
2 patients who might be particularly vulnerable during the
3 transition, whether it's ventilator dependent or wound care
4 patients or whatever, but I think that's all built into the
5 system, so I think we're in good shape here.

6 DR. CROSSON: Thank you.

7 Further comments?

8 Craig.

9 DR. SAMITT: This is awesome work, and I also
10 endorse the recommendation wholeheartedly. I guess I
11 wanted to ask beyond just the recommendation. I am curious
12 what Carol is going to do next.

13 [Laughter.]

14 DR. SAMITT: And the work has been so great, I
15 just wonder whether there are other areas of applicability
16 to similar thinking and whether there's a whole other
17 category of similarly where we're not seeing the right care
18 in the right place at the right cost, and whether it's, you
19 know, pre-acute, urgent care, freestanding ER, ER, I don't
20 presume to know which the right category would be, but I
21 just wondered whether we should be evaluating a similar
22 philosophy and methodology in other areas of care.

1 DR. CROSSON: I see Warner and David.

2 MR. THOMAS: I think this is great work as well.
3 I think that the two comments I would make is, one, I
4 really need -- or I would really strongly encourage us to
5 make sure that we're pretty focused in the chapter around
6 the regulatory components of this, because I think it will
7 be difficult to implement if there is not the right
8 flexibility to be able to move patients within these
9 different levels of care and to be aggregating more
10 patients together versus bifurcate them into, you know,
11 LTCH, SNF, rehab, which I think has created a lot of
12 problems, frankly, for providers.

13 You know, going back to Bill's comment, I think
14 one of the challenges you have when you have a 20-bed SNF
15 or a 20-bed rehab is physician coverage is very
16 challenging, whereas if you have 50 or 60 patients
17 together, physician coverage becomes a lot easier. So that
18 aggregation of patients I think is going to be really
19 important.

20 I would also make the comment that I would hope
21 that there would be flexibility to create models or pilots
22 between now and 2021 because this is a massive change for

1 this component of the industry, and although I support the
2 relatively short transition period, I think we can't
3 underestimate the major impact it's going to have. So I
4 hope there's some time in the interim where there can be
5 pilots for organizations that want to be more proactive and
6 engage on this, that they may have the opportunity to do
7 that.

8 The last comment I would make is, you know, I
9 think the 5 percent reduction, just lowering aggregate
10 payments 5 percent, I think especially in light of other
11 discussions we have had around other components of
12 spending, is pretty significant change. If you look at the
13 amount of savings here compared to, say, the drug
14 discussion we had this morning, which was only, you know,
15 250 million or what-not, and this is, you know, several
16 billion dollars, it's a pretty significant change in a
17 payment reduction when you're also going through a
18 significant change in a model modification.

19 So I just think that needs to be or should be
20 referenced in the chapter, that that's a challenge. And
21 maybe that payment change could be implemented over time to
22 allow people to adapt to this new model, which I think is

1 going to be a challenge for a lot of folks. And I think,
2 frankly, there's going to be some pretty significant
3 winners and losers that go through this. And I think the
4 model change coupled with a pretty significant cut may be
5 challenging to do simultaneously.

6 DR. NERENZ: Again, thanks to Carol. Wonderful
7 work. I have said it before and repeat it here. It is
8 great stuff.

9 The term "patient-centered" I think is a trite
10 and overused phrase, and sometimes I can't even tell what
11 it means. But I think it has a tangible meaning here. One
12 of the features I like about this is that it really shifts
13 to a model that is linked much more closely to patient
14 needs and care requirements. I think that's a good thing.

15 From that then, if this does get accompanied by
16 the appropriate regulatory relief, some of which may be
17 outside of our purview, meaning maybe there are some Joint
18 Commission things that have to go along, what that does is
19 open the door to innovation and creativity so that there
20 may be sites and levels and models of post-acute care that
21 are wonderful that don't even exist right now. And I like
22 that. I think that's a good thing. So I just want to

1 emphasize that it's -- among many reasons for favoring it,
2 I want to emphasize that one.

3 DR. CROSSON: Sue.

4 MS. THOMPSON: I just wanted to take the
5 opportunity, Carol, to say thank you again. Excellent
6 work, and it's been fun to be a part of it. And I want to
7 acknowledge even between last month and this month your
8 incorporation of additional thinking, especially around
9 alternative payment models, and how this will play into
10 bundles, et cetera. So I appreciate that very much.

11 Thank you.

12 DR. CROSSON: Okay. Seeing no further comments,
13 then we'll proceed to the vote. You have the draft
14 recommendation before you. All Commissioners in favor,
15 please raise your hand?

16 [Show of hands.]

17 DR. CROSSON: Opposed?

18 [No response.]

19 DR. CROSSON: Abstentions?

20 [No response.]

21 DR. CROSSON: Thank you very much. It passes
22 unanimously. Thank you, Carol, again, and we'll proceed

1 with the next presentation.

2 [Pause.]

3 DR. CROSSON: Okay. Our next order of business
4 is an overview of the medical device industry. We've got
5 Brian and Eric here to take us through this not entirely
6 ground for the Commission, but in relative terms I think
7 so.

8 Brian, it looks like you're ready to start.

9 MR. O'DONNELL: Good afternoon. Today we will
10 continue our discussion of the medical device market by
11 examining four topics: unique device identifiers,
12 gainsharing, price transparency, and physician-owned
13 distributorships.

14 The goal of today's discussion is to receive
15 feedback from the Commission on policies of interest and
16 potential areas of future work related to medical devices.

17 Before I begin discussing these topics, I would
18 like to thank Sydney McClendon for her assistance with this
19 work and briefly review some background information that
20 Eric presented in September.

21 First, the term "medical devices" applies to a
22 broad range of products, from very simple medical supplies,

1 such as latex gloves, to more complex implantable medical
2 devices, or IMDs, such as pacemakers.

3 The Food and Drug Administration, or FDA, is
4 responsible for regulating medical devices before they
5 enter the market and for monitoring the performance of
6 devices after entrance.

7 The FDA's premarket requirements vary based on
8 devices' risk. For most low-risk devices, manufacturers
9 must notify the FDA before bringing the product to market,
10 but no FDA review is required. Most moderate-risk devices
11 go through what is referred to as the 510(k) process under
12 which the manufacturer must demonstrate that its device
13 is "substantially equivalent" to another device that is
14 already on the market but does not have to submit data
15 proving the device's safety or efficacy. For most high-
16 risk devices, manufacturers must go through a premarket
17 approval process, under which manufacturers submit data to
18 the FDA that demonstrates the device's safety and efficacy.

19 The FDA cannot fully assess the safety and
20 efficacy of medical devices prior to market entry, so FDA
21 conducts post-market surveillance to detect and address
22 device failures and other quality issues. FDA's

1 surveillance involves passive methods, such as adverse
2 event reporting by manufacturers, and more active methods,
3 such as analyzing data through its Sentinel System.

4 While the FDA regulates medical devices, Medicare
5 has a prominent role as a payer. Medicare pays indirectly
6 for medical devices by reimbursing providers when they use
7 medical devices to deliver care. With some exceptions such
8 as durable medical equipment, Medicare generally does not
9 pay for the cost of each device separately and instead
10 makes a single payment that covers all of the inputs that
11 are used to provide a particular service, including any
12 medical devices.

13 In terms of the size of the device market, recent
14 estimates vary, ranging from \$119 billion in 2011 to \$172
15 billion in 2013. In terms of structure, there are over
16 5,000 U.S. companies that make medical devices. While most
17 are small and narrowly focused, a few large, diversified
18 companies account for most of the industry's overall sales.

19 The profitability of these companies also vary.
20 Small publicly traded companies are often not profitable.
21 Because these companies are less diversified than large
22 device companies, their success or failure may depend

1 heavily on a particular device.

2 In contrast, the large, diversified device
3 manufacturers, which receive a significant portion of their
4 revenues and profits from the sale of IMDs, have
5 consistently had 20 to 30 percent profit margins. For
6 Medicare-covered services, hospitals spent \$14 billion on
7 IMDs and \$10 billion on medical supplies in 2014.

8 In addition to representing a larger share of
9 total spending, the rate of growth in spending for IMDs was
10 nearly twice as high as the rate for medical supplies from
11 2011 through 2014. Medicare also pays for devices in other
12 settings, such as ambulatory surgical centers and physician
13 offices.

14 Now that I've given some basic background on the
15 device industry, I'll give an overview of each of our four
16 topics, discuss how the topic relates to medical devices,
17 and lay out some policies for the Commission's
18 consideration.

19 The first topic is unique device identifiers. A
20 unique device identifier, or UDI, is a code that is
21 assigned to only one device by an FDA-accredited issuing
22 agency.

1 The requirement that devices have UDIs is
2 scheduled to be fully phased in by 2020. However, while
3 manufacturers are required to have UDIs for their devices,
4 there is no mandate that providers use UDIs.

5 A UDI consists of two parts: the device
6 identifier (which identifies that manufacturer and model of
7 the device) and the production identifier (which identifies
8 more granular information such as serial numbers).

9 While there is broad agreement on the need for
10 UDIs and the inclusion of UDIs in data sources such as
11 electronic health records, stakeholders disagree whether
12 UDIs should be included on administrative claims.

13 There is currently a draft proposal to add a
14 field for device identifiers for high-risk IMDs in the
15 current round of revisions to physician and hospital claim
16 forms.

17 Proponents believe that including the device
18 identifier on claims will allow researchers to leverage the
19 scale, availability, and longitudinal nature of claims to
20 improve post-market surveillance and provide the
21 information necessary to better understand the short- and
22 long-term costs and value of devices.

1 Opponents believe including device identifiers on
2 claims will be costly to implement and are not needed for
3 post-market surveillance.

4 This next slide lists some possible benefits of
5 the new UDI system if providers consistently use UDIs and
6 UDIs are incorporated in various data sources.

7 Most prominently, UDIs can improve quality. For
8 example, UDIs can provide critical information to providers
9 at the point of care, which could help reduce medical
10 errors. UDIs can also help the FDA improve its post-market
11 surveillance system and improve its ability to conduct
12 recalls, which have historically been challenging in the
13 device market.

14 UDIs may also be used by Medicare and others to
15 improve our understanding of the value of specific devices
16 and to reduce costs. For example, adding the device
17 identifier portion of the UDI to administrative claims
18 could help Medicare better understand the downstream costs
19 of failed devices and track required payments under
20 Medicare's device credit policy, which requires a reduced
21 payment to hospitals if manufacturers provide a credit to
22 the hospital for a failed device.

1 Given the development of UDIs, the second bullet
2 on this slide lists three possible items for the
3 Commission's consideration.

4 The first two sub-bullets represent efforts to
5 ensure that, once UDIs are fully phased in by
6 manufacturers, they are used throughout the health care
7 system.

8 For example, the Commission could consider
9 policies to require or encourage hospitals to retain and
10 use UDIs for IMDs in order to facilitate appropriate care
11 and enhance post-market surveillance.

12 The third bullet discusses requiring
13 manufacturers to pay what we are calling a "device failure
14 penalty" for failed devices or for devices that fail at
15 high rates. This policy responds to the fact that Medicare
16 and beneficiaries currently pay for many failed devices to
17 which the program's device credit policy does not apply,
18 such as devices that do not have a manufacturer warranty.
19 In addition, Medicare and beneficiaries also pay for all
20 the related costs associated with revision procedures and
21 other downstream costs related to failed devices, which can
22 be substantial.

1 Future work in this area might involve
2 investigating how to structure such a penalty, which
3 devices the penalty should apply to, and how to define a
4 device failure.

5 The next topic is hospital-physician gainsharing.
6 While gainsharing can take myriad forms, the term generally
7 refers to programs that allow hospitals to share savings
8 with physicians if costs are reduced below a benchmark.

9 Previous gainsharing programs have focused on
10 reducing device costs. For example, hospitals have shared
11 savings with physicians that resulted from physicians
12 agreeing to limit the number of manufacturers from which
13 they request devices, which in turn allowed hospitals to
14 promise manufacturers more volume and obtain lower prices.

15 Physicians and hospitals often have misaligned
16 incentives, as physicians have substantial influence over
17 the device used but hospitals bear the costs of such
18 devices. Therefore, physicians often have limited
19 incentives to seek lower-priced devices. Gainsharing
20 aligns physician and hospital incentives by allowing
21 physicians to benefit from reducing costs, generally after
22 meeting some type of quality benchmark.

1 Some are concerned that such arrangements could
2 harm patients by, for instance, providing an incentive to
3 stint on care, and could enable hospitals to pay physicians
4 for referrals.

5 Gainsharing can also violate federal laws, such
6 as the anti-kickback statute. Because of the legal risks,
7 providers are hesitant to engage to in gainsharing
8 involving Medicare fee-for-service beneficiaries outside of
9 programs approved through the OIG's Advisory Opinion
10 process or demonstrations that waive certain fraud and
11 abuse laws.

12 Empirical research on gainsharing, including
13 evaluations of OIG-approved programs and other
14 demonstrations, has largely found that gainsharing leads to
15 cost savings, while improving or not affecting quality.
16 Further, some of the concerns initially raised about
17 gainsharing programs might be mitigated by relatively new
18 quality programs.

19 For instance, opponents of gainsharing contend
20 that such arrangements could provide an incentive to
21 discharge patients too soon to save costs. However, the
22 Hospital Readmissions Reduction Program, which began in

1 fiscal year 2013, penalizes hospitals for excess rates of
2 readmissions and could, therefore, discourage such
3 behavior.

4 In terms of potential policies in this area, the
5 Commission could consider reiterating its 2005
6 recommendation in support of gainsharing arrangements or
7 combining gainsharing with efforts to improve price
8 transparency, which I discuss on the next slide.

9 Specifically, the next topic is price
10 transparency for IMDs, which are devices such as pacemakers
11 and knee and hip implants.

12 Some are concerned that the IMD market has
13 characteristics that lead to high prices. Relative to the
14 market for medical supplies, price competition is limited
15 in the IMD market because manufacturers often compete on
16 differentiated products, and the market is also highly
17 concentrated.

18 IMDs can also be technologically advanced, which
19 can be a barrier to entry for new competitors, and can be
20 very expensive, accounting for a large share of the costs
21 of certain procedures.

22 Despite these high costs, IMD prices, net of

1 rebates and discounts, are not readily accessible. Even
2 when hospitals purchase IMDs, they frequently do not know
3 what other institutions paid for the same devices.

4 Patients and physicians also frequently have
5 limited knowledge of device prices and limited incentives
6 to seek such information.

7 Manufacturers have enforced this lack of
8 transparency by inserting confidentiality clauses into
9 their purchasing agreements with hospitals and suing for
10 disclosures.

11 At least in part due to the opaque nature of IMD
12 pricing, there is wide variation in the prices that
13 providers pay for the same device.

14 Little empirical research has studied the effects
15 of price transparency on prices in consolidated health care
16 markets similar to the market for IMDs.

17 Nevertheless, proponents believe price
18 transparency will reduce the variation in prices and
19 improve the ability of hospitals to negotiate lower prices.

20 Opponents generally believe that price
21 transparency in highly concentrated markets could lead to
22 higher prices.

1 A policy for the Commission to consider is
2 exploring how to implement a price transparency program for
3 IMDs. Work in this area could involve determining which
4 device prices should be made public, the timing of
5 disclosure, and exact type of pricing data that would be
6 disclosed.

7 Also, any transparency policy would likely need
8 to be coupled with policies that give hospitals and
9 physicians the tools and incentives to seek lower device
10 prices.

11 The last of our four topics is physician-owned
12 distributorships, or PODs. PODs are entities that make
13 money from selling devices ordered by their physician-
14 owners for use in procedures the physician-owners perform
15 on their own patients.

16 PODs can be structured in different ways. Under
17 the distributor model, PODs operate as intermediaries
18 between device manufacturers and hospitals that purchase
19 devices -- that is, a device manufacturer sells a device to
20 a POD, and then the POD resells the device to a hospital at
21 a higher price. Under the manufacturer model, a POD might
22 contract with a manufacturer to produce the device and then

1 sell their devices directly to a hospital. Under the GPO
2 model, physicians form a POD in order to aggregate their
3 purchasing power and get bulk discounts from manufacturers.

4 Regardless of their structure, PODs create
5 incentives for their physician-owners to perform more and
6 potentially inappropriate surgeries because they directly
7 profit from the use of more devices.

8 PODs have predominantly been present in the
9 market for spine devices, although some are concerned that
10 the model could be spreading to other areas.

11 Using data from 2011, OIG found that nearly one
12 in five spinal fusion surgeries used devices acquired
13 through PODs. The OIG also found that growth in spinal
14 surgeries was three times as high at hospitals that used
15 PODs compared to those that didn't and that devices
16 purchased through PODs were either equal to or more
17 expensive than those not purchased through PODs.

18 The OIG also put out a Special Fraud Alert in
19 2013 stating that PODs were inherently suspect under the
20 Medicare anti-kickback statute. The Fraud Alert listed
21 some specific POD characteristics that were particularly
22 troublesome, such as PODs where payments to physicians are

1 tied to the volume or value of devices used.

2 In response to the Fraud Alert, some hospitals
3 voluntarily instituted hospital policies that restricted
4 their dealings with PODs. PODs have reportedly shifted to
5 hospitals without such policies.

6 PODs have also avoided reporting under the Open
7 Payments program. Some PODs may not be required to report
8 or may have changed their structure to avoid reporting.
9 Other PODs may be required to report but fail to do so.

10 Given this information, the Commission could
11 consider strategies to improve POD reporting under the Open
12 Payments program and requiring hospital-level POD policies.

13 For PODs that are currently covered by the Open
14 Payments program, better enforcement by CMS could help
15 address non-reporting. However, this does not address PODs
16 that are not required to report or those that have changed
17 their structure to avoid reporting. For such PODs, the
18 Commission could explore a recommendation explicitly
19 requiring PODs to report under the Open Payments program.

20 The Commission could also consider exploring a
21 requirement that hospitals develop policies requiring PODs
22 to inform hospitals of their physician ownership and limit

1 their dealings with PODs to those whose structure
2 explicitly complies with the Special Fraud Alert.

3 While some hospitals have developed similar
4 policies, other hospitals, such as small or rural hospitals,
5 might lack the leverage to voluntarily restrict their
6 dealings with PODs. Also, requiring PODs to report their
7 physician ownership to hospitals could improve
8 transparency, as those reports could be used to improve
9 adherence to the Open Payments program and because the OIG
10 has found that many hospitals that purchased devices from
11 PODs were unaware that they were doing so.

12 This last slide summarizes the potential policy
13 options that I have mentioned throughout the presentation.
14 As I mentioned earlier, we are interested in feedback from
15 the Commission on these items or other items related to
16 medical devices that the Commission is interested in
17 pursuing.

18 And with that, I look forward to your comments,
19 and I turn it back to Jay.

20 DR. CROSSON: Thank you, Brian.

21 Let's start with questions on this side. Can I
22 see hands for clarifying questions? Let's start on this

1 side with Warner.

2 MR. THOMAS: Do we know how many PODs there are
3 out there and where they're more prevalent? Is it simple
4 size facilities or is it --

5 MR. O'DONNELL: Right. So I think most responses
6 that I have on PODs begin with the fact that no one really
7 knows exactly how many exist. There have been efforts to
8 kind of quantify them, and the best estimate that I've seen
9 was in the Open Payments final rule where CMS estimated
10 that there were 260 PODs that existed in 2013. They
11 acknowledge that was using the Senate Finance's report on
12 PODs and that they were estimating. They didn't know for
13 certain. But that was the best estimate that I've seen out
14 there.

15 The other thing that you said is that Senate
16 Finance did find that a lot of these were in California, so
17 that's the one geographic thing that I would note.

18 MR. THOMAS: Thanks.

19 DR. REDBERG: Thanks. A really interesting
20 report. On Slide 12, you mentioned that POD prosecutions
21 have been limited, even though the OIG suggested they were
22 suspect under the anti-kickback statute. Why is that that

1 they've been limited?

2 MR. O'DONNELL: Right. So from what I
3 understand, there are cases ongoing with Dr. Sabit and Apex
4 Medical Technologies, but in my conversations, the anti-
5 kickback statute, which this implies, is an intent-based
6 statute, and so they feel like they need kind of a smoking
7 gun to take this to court and that it's hard to prove that
8 at different times.

9 MS. BRICKER: I wanted to better understand the
10 comment you made around hospitals often don't know that
11 they're purchasing from a POD. How is that possible?

12 MR. O'DONNELL: Right, so that comment stems from
13 how the OIG conducted their 2013 study, and essentially
14 what they did was that they surveyed hospitals, and they
15 said, "Are you buying from a POD? Yes or no." And then
16 they verified that with receipts. Right? And so some
17 hospitals said, "Yes, we're buying from PODs," and they
18 listed a name. And then when they went to other hospitals
19 and said, "No, we're not buying from hospitals," and they
20 listed the name, and the names matched someone who bought
21 from a POD. What they found -- and they cleaned the data
22 and did some checking. What they found was that -- I

1 forget the exact number, but a decent share of hospitals
2 actually didn't know that these entities were PODs.

3 MS. BRICKER: I would just figure there has to be
4 some sort of due diligence on the part of someone buying
5 something that's going to go in someone's body, like you
6 would know, you know, what is this company?

7 DR. DeBUSK: Actually, I could follow up on that.
8 I have run into orthopedic practices where the CEO of the
9 practice didn't even realize that they were using a POD,
10 because what happens, you know, they don't call it "Dr.
11 Jones' POD Incorporated." It will say, you know,
12 "Southeast Spinal Concepts, Inc." Well, you don't know who
13 you're buying from or the ownership, and there's some
14 elaborate ways, like there is something called the "40/40
15 rule" where, if 40 percent of your POD is owned, or less is
16 owned by the referring physicians, and I think 40 percent
17 of your referrals come, there are ways to sort of slip
18 under the radar, and that makes it even more complicated.

19 MS. BRICKER: I just wonder if there's something
20 we should do. You know, when you're purchasing drugs, you
21 have to ensure a certain pedigree, and you have to know
22 where they're coming from. Right? Like you can't just

1 contract with Amy's Wholesaler and not do some sort of due
2 diligence. So I was just curious if there's something more
3 here we should do around you've got to know who you're
4 buying from and that it's legitimate and, moreover,
5 identify whether -- you know, their ownership and if they
6 are, in fact, a POD.

7 DR. DeBUSK: One system -- and I have a copy of
8 the form. Several years ago, one national health care
9 chain had a very, very aggressive anti-POD policy. I mean,
10 it was a multi-page questionnaire. And, originally, when
11 they rolled the rule out, if you read the questionnaire,
12 what it sounded like was even if the physician was part of
13 a POD that didn't take those types of cases to the hospital
14 at all, he just had ownership in some other POD, that they
15 were -- their privileges were revoked. It was a very
16 stringent policy. But from what I understand, I think
17 they've backed off of that just a little bit.

18 Again, I have a copy of the form. I'll send it.

19 DR. CHRISTIANSON: [Presiding.] That's very
20 interesting information.

21 I have a quick question for Brian. This is not
22 on PODs. It's on the identifiers. So most of the stuff

1 I've seen in the literature, and I think what you are
2 saying in this chapter, is the argument against more
3 information, is that it costs more to collect, and the
4 argument against that is, but there are cost savings if you
5 can avoid adverse events. Is that kind of it in a
6 nutshell, and if it is, is there any way we can get any
7 estimates of what the costs are to collect the information?

8 MR. O'DONNELL: Right. So I think you are
9 referring to, specifically, the device identifier portion
10 on the claims, and I think the argument against it, just to
11 lay the groundwork, is that, you know, folks who are
12 opposed to that say, yes, we kind of acknowledge the need
13 to put, you know, the full UDI into the EHR and into device
14 registries, but that if you are specifically -- or solely
15 focused on post-market surveillance, they don't believe
16 that just a DI on the claim adds much value. So that's the
17 argument.

18 In terms of --

19 DR. CHRISTIANSON: The argument is not based on
20 any additional cost of including that information?

21 MR. O'DONNELL: No. The bang for the buck isn't
22 there, is essentially the argument, and the only estimate

1 I've seen is that CMS has come out and said that they will
2 need extra funds to update their legacy computer systems to
3 process claims. I don't know that I've seen any estimates,
4 you know, on the physician side of the house, like what
5 admin burden that adds to them. So then they'd give
6 examples of, you know, the process of getting the UDI or
7 the DI into the claims, you know, they said will involve
8 computer updates on their end but also retraining staff and
9 redoing some of the processes. But I haven't seen a good
10 figure out there.

11 DR. CHRISTIANSON: Basically we don't know how --
12 to use a word that Warner uses, material -- how material
13 those costs would actually be.

14 MR. O'DONNELL: I haven't seen an estimate, no.

15 DR. COOMBS: Yeah.

16 DR. HOADLEY: So I also have a question on the
17 UDI. You talked about, in the reading materials, three
18 different agencies that have been authorized to do these
19 and they all have different formats, and I know we have,
20 also, on the NDC codes for drugs, there are differing
21 formats.

22 Was there a rationale to, you know, allowing this

1 kind of multi different ways to do this, as opposed to
2 having one uniform format and/or one company doing it? Was
3 there a rationale for this kind of diversity?

4 MR. O'DONNELL: Yeah. I don't know that I can
5 answer your question specifically but I would note a couple
6 of things, is that there are three different issuing
7 agencies. One specializes in, you know, blood products, so
8 it's kind of a specialty kind of type of entity, and the
9 other two seem to have some overlap in their products. So
10 I'd say at least one, there's some specialization--

11 DR. HOADLEY: Okay.

12 MR. O'DONNELL: -- for the agencies, and even
13 though their -- you know, their structures can vary, there
14 are rules and guidelines that the agencies have to abide
15 by, so they can't just make changes, you know, that they
16 want to. So, yes, there are different formats but there
17 are standards that they have to abide by.

18 DR. HOADLEY: I mean, I know on the NDC, as a
19 researcher, it's just, you know, an annoying extra step to
20 have to go through and make sure that when you are pulling
21 those codes into a database that you're reading the
22 different formats, you know, consistently, and it's a

1 source of error. So it just -- it seems shortsighted to
2 have allowed things to develop that way.

3 DR. HOADLEY: Let's just keep going up this row.
4 So that would be you, Bruce.

5 MR. PYENSON: Thank you very much, Brian. I have
6 a broad question on scope. So I think implantable medical
7 devices, I can understand, and it seems like then there's
8 another level of devices in the scope of this work that are
9 -- require some form of approval, and then there's a whole
10 bunch of other things that hospitals and providers buy.
11 You know, it could be bed sheets, on and on. So it sounds
12 like the scope for this is anything that requires approval.
13 Is that --

14 MR. O'DONNELL: So, I mean, yes, the scope is
15 broad and I think we focus on some of the higher-end
16 devices, just because, well, there's a lot of money
17 involved in that and there's been some other issues, kind
18 of market-based issues related to them. But, you're right.
19 The scope is -- covered all devices.

20 MR. PYENSON: So by -- as a follow-up question,
21 the actual food chain, or distributorship sales process, I
22 think often runs through GPOs for any of this, and I'm not

1 sure if the distinction we're making between things that
2 the health care system buys that Medicare doesn't directly
3 reimburse for, that fit into this bucket, is defined in a
4 way that corresponds to the transactions that occur in the
5 health care system today.

6 So just as a scoping idea -- I'll try to convert
7 this into a question -- when you think of a hospital and a
8 hospital budget, probably the biggest single chunk is
9 labor, and then there's another chunk that's utilities,
10 energy, things like that, and depreciation, and then
11 there's another chunk that I would say are purchases of
12 stuff. And from that purchasing of stuff, if we had to put
13 a volume on that, I think that would be pretty big, into
14 the, you know -- perhaps a lot bigger than the numbers
15 here. And I'm wondering if you have any sense for that, of
16 that purchasing of stuff, what portion of that is what
17 we're calling medical device industry?

18 DR. CROSSON: [Presiding.] Let me see if I can
19 understand. So I think, Bruce, what you're asking, for a
20 hospital or a medical office there's a whole bunch of stuff
21 it takes, you know, furniture, light fixtures, you know,
22 you mentioned sheets, things of that nature, some of which,

1 arguably, have some contact with a patient and some that
2 don't. So are you asking, how do you define what is a
3 medical device versus some other entity that's purchased by
4 a medical facility, that is not a device but is involved in
5 the economic transactions?

6 MR. PYENSON: So I'm trying to get a scope of
7 what portion of the budget --

8 DR. CROSSON: -- of the Medicare budget is
9 devices?

10 MR. PYENSON: Or even a hospital's --

11 DR. CROSSON: Okay.

12 MR. PYENSON: -- or a physician office, is
13 devices, and what portion is other stuff --

14 DR. CROSSON: Other stuff they buy.

15 MR. PYENSON: -- they buy, because what's behind
16 that is -- my view is that a lot of that all comes through
17 the same deals, and the same middlemen, and the same
18 distributorship.

19 DR. CROSSON: Okay.

20 MS. THOMPSON: In response to that question, I
21 think I know where you're headed. In the overall operating
22 budget of a hospital, roughly, what, 40 percent is labor,

1 and in the materials 15 percent is in supplies. And what's
2 the relevance of that? I think what the relevance of that
3 is what we're experiencing. Medicare isn't buying these
4 devices. The hospital is buying these devices, and if the
5 price goes up, it leaves fewer dollars for labor -- nurses,
6 physicians -- to care for patients. So the beneficiary's
7 response is, you know, he or she is going to get the device
8 the physician chooses, and the hospital is left with fewer
9 dollars to buy the labor, or everything else that it takes
10 to run a health system.

11 So I think that's a really relevant point that
12 you're making which underscores the relevance of this
13 really complicated chapter, because it's like how do you --
14 it's a little bit like picking up Jell-O. It's like -- you
15 know, it's pharmacy all over again. And so where do we
16 focus to get some bank for our buck in this discussion, is
17 what I'm trying to get my head around, and I can't quite
18 get there yet because the issue that you raised, Bruce, is
19 right on the money, and the beneficiary is the person who's
20 negatively affected in this discussion.

21 So that's -- I'm just trying to understand where
22 do -- what do we go after to take a chip at this.

1 DR. MILLER: So I think there's potentially two
2 questions on the table, which is just a dollar question.
3 How much of some denominator does something represent? But
4 then I think there is a question of, what do we do with
5 this information?

6 Now, without a lot of consultation with anyone,
7 at either end of the table, the way I would tend to think
8 about this -- and remember, we did get kind of a sweeping
9 request of like, "We've never looked at this. Would you
10 kind of tell us the story?" So, we're trying to -- you
11 know, we're trying to tell the whole story.

12 For myself, with zero consultation with anyone,
13 and this is not a round one comment, would be that when you
14 get to the stage of talking about policy, if you think
15 about the policies that we're talking about, you know,
16 things like gainsharing, the UDI, I'm going to skip the POD
17 thing for a moment, and, you know, price transparency, my
18 advice would be to focus on the implantable devices. I
19 think those are a big-dollar block. I think when I talk to
20 hospitals, and, you know, Warner is in, I believe, on this
21 too -- he's not here right this moment -- that's the thing
22 that is the physician preference item, and I'm, you know,

1 saying you're buying this one, even if this one is just as
2 good and it's lower priced. That's the issue.

3 So if you get to that point in the conversation,
4 my advice would be if you're thinking about supplies and
5 gloves and things like that stuff, I would say direct your
6 attention over to, at least for a starting point, the
7 implantables, and that's said with no consultation
8 whatsoever.

9 DR. CROSSON: Let me -- we're still on round one,
10 and I want to see if -- Bruce, are you finished? Okay, so
11 we go Kathy.

12 MS. BUTO: Back to PODs for a second. You had a
13 statement, and it was in the report and you also made it,
14 that PODs can change their structure to avoid reporting.
15 Could you say more about that, like what reporting are we
16 talking about? The relationships, or what exactly?

17 MR. O'DONNELL: Right. So I was talking about
18 avoiding reporting under the open payments program.

19 MS. BUTO: Okay.

20 MR. O'DONNELL: Right.

21 MS. BUTO: So that's the relationships with
22 physicians and so on.

1 MR. O'DONNELL: Right. So under the open
2 payments, a lot of PODs, CMS said, should be considered
3 GPOs, but then the PODs allegedly have responded by
4 changing their structure so they don't fit that definition
5 and, therefore, don't have to report.

6 MS. BUTO: Okay.

7 The other question I have is how do they get away
8 from Stark, the Stark Laws, physician ownership and
9 reporting, which is, in my experience at CMS, was the most
10 complicated rule we had to develop, in terms of ownership
11 relationships. The real exceptions I can remember were
12 solo physicians, which is an odd exception because it
13 covers a lot of people, and I thought group practices, but
14 nothing like a POD would have been exempt, as I recall, but
15 Ariel knows the answer.

16 MR. WINTER: So the issue -- well, I'll tell you
17 what I know, which is a little bit dated, but the issue is
18 that the Stark Laws only apply to designated health
19 services, and the devices -- implantable devices or other
20 kinds of devices -- are not considered a designated health
21 service. So, therefore, the way CMS has interpreted the
22 Stark Laws, PODs or other entities that sell devices to

1 health care providers are not part of Stark.

2 MS. BUTO: They're not covered by the law.

3 MR. WINTER: They're not covered by Stark.

4 However, CMS, several years ago, asked for comments. They
5 had received requests from folks that PODs -- that devices
6 should be considered a designated health service because
7 they are used for designated health services -- in other
8 words, hospital services -- and they asked for comment
9 about whether or not these types of entities should be
10 regulated under Stark. And we got comments --

11 MS. BUTO: So they have the discretion --

12 MR. WINTER: -- but in the end they said -- they
13 deferred any action.

14 MS. BUTO: Okay. So somebody thought they had
15 the discretion, because the underlying purpose of Stark was
16 to get at referrals that were driven by self-interest,
17 which is exactly what this is. Okay. Got it.

18 DR. CROSSON: Okay, Paul.

19 DR. GINSBURG: You know, we've talked a lot about
20 the potential harm that PODs can do to beneficiaries and
21 the taxpayers and ways to deal with that, but there's a
22 basic question. Is there anything socially redeeming in

1 PODs?

2 [Laughter.]

3 DR. GINSBURG: And if not, should we be thinking
4 about different policies that are far more aggressive?

5 DR. MILLER: Yeah, Brian.

6 [Laughter.]

7 MR. O'DONNELL: Social redemption, I had in my
8 notes.

9 [Laughter.]

10 MR. O'DONNELL: Well, I mean, I will say this,
11 and that's the sense of, there are some folks who advocate
12 for PODs, and they say, well, we can save a bunch of money
13 because we, as doctors, can get together and, you know,
14 negotiate better prices for volume and whatnot, and they
15 published a case study that said they reduced prices. And
16 I think my response to that is that it proves that there
17 could be some fat on the bone there, but that, you know,
18 the profits -- you know, there's bad incentives built kind
19 of inherent into the POD. So I think that's the one thing
20 I would say there.

21 DR. CROSSON: Brian.

22 DR. DeBUSK: I'm going to save my POD comments

1 for round two, but I do have a round one question on UDI,
2 particularly the device identifier in claims. If you were
3 dealing with an APM, whether it's an ACO, it's a CJR, or
4 maybe even an APM we haven't even developed yet, if you
5 were trying to measure changes in clinician behavior -- say
6 the devices -- to Mark's point earlier, these implantable
7 medical devices -- if you were trying to track, on a large
8 scale, how being in an APM may or may not have influenced
9 their choices -- say moving to lower-quality devices or
10 something like that -- but for putting the DI on the claims
11 form, what would your Plan B be? What would the
12 alternative be?

13 MR. O'DONNELL: Right, and I think that's a fair
14 point and I think that, you know, in a perfect world,
15 right, the information from EHRs would be more accessible.
16 But I think in the world that we live in, I think that's
17 the argument for putting on claims, that it's more
18 available to researchers to do those types of analysis.

19 DR. DeBUSK: So Plan B is that all the HER
20 vendors are going to finally decide to work together and
21 play Kumbaya and interchange data and standardize their
22 dictionaries and all that.

1 DR. MILLER: You seem skeptical.

2 [Laughter.]

3 MR. ROLLINS: You could also envision --

4 DR. DeBUSK: I'll take the under on that bet.

5 MR. ROLLINS: You could also envision CMS going
6 at it in a more limited fashion by doing sort of audits and
7 evaluations of certain participants and demos, to sort of
8 profile on a smaller scale what's going on.

9 DR. MILLER: And just -- there is the kind of
10 analysis that you're talking about, like, you know, in a
11 baseline or benchmark type of way could you see, you know,
12 an effect. But then the other reason I guess people talk
13 about it on a claim is whether you could begin to see
14 faster than some of these other types of oversight, whether
15 you're starting to have a problem from a device.

16 DR. DeBUSK: But even if you saw, say, a shift in
17 the mix -- let's say I went from buying two-thirds Bo
18 Jackson hips and one-third Medicare hips, and I flipped
19 those percentages, you could see in the aggregate -- and I
20 agree with you, there would be a lag -- but you still
21 wouldn't be able to be -- it wouldn't be actionable data in
22 that I couldn't say, well, oh, here's the orthopedic

1 practice that's really engaging in the undesirable behavior
2 and here are the guys that are still doing, presumably, the
3 good or the right thing. I think it would be hard to tease
4 that apart unless you dug into each individual EHR, and I
5 think that gets back to --

6 DR. MILLER: No. I wasn't making an argument for
7 the EHR. I was making an argument for two different uses
8 of the claims data, which is not just to show whether
9 you're -- you know, getting a price effect or a shift in
10 the mix of devices over time. There's also a surveillance
11 function. You might be able, on a national basis, to begin
12 to see a problem emerge. If people were being readmitted
13 because of a device failure, you might be able to also look
14 at the claims data, and more quickly than some of the other
15 surveillance things, without precision, but to know
16 something is up.

17 DR. DeBUSK: I missed that.

18 DR. MILLER: I know. I wasn't clear.

19 DR. CROSSON: Okay. I see no more clarifying
20 questions. We've got this slide up and I'm remembering.
21 But I do want to say a little bit about what we want to do
22 here.

1 I think we've already heard, in the clarifying
2 question a lot of interest in a lot of different pieces
3 here, but I think what Mark and the staff need -- I think
4 we heard Mark a minute or so ago, say, you know, help us
5 prioritize here. What, among all these different things
6 and different approaches that we've got on the table,
7 should we do first, second, and the like?

8 So I would ask you to be thinking about that and
9 we'll have Rita lead off the discussion.

10 DR. REDBERG: Thanks, Jay.

11 So I think it's a -- I'm really glad that we're
12 talking about this and that Warner brought it up, because,
13 you know, I've been interested in sort of why we have such
14 an expensive health care system and our outcomes lag behind
15 many other countries in the world, and a lot of it, I
16 think, is related to technology because we use -- and of
17 that a lot of that is devices. We use a lot more in this
18 country than anywhere else and we pay a lot more for it.
19 And so, you know, I started, maybe like 10 years ago,
20 looking a little bit into background, medical device
21 approvals, because most of what Medicare is paying for is
22 what FDA has approved. And you did cite our JAMA paper

1 from 2009, in the chapter.

2 But basically, I -- and as a cardiologist
3 obviously I've been recommending devices for years before I
4 started looking at the approval process and I was quite
5 shocked to discover that most devices -- and we only looked
6 at high-risk implantable devices, because, you're right,
7 it's Sutton's Law. That's where the money is.

8 But even in these high-risk devices, most are
9 approved without -- you know, we think for drugs it's two
10 randomized controlled trials. Most devices have one trial,
11 and most of the time it's not a randomized, controlled,
12 blinded trial. You know, they use what they call
13 historical controls, which mean you take controls from some
14 other study. Not -- you know, the reason randomization is
15 such a high-quality study is because you have the same
16 group and you've controlled for everything, and it's
17 impossible to do that without randomizing and blinding.

18 So I will just say -- and that was for the
19 premarket approval, which, as you said, is only a few
20 percent of all devices. There are other devices that you
21 might think are high risk because they're implanted in your
22 body, like some heart valves, metal-on-metal hips, but

1 they're not considered high risk, and they don't go through
2 that premarket approval process. So even just looking at
3 the most high risk, you know, the data was a lot less than
4 one would think in order to start putting devices in
5 people, because, remember, these are implantable devices.
6 It's not like a drug, when you discover it's not, you can
7 just remove it -- I mean stop taking it. Now you have
8 something inside someone, and so I come back to that device
9 failure, but it's a big deal to have a device that you find
10 out is not just not effective but harmful, and now it's in
11 you and you have to decide what to do. It's a big problem
12 for beneficiaries.

13 So after we started looking at premarket, we
14 looked at post-market, and, again, you know, there's a lot
15 of pressure on the FDA, especially since passage of 21st
16 Century Cures a few months ago, to get devices on the
17 market faster. And I think that's a big problem, and it's
18 a big problem that sort of starts with FDA, but then comes
19 back to Medicare, although it's noted in the chapter
20 Medicare doesn't have to cover all FDA-approved devices.
21 But there's a lot of pressure on Medicare to cover FDA-
22 approved devices. So I think part of it is we need FDA to

1 be more in sync with kind of, you know, standards of
2 reasonable and necessary, and I think the agency is
3 certainly signaling very loudly they're going the other way
4 and trying to get devices on the market faster and not --
5 which means -- faster generally means without randomized
6 controlled trials, and, you know, the head of the FDA
7 device just had something in the New England Journal
8 yesterday suggesting you did not even need clinical trials
9 for high-risk devices, computer simulations would do. And
10 I think that's kind of a dangerous idea to say that we
11 wouldn't have to study a high-risk device in people that,
12 you know, I don't think anyone would really want to be the
13 test person for a high-risk device that's never been tested
14 but there were computer simulations, because we don't have
15 time but I could give you lots of examples where things
16 look good in simulations and they didn't work so well in
17 people.

18 So there is a big move now to doing more post-
19 marketing, and I think that's a good idea. But, you know,
20 six years ago, the IOM had a report saying to get rid of
21 510(k) that the FDA could commission -- and also to improve
22 post-marketing, the FDA proposed and there is talk, but it

1 is still talk, about this NEST system. But right now, you
2 know, we have very, very poor adverse event reporting,
3 which means that we don't even know how many devices that
4 we're putting in Medicare beneficiaries are failing and are
5 dangerous, I mean, let alone metal hips, which I mentioned,
6 we learned about because Britain and Australia had
7 registries. Like six, seven years ago, we had a California
8 Technology Assessment Forum meeting, and we were reviewing
9 the data on metal-on-metal hips, which the orthopedic
10 surgeons were very excited about, and one who had come to
11 tell us about how great they were and they were putting
12 them in younger and younger people because they were
13 thought to last a long time. And I said, "How can you be
14 so sure when there has never been a randomized controlled
15 trial?" And he looked at me and said, "It would be
16 unethical to do a randomized controlled trial, these are so
17 good." Well, six months later, it was off the market
18 because the data had then come in from other countries that
19 there was like a 40 percent revision rate.

20 So I think, you know, premarket and post-market
21 could be a lot better, and, you know, as you put in the
22 chapter, we're paying billions of dollars for these devices

1 in Medicare beneficiaries, and that is good if they're
2 improving outcomes. But we don't have data for most of
3 them that they're improving outcomes. And then they're
4 causing problems.

5 And I think, Jay, you started with one of our
6 other discussions that our principles were solvency and
7 cost burden of beneficiaries, and these are very expensive
8 devices, which, again, if we have data that they're leading
9 to clinical improvements, that's great. But there are more
10 and more devices getting no the market that we don't have
11 that data for.

12 So I'll just -- you know, another -- well, I
13 mean, the adverse event reporting right now, it's estimated
14 only a few percent of all adverse events get tracked in the
15 MAUDE database. You mentioned Sentinel, but Sentinel is
16 only for drugs. We don't have Sentinel tracking for
17 devices. There are some individual registries now. The
18 registries are not publicly available, and they're not
19 accessible, and it's not clear how much of the reporting is
20 accurate. But it's hard to know because you can't publicly
21 access the database.

22 And then we talked a little bit about prices, and

1 as I said, the prices are way higher in this country.
2 There have been some stories -- I mean, there's not a lot
3 of price transparency, but there have been stories of
4 people that go to Europe to get devices because they're so
5 much cheaper than it is in the U.S.

6 So I think the idea of the device failures
7 penalty is intriguing because, I mean, like I said some --
8 you know, metal-on-metal hip, there have been a number of
9 ICD lead recalls. It's estimated there's hundreds of
10 thousands of Americans that have defibrillators, so, you
11 know, these potentially life-saving devices, but when they
12 don't work, they also could kill you. And now once they --
13 and people now have many -- there have been several recalls
14 on different -- Riata and Fidelis Sprint. And so then you
15 have this person -- it's very hard to track them because we
16 don't right now have device identifiers. Even if you track
17 them, you have the problem of what to do. Should you take
18 it out and put someone through another life-threatening
19 procedure or leave it in with the uncertainty that this may
20 lead to serious outcomes, including death?

21 One of my colleagues, Zian Tseng, has a study in
22 San Francisco that I think he's now expanding where they do

1 explants on people that have died with devices in place,
2 defibrillators and pacemakers, and found that there were a
3 number of unexpected deaths that were actually related to
4 the defibrillator or pacemaker due to a misfire. And they
5 would not have been known except that he's doing this
6 autopsy study with the San Francisco Examiner, which he
7 published in JAMA Internal Medicine, and now they're
8 expanding the study, so my point being I think it's the tip
9 of the iceberg in terms of how much we're not -- we don't
10 know how much harm there is from devices, and I just think
11 it's important to understand both the benefits and the
12 harms before we have widespread use. And, unfortunately,
13 with implantable devices, as I said, it's hard to remove
14 them once they're approved. So I do think the standard
15 should be higher, and I'm concerned that the FDA is clearly
16 signaling they're going to lower the evidence standards in
17 order to get these devices on the market more quickly.

18 I think it's only an advantage to get things on
19 the market quickly if we know they work. It's not an
20 advantage to get dangerous devices on the market more
21 quickly.

22 So gainsharing reminds me a little bit of

1 bundling, and, you know, the bundling initiatives, at least
2 in the spine -- and I'm sure Brian can speak more about
3 this - have certainly been successful in lowering the price
4 because it did change the incentive. The incentives are
5 not there, as you explained. Before the bundling
6 arrangements, there was not really much incentive to
7 purchase devices at lower price. I think the main issue
8 people have with bundling is that it still doesn't get at
9 the appropriateness, so if you are going to pay less, you
10 know, you might do more procedures.

11 And the last thing I'll say -- and you did cover
12 it in the chapter -- is that there are a lot more financial
13 arrangements between device companies and physicians
14 implanting devices, and a lot of those are opaque to
15 patients, so patients don't know when a physician is
16 recommending a device that they actually have a financial
17 interest in the knee or hip that they're recommending, or
18 the cardiac device. You know, the biggest -- it's
19 cardiacs and orthopedists that are the biggest devices. I
20 think that's another area that we could certainly look at
21 and do a lot better at making those relationships
22 transparent at least, because I think it's a big problem.

1 I'll stop there and hopefully give us more time
2 for discussion.

3 DR. CROSSON: Okay. Thank you, Rita.

4 Let's have further discussion and, again, focus
5 on prioritization here. I can't remember where I started
6 last, but let's start with Craig and then Amy.

7 DR. SAMITT: So I think this has been -- I think
8 all of these topics seem to be very valid. What I'm
9 struggling with is a lot of what Bruce introduced and
10 others, Rita in particular, have mentioned. I have a hard
11 time appreciating which of these potential areas will most
12 support our principles and will help address the challenges
13 and the problems we're trying to solve. I tend to agree
14 with Mark that I think the biggest bang for the buck is an
15 IMD. I also similarly have concerns about PODs. But I
16 can't fully appreciate how material and substantive those
17 policy areas really are, and so I don't know whether it
18 would be helpful to even quantify, either in terms of
19 quality improvement or sustainability and cost, how these
20 all interrelate and which ones truly are material.

21 For example, UDIs, I just -- when we've studied
22 this at Anthem as well, the cost of implementation for

1 inclusion in claims form is extraordinarily high, and the
2 question is: Is that cost worth the potential benefit that
3 comes from UDI inclusion on claim forms? It's kind of hard
4 to understand the cost-benefit associated with that.

5 That aside, I think device failure penalty I
6 would separate out from UDI. I think that's something that
7 I would imagine we could still put in place regardless of
8 UDI on claims forms. So it's hard for me to appreciate the
9 value of each of these distinctly.

10 The only other thing that I would add is, as I
11 was especially listening to the discussion about price
12 transparency and the PODs, it went back to a lot of our
13 drug discussions and our recommendation for the Drug Value
14 Program. And it made me wonder, should we have a Drug and
15 Device Value Program that has similar requirements that
16 drive transparency and cost competitiveness and avoids some
17 of the POD issue, if we thought of a D-DVR as opposed to
18 just a DVR.

19 DR. CROSSON: Do you want to --

20 DR. MILLER: Yeah, let me say -- first, just a
21 real quick clarification, and I know you didn't necessarily
22 mean it. I wasn't advocating for, you know, UDI over any

1 of these other things. This is for you. I was just trying
2 to agree with Brian that there's EHR and there's UDI, and I
3 was thinking there were some differences there that I want
4 to tease out.

5 One thing I would say, to the extent -- more
6 directly in trying to respond -- and I agree, we're kind of
7 asking you to do something, you know, where you're like
8 pick, but I don't really know, and we're sort of trying to
9 thrash around, too, at the staff level.

10 One thing I would put across to you in terms of
11 your DVP point, one of the disconnects in an idea like
12 that, which we could explore and come back to, is that, you
13 know, the hospital is providing the surgery to implant a
14 device, the physician is doing the surgery, and there's a
15 disconnect between those two actors, where the hospital
16 might be saying, "I think this device is just as good as
17 any other, and we could get it at a lower price," and the
18 physician says, "No. I want this particular device." And
19 you can have big arguments whether that's all clinically
20 driven, but then start asking questions about financial
21 relationships. And I'm setting all that complexity up
22 because I want to say gainsharing is intended to try and

1 get at that, where it says, okay, if you could clear some
2 of the kickback types of underbrush and say you are allowed
3 to share those savings if you as a hospital and you as a
4 physician come together on a price, then the notion of
5 whether it's called a DVP or -- but the idea of negotiating
6 becomes a more aligned function, whereas right now the
7 hospital is saying, "I want a low price," and the physician
8 is saying, "I want this device." And I know that's way
9 simplistic, but I would put that thought in your head if
10 you want to go down the, you know, large quotes, DVP type
11 of road.

12 DR. CROSSON: Okay. So we've got Warner, Sue,
13 and then David and then Amy. Go ahead, Warner.

14 MR. THOMAS: Just a couple of comments. I guess,
15 first of all, I would encourage us to take a much harder
16 approach on the PODs. I just don't see how they're helpful
17 for the program or helpful for beneficiaries. And I think
18 going to Mark's point, they certainly could create mixed
19 incentives. And so I would encourage us to be very direct
20 about the challenges with them. At a minimum, I think
21 there ought to be more reporting. Frankly, I think there
22 ought to be a way that we try to do away with them over

1 time because I just don't find them to be real helpful.

2 The comment around device failure penalties, I
3 would like to see us understand this in a lot more detail
4 just because I don't think there's a lot of understanding
5 about this in the industry in general. I don't think
6 there's a lot of clarity around it. To me, it's very
7 similar to readmissions or, you know, that whole scenario.
8 So I think we ought to be looking at companies to be very
9 clear about what sort of device failures they have, what
10 are the rates, how does that compare, what's the
11 transparency around that, so I would encourage us to look
12 at that very closely.

13 You had a comment in the article as well or in
14 the chapter as well indicating that the device or implant
15 cost could range from 30 to 80 percent of the Medicare
16 payment, and I'd also like to just understand a little bit
17 more around what that really looks like for common high-
18 volume types of procedures like joint replacements or
19 cardiac implants, going to Rita's comment. I mean, you
20 know, is that -- I mean, 30 to 80 percent is a wide range,
21 so are there more that are in the 80 percent range or are
22 there more in the 30? I think it would be helpful to

1 understand that because to me it plays into Medicare
2 pricing.

3 The last thing I'd like to put on the table for
4 consideration, going to Mark's comment, I think the
5 gainsharing and having gainsharing be easier to do and,
6 once again, with the appropriate transparency, I think it's
7 something that should really be considered.

8 I also think another concept that ought to be
9 considered is thinking about especially for hospitals that
10 qualify in the 340B area is a 340B type of program for
11 devices and implants. We're doing this in the drug area.
12 It's only available to organizations that have a higher
13 level of indigent or Medicaid patients. You know, I'm not
14 sure why we wouldn't see the device companies that are
15 running, you know, 20 to 30 percent margins, as outlined in
16 the chapter, providing the same type of benefit to
17 organizations that are taking care of a disproportionate
18 amount of patients who are less fortunate in the country.

19 So I would like to see us explore that concept as
20 well because I think it could be helpful to those
21 organizations that do have a disproportionate share of
22 those folks. And I think it's also a contribution that the

1 device industry could be making to, you know, indigent and
2 folks that are unfortunate, folks who are in the Medicaid
3 program. So, anyway...

4 DR. CROSSON: Thank you. Sue passed. David.

5 DR. NERENZ: I think like others I was
6 particularly interested in the POD part of this chapter,
7 things there that I hadn't been aware of, and clearly the
8 general painting of it is pretty negative.

9 One of the things I was surprised by is how
10 little effective force there seems to be particularly among
11 hospitals against this. If part of the evil of it is the
12 rising of prices either for particular devices or then sort
13 of the increased use of devices, including cases where
14 they're inappropriate, it would seem like in those examples
15 that there would be, I would have guessed, a lot of strong
16 counter pressure by hospitals.

17 So, for example, for a set of procedures, use of
18 a POD benefits the physicians, but it results in a higher
19 price, that goes directly to the hospital bottom line in a
20 negative way, and I'm surprised there's not greater
21 pushback.

22 Now, in the domain of unnecessary procedures

1 being done, for example, you know, that's an adverse effect
2 at the ACO level, that's an adverse effect at some other --
3 I'm not sure how MA plans quite play into this because they
4 may be buffered by, you know, DRG-based hospital pricing.
5 But, you know, in general, I guess the observation -- and
6 maybe you can just say more about it if there's anything
7 more to say -- is, you know, why are there not more
8 effective counter forces? But then also looking forward,
9 it would seem like initiatives that we talk about under
10 other headings. Like, for example, bundled episode payment
11 would conceivably have a positive effect if implemented in
12 a stronger form; you know, stronger ACO incentives, for
13 example, might get at it another way. Even when you talk
14 tomorrow about provider consolidation, the dynamics here
15 might be different if the surgeons are employed by the
16 hospital than if they're not.

17 So I'm just thinking that some of the avenues of
18 approach here may be in other domains of our discussion.

19 DR. CROSSON: Thank you. Amy.

20 MS. BRICKER: I just found the chapter to be
21 absolutely fascinating, and really, I am appreciative of
22 all of the work.

1 I am in absolute support of continuing to explore
2 the notion of unique device identifiers, and what was most
3 interesting to me are the comments that have been made by
4 Rita and others around failure. And to further explore
5 warranties associated with failure, it seems like it would
6 be a tremendous opportunity here. So in order to actually
7 make that work, you'd have to be able to identify the
8 device and the patient.

9 So is there some cost to it? I would assume yes,
10 but it would be interesting to see if warranties were
11 actually invoked, the savings or the ROI associated with
12 that effort.

13 I am in support also of price transparency, and
14 in the chapter, it is mentioned that it was -- and in your
15 talking points, you talked about this was a breach of
16 confidentiality for hospitals to share this information
17 with physicians, and so they have now resorted to color-
18 coding the device. I think that is just bizarre. I don't
19 understand exactly why you're -- the person that is
20 actually making a decision shouldn't know the price
21 associated with that decision. That sort of blows my mind,
22 so I am in complete support to price transparency to the

1 physician, not to other manufacturers, not to put it on a
2 billboard. That's counter to, I think, what then --
3 essentially raise pricing, but absolutely to the physician
4 and maybe also to the patient.

5 We don't really talk about that too much, but I
6 think the patient should know the price. I think the
7 patient should know if they have options, and I absolutely
8 think the patient should know if the physician that they're
9 sitting across from has a financial incentive to put that
10 device in your body. I think all those things should be
11 known to the patient.

12 But fascinating work. Thanks.

13 DR. CROSSON: Thank you.

14 Jon.

15 DR. CHRISTIANSON: So back to the device
16 identifier, I would like to have a better idea, Brian, of
17 how much more valuable information we get from including
18 not only the device identifier but the production
19 identifier and how critical that is to the surveillance
20 activity to have both.

21 I would also like to know -- Craig says with
22 this, it is going to cost an enormous amount of money. I

1 would like to know how much of that is a one-time
2 expenditure, in which case we could amortize it over the
3 future.

4 And I am really worried about the future for the
5 reasons that Rita suggested, which is if we are going to
6 make it easier to get new devices to market, without a lot
7 of testing, then I think it becomes more and more important
8 that we get them off the market quickly if they're not
9 working and if they're causing problems for beneficiaries.
10 And that means, I think, going the claims route right now,
11 because I'm with Brian. I'm not going to sit around and
12 wait for all of the electronic health records people to get
13 together and coordinate things.

14 Then way back to what Sue said earlier, how do
15 you get your hands around what to do here, for me, the
16 device identifier plays into quality of care for our
17 beneficiaries, and one of the things that we are trying to
18 do as a Commission is improve quality of care.

19 So, yes, we can't get the devices out of people,
20 necessarily, that have been implanted that have later
21 proved to be a problem, but we can stop continuing to
22 implant those devices in new folks, and that is a quality

1 issue. So I think that's a very clear thing. Even though
2 we don't pay for medical devices, it's a very clear way
3 that Medicare can connect with medical devices.

4 DR. CROSSON: Thank you.

5 We have got about 15 minutes left. Comments?

6 Jack.

7 DR. HOADLEY: So one of the things that I am
8 struck by, we have talked, in some cases, here about
9 similarities between some of the things we are hearing
10 about devices with drugs. The big difference -- and I
11 think that point has been made -- is that for the most
12 part, the devices are paid inside payment systems. So
13 Medicare is not making a direct payment, whereas at least
14 on the Part B drugs, Medicare is paying directly.

15 Now, we've got some Part A drugs with some other
16 issues there too. So it seems like that -- it's all
17 complicated, but that's part of how we have to keep
18 thinking about framing this.

19 Trying to think about prioritizing, I'm thinking,
20 again, what are the potential benefits versus the cost, but
21 it's both from the system point of view. So if, to Craig's
22 comment, it's expensive to do that, it doesn't mean we

1 don't do it. It just means we need to think about that.

2 We've also got to think about it, I think, in
3 terms of our time and effort, both staff and Commissioners,
4 and some of these things take huge research undertakings.
5 That may not be the right payoff or huge amount of time for
6 us to get a handle on, and the payoff in terms of taxpayer
7 dollars or whatever is small.

8 Those are maybe obvious points, but I thought I'd
9 say them.

10 I, like a couple of people here, many people here
11 -- the financial incentive issues hit hard. I mean, I was
12 going to ask a comparable version of what's the socially
13 redeeming value of the PODs kind of question. And I think
14 a number of us seem to be trying to understand that. Is
15 there a good reason for these to exist?

16 So, at the very least, this notion of improving
17 the open payments reporting, maybe that's the kind of thing
18 that we should speak to quickly, so that will help provide
19 the data that might let us see if there's an answer to is
20 there any good purpose for these things, or we can also
21 just go more directly if we really don't think there is.

22 I would put the same kinds of questions up in

1 terms of the transparency and gainsharing kinds of issues.
2 To me, my gut reaction is to say, "Yes, more transparency."
3 I may think about it even more broadly than, say, Amy does,
4 but at least we agree on the parts of transparency to the
5 purchasers or to the physicians. And that seems like it
6 could have some important payoff in terms of undertaking
7 financial incentives.

8 The gainsharing, I just really want to
9 understand, if we are going to go that route, what are all
10 the incentives that are going on, making sure that we do it
11 in a way that doesn't create bad incentives.

12 And then trying to think about where the sort of
13 low-hanging fruit-type of issues are, again, one of them, I
14 think, is the open payments kind of thing. I don't think
15 we need to do a lot of research or spend a lot of time, and
16 there's not a lot of cost in the system to say, "Yes, that
17 payment, that reporting system should be improved."

18 Initially, I was going to say that some of these
19 UDI issues felt like low-hanging fruit, but now I am
20 hearing the complexities. Although, like Jon, I think one-
21 time cost versus ongoing costs are part of what we need to
22 understand there, and I hear in other context, "Oh. Well,

1 that is expensive to do." And I'm saying it is expensive
2 the sense that it disrupts your current routine. Is it
3 actually that much cost as long as we do it on some kind of
4 a time frame where you're revamping systems, anyway? Is
5 there a point at which -- okay, if I tell you to do it and
6 you got to do it in the next six months, yeah, that's
7 really expensive. But if I tell you to do it as you phase
8 in the next round of your systems updates, maybe it's not
9 so. If there is any way to get some insight on that, then
10 maybe we can say, "Oh, it's not really that expensive after
11 all."

12 DR. CROSSON: Alice.

13 DR. COOMBS: So I just wanted to speak to a
14 couple of things. One is our role in terms of quality and
15 if there is an intersection in terms of what lane we're in.

16 I feel like this is a very difficult area to be
17 in and to say that it's directly related because of the
18 setup of the Medicare, how it is processed in terms of
19 Medicare reimbursements.

20 But I do agree that the device failure penalty is
21 huge, because I have been in the cath lab when you have to
22 take out an AICD that has had a recall. It is a big burden

1 for the patient, and not to mention, many of them require
2 anesthesia because they go and they test the threshold.
3 They have to be shocked. I mean, first thing, induce
4 refib, and then we shock them. So it's a big deal, and it
5 lasts for a long time. And so many patients, they have the
6 inconvenience of hospitalization, and I don't know what
7 other kind of parameters are there for what they have to
8 pay out of pocket just to have this recall.

9 Now, it is said that the companies actually cover
10 the recall. I don't know what the logistics of that is,
11 but --

12 DR. REDBERG: They cover the device, not the
13 hospitalization.

14 DR. COOMBS: So they may cover just the device,
15 but I actually went down to the lab to talk to an EP chief
16 and ask him, "Do you know how much this device that you're
17 putting in costs?" And he was able to actually tell me
18 that we work this out, and we're actually better than most
19 of the other purchasing companies. So he was very aware of
20 the device.

21 But I just wanted to speak to one thing, and
22 that's the POD. So believe it or not, the role of a POD

1 might be that these so-called doctors are usually in the
2 field sometimes. An orthopedic surgeon who no longer does
3 orthopedic surgery will know strategically what to sell and
4 how to promote and how to market to orthopedic surgeons, so
5 that there is a favorable kind of reception to the
6 specialty based on physician helping with the strategy.

7 Now, they themselves may not go into the
8 operating room. They may have a rep come into the
9 operating room, and they are sitting there. I have been in
10 these cases. They are sitting there the entire time. It
11 is to the degree of the support of how that rep understands
12 the process of putting in the knee or the hip or whatever
13 they are doing. So part of that POD has a lot to do with
14 how successful they are at marketing, and it has a lot to
15 do with physicians having had a part of that.

16 How do we get at it as MedPAC? And I'm thinking
17 that the best way to consider it is to use the open payment
18 but also to include it in our other chapter, because I
19 think it is going to be hard for us to get at all of these
20 things under the situation we're in right now. So I would
21 say the PODs probably should be included in our open
22 payments chapter and better address it there as opposed to

1 trying to deal with it solely on this whole notion of DME,
2 because it's conflicted in some regards because I don't see
3 it as the physician who's actually still practicing and
4 actually telling to themselves as a Stark arrangement. I
5 see it as a business venture that is promoted because of a
6 finite knowledge base that the physician who owns that
7 company has, and so that's a very different approach.

8 I don't see that person as working continually in
9 the field, but having an expertise that actually allows
10 them to be able to sell and to be able to market to a
11 group, I think price transparency is key.

12 But I think one of the things is if you have an
13 accountable care organization and someone puts -- Dr. X
14 puts in the bad hip every time, has a return to the OR,
15 trust me, the primary care doctor is going to say, "I've
16 had three of my patients who have gone to Dr. X. They have
17 not had a good result." The system will begin to correct
18 itself in terms of referral patterns to low-performing
19 interventionalists, whether it be cardiac, whether it be
20 orthopedic surgeon.

21 So I think health care reform advancement and to
22 APMs and ACOs will in and of itself correct some of what's

1 going on with poor performers with procedures.

2 DR. CROSSON: Thank you.

3 Bruce, Kathy.

4 MR. PYENSON: Well, thank you very much for rich
5 material.

6 I have a couple of suggestions for further
7 research, if I could, on this, and some are easier than
8 others.

9 One of them is that I believe using the Medicare
10 data, we can identify for some categories, relevant
11 categories, the cases of likely implantable failure. So
12 the case, for example, that Alice had mentioned, we could
13 probably come up with a fair certainty on what we're
14 talking about there.

15 Now, that's not just interesting from an analytic
16 case, but if we can come up with a reasonable methodology
17 for that using ICD-10s and CPD codes and things of that
18 sort, then we could actually suggest a policy that the
19 hospital is liable for the extra cost, which would induce a
20 market of guarantees from the manufacturer to cover the
21 hospital cost.

22 So I think there's a direct string from the

1 analytics, which I think is capable without -- we're able
2 to do that without new coding or anything else for at least
3 a subset of these kinds of conditions.

4 Another on the cost issue, I think there's a
5 couple of approaches. One, which is probably easy and
6 imprecise is using Medicare cost reports. I believe
7 there's cost centers for some of the kinds of stuff we are
8 talking about and perhaps a cost center base, ratio cost to
9 charges kind of approach that we could use to try to come
10 up with some kinds of estimates of at least what's flowing
11 through the hospital system.

12 I share Brian's view of electronic medical
13 records, and I am almost at the point of having that view
14 about cost accounting as well, but there are databases,
15 large databases of hospitals that have cost accounting
16 systems and could probably make available their database to
17 MedPAC for this kind of research as well, which would be a
18 more longer-term kind of issue but probably better results,
19 so a couple of thoughts there on ways to move ahead with
20 the guarantee and also the scoping out what sort of dollars
21 we're talking about.

22 DR. CROSSON: Kathy.

1 MS. BUTO: Yes. So, first of all, I wouldn't
2 limit this to implantables because imaging and diagnostics
3 are -- I think were -- I don't know if they were are -- the
4 fastest-growing area of medical devices' cost. I don't
5 know if they still are, but I would at least take a look at
6 that, that category.

7 I was listening carefully to Rita, and I think
8 she identified three important buckets. One is safety and
9 surveillance. The second is the cost of unnecessary care,
10 and the third is just the payment incentives issues, right?

11 So, on the first one, I do think Medicare has a
12 role, could have a role of gathering more data post-
13 marketing and working more closely with the FDA. So I
14 would encourage us to think about that. I don't think we
15 have to do a lot of work on that, but they have begun on a
16 couple of instances to try to collaborate more with the
17 FDA.

18 On the cost of unnecessary care, I go back to a
19 comment at the last meeting, which is, I think, generally,
20 we have to tackle this issue of appropriateness of care,
21 whether it's device-related or other drugs, other things.
22 We haven't really taken that on, and I hope we will in the

1 future.

2 On the incentives piece -- and I look at -- let
3 me just touch on the items up there. The device failure
4 penalty that I am aware of, actually, when there is a
5 failure can cover the cost of the device, some cost or the
6 hospitalization or partial cost, but also all of the
7 ancillary testing and ambulatory follow-up that goes with
8 that, because it isn't just re-operation.

9 And I know in the instance of my former company
10 that an offer was made to replace the device, not just with
11 their device, but any device that the hospital chose. So,
12 again, just getting away from the circular, you just
13 replace a defective product with your next-generation
14 product. The hospital was given the freedom to select, and
15 then the company would pay for that device. So there are
16 ways you can structure this that's more than just a penalty
17 but actually covers a lot of the ancillary costs.

18 On the gainsharing proposal, I think that's
19 certainly worth exploring. I'd also like us to think about
20 -- and I don't know how this would work particularly, but
21 in the ancient past, CMS looked at centers of excellence
22 for bypass surgery and cataract surgery that included not

1 just the procedure, the device, but also the physician
2 payment. And that got around some of the IG gainsharing
3 concerns because it was really a bundled payment.

4 What the hospital got in exchange was some
5 designation as a -- it had to meet certain standards, which
6 drove some volume, and there were savings, and quality was
7 as good or better than before the center of excellence
8 demo. But, again, it's ancient history, and maybe the
9 program has moved way beyond that. I just think it is a
10 broader concept and more like bundling that includes a
11 physician payment that tends to incent everybody to try to
12 get the best overall result and do the best -- get the best
13 savings out of it that's possible.

14 On the POD, I agree with Paul. I don't see any
15 reason -- I think Paul and Warner -- no reason at all for
16 the PD that I can imagine, but at least the open payments
17 reporting. And it seems to me re-raise the question of
18 physician ownership rules and the applicability here
19 because it drives behavior. Even though I am hearing Alice
20 say that it may not be the same physicians who are
21 operating, it does seem to drive greater utilization, so
22 that suggests some interest of some kind.

1 And I know ownership and referral rules apply to
2 diagnostic tests, so I just wonder why this kind of input
3 wouldn't be covered as well.

4 I think that was it.

5 MR. O'DONNELL: Can I just clarify one thing
6 really quickly? And I have heard this from Alice and now
7 Kathy. From what I understand, not all devices have
8 warranties. So what you were saying, that if a device
9 fails, there is a warranty to pay for the replacement
10 device in certain cases, I think that's true in certain
11 cases, but a lot of other cases, there aren't any
12 warranties that exist in the marketplace.

13 MS. BUTO: Yep.

14 MR. O'DONNELL: And then also, from what I
15 understand, it is not common to pay for the downstream cost
16 as well.

17 MS. BUTO: Right. I was just suggesting --

18 MR. O'DONNELL: Yeah.

19 MS. BUTO: -- a policy we could consider, not
20 what's out there now.

21 MR. O'DONNELL: I agree. Yeah.

22 DR. CROSSON: Okay. Paul.

1 DR. GINSBURG: Yeah. On --

2 DR. CROSSON: Sorry. One second, Paul.

3 DR. GINSBURG: Sure.

4 DR. CROSSON: Do you want to comment on that?

5 DR. REDBERG: Well, it's a comment on -- well,
6 it's to thank Kathy for making cohesive my eight years of
7 ramblings on the device industry, but also specifically on
8 FDA and CMS.

9 It occurred to me, there has been coverage with
10 evidence development that has been a coordinated effort
11 between FDA and CMS, where a device looks promising -- or
12 it could be for anything, but for this case, devices looks
13 promising, but there isn't sufficient data to say that it's
14 reasonable and necessary, that CMS can cover in a limited -
15 - only in the context of a clinical trial, which really
16 only works if you can only get that device in the context
17 of the clinical trial, because otherwise -- like with the
18 atrial septal occluders, people do it off label and get
19 reimbursed, and then you have to say, "Okay. Now we're
20 going to go look. Did it work? Then we'll cover it. If
21 it didn't work, we're not going to cover it." But that, I
22 think, is a really fertile area for FDA and CMS going

1 forward in terms of gathering data, ensuring access, and
2 working with the evidence to make sure that Medicare
3 beneficiaries are getting reasonable and necessary and safe
4 and effective devices.

5 DR. CROSSON: Sorry. Paul.

6 DR. GINSBURG: Sure.

7 On the price transparency issue, we know that
8 when markets are un-concentrated, price transparency is
9 wonderful. When they are concentrated, especially if one
10 side is concentrated, the other is not, then it is
11 potentially problematic. I think the implantable device
12 market is like that.

13 And one thing that we might want to explore is
14 whether given the fact that Medicare and the hospitals have
15 very closely aligned interests and the hospitals being able
16 to get good prices on these devices, whether we could have
17 a program where Medicare collective transaction price data
18 and share them carefully on a confidential basis with
19 hospitals who would use it for buying. This would not be
20 released to the public. This would not be public
21 information.

22 One further thought, Amy brought up the

1 intriguing thing about should the beneficiaries get the
2 price transparency information, and I would say given the
3 way the Medicare benefit structure is set up, absolutely
4 not, because they pay the same, no matter whether they get
5 the Jack Nicklaus hip or the basic hip. So I can envision
6 all the advertising: "Go for the Jack Nicklaus hip. Tell
7 your doctor that's what you want." Yeah, I don't think
8 we're ready for that.

9 I was very intrigued with Bruce's idea about
10 making the hospitals, in a sense, requiring a warranty to
11 be given by the hospitals for implanting devices because,
12 in turn, they would, I think, go to the manufacturers,
13 basically get warranties from the manufacturers, and it
14 would be much easier for Medicare to enforce this.

15 DR. CROSSON: Paul, do you know of a hospital
16 where I could get one of those Jack Nicklaus hips?

17 [Laughter.]

18 DR. MILLER: It's the one with the red stick.

19 DR. CROSSON: Brian.

20 DR. DeBUSK: First of all, I think Mark earlier
21 in his comments really framed the root cause of a lot of
22 these issues when he talked about the misalignment between

1 physicians and hospitals or the lack of alignment, which
2 will just go to teach me not to separate my Round 1 and
3 Round 2 comments because that's where I wanted to get it
4 in.

5 But I do think you framed that really, really
6 well, and I think we as a group, one thing we could do that
7 would be very beneficial is to build a framework for
8 physician-hospital gainsharing, and if we could create -- I
9 know it's a vague concept, but if we could create that
10 clear bright line, so people would know when they're
11 operating and in a compliant way, you could also eliminate
12 -- for example, eliminating things like PDs, just put that
13 on the other side of the line. Just flat out make a POD
14 illegal.

15 But I think there's a framework here where we
16 could -- for example, we could speak to stenting. We could
17 speak to induction, where you get more procedures simply
18 because of the opportunity. We could speak to vigilance.
19 How are you going to measure the effects of these systems?
20 But I think if you had that framework where we could drop
21 it into any APM -- so if a fee-for-service hospital could
22 operate within that framework, an ACO with BPCI, something

1 that was almost like a safe harbor for that -- and I'll
2 give you a good example, for I saw something really
3 creative, and I don't know if this was done intentionally
4 or by accident.

5 But some of the APMs that are out there that do
6 episodic payments, they will cap the physician incentive to
7 150 percent of the fee schedule. So I might be in, say, a
8 BPCI or something with a hip. Well, my approach may be to
9 rationalize post-acute care. Well, my colleague's approach
10 may be to try to save money on the implant itself. We may
11 all have different ways to try to improve care, but you
12 know you're in a sandbox there where you're not going to go
13 past 150 percent of the fee-for-service.

14 So I think if we had that very clear framework,
15 so that the physicians who would normally be hesitant --
16 because that's the other issue. The way we do it now,
17 alignment is really just a series of OIG rulings and
18 guidance and all that. Well, the more conservative
19 physicians don't even want to get close to the line. The
20 bolder physicians -- I mean, there are PODs out there today
21 that are 100 percent owned by one person, where 100 percent
22 of the referrals come from that one person. They are what

1 we call "100-100 PODs." I mean, it's the doctor paying
2 himself to do cases. There aren't a lot of them, but
3 they're out there.

4 So you've got this group of very bold people and
5 then this group of people who are very conservative, and
6 what you'd like to do is help us -- I think what we could
7 do as a Commission is help draw that bright line and then
8 try to make that line as applicable to as many different
9 situations as we can. It's almost like a reusable set of
10 principles for physician-provider alignment.

11 And the final thing I am going to say on that, I
12 think if you had that, it might actually take some of the
13 pressure off around consolidation, because we're going to
14 talk, I think, tomorrow about provider consolidation.
15 Well, as an independent practicing physician, if I thought
16 there was a way that I could align better with my hospital
17 and not necessarily become an employee or basically be
18 forced into a bigger group, I think you'd have some
19 opportunity there too. So you may be able to solve a lot
20 of problems with a very robust set of gainsharing
21 principles.

22 DR. CROSSON: Okay. Thank you for a very rich

1 discussion.

2 I think, in all honesty, it's a little hard to
3 sum up here. I think Mark and Jim have captured all of
4 this input, and so kind of --

5 [Laughter.]

6 DR. CROSSON: We may need a little bit of a meta-
7 analysis here, more than I can do at the moment. I did
8 hear a few things, though, I think.

9 Number one, Mark mentioned let's focus on where
10 the money is, and it's in implantable medical devices. I
11 heard a modest support for that. Not many people were
12 saying, "No. Let's go look at tongue blades and towels and
13 things of that nature," although I think, Kathy, you did
14 add imaging stuff, which I think is fine. We could add
15 that. But I do think there is a sense here that rather
16 than look at the whole realm of devices, that whatever work
17 we do, it ought to be concentrated in some area of high
18 cost or high impact on quality. I think I heard that.

19 I did hear broad support for some process to
20 track the use of these devices, and then as a derivative of
21 that, things like reimbursing for failure or tracking for
22 unrecognized problems, et cetera, like that. Now, which

1 particular method of tracking is the best, I think,
2 probably, we could do a little more work on, and I think it
3 ties into the next point, which is as we start to narrow
4 even further here, the notion of bang for the buck is
5 important here, not just from the perspective of how much
6 money could be saved for the Medicare program, but the
7 impact on beneficiaries, in some relative terms. And I
8 think you've done some of that. Perhaps we could do a
9 little bit more of that.

10 I think particularly with Brian's last comment,
11 but others as well, the notion of trying to bring together
12 potentially conflicting interests that exist now between
13 physicians and whatever support mechanism they've got going
14 on in terms of choosing devices and the interest of the
15 hospital and then the interest of the Medicare program,
16 some process to make some suggestions as to how that might
17 work better. Gainsharing is certainly one of them.

18 And then I heard a fair number of people
19 essentially questioning the issue of PODs and their
20 existence, and maybe this is one of the easier areas here
21 that we could -- I say that because I don't have to do the
22 work, but essentially say, "Okay. If there is a value,

1 this is what it is. Here is the whole list of arguments
2 for why there is no value, and here's some suggested
3 interdictions that we could recommend." And that may be a
4 circumscribed area of work.

5 That's honestly the best I can do at this point,
6 and I think, as I said in the beginning, we need some more
7 work to make sur that that's the right representation of
8 all the great ideas that we've had here.

9 So, on that notion, thank you very much, Brian
10 and Eric, and we will move on to the next presentation and
11 discussion.

12 [Pause.]

13 DR. CROSSON: Okay. So we have, in the past,
14 looked at regional variation in Medicare Part A and Part B
15 spending and service use, and at the request of the
16 Commission, we have asked you to come back and tell us
17 what's happening.

18 DR. ZABINSKI: All right. There are substantial
19 differences among geographic areas in how much Medicare
20 spends on beneficiaries, and this geographic variation has
21 been an issue of interest among researchers and
22 policymakers. In particular, there is little evidence that

1 the higher spending and service use result in better health
2 outcomes.

3 In previous work, the Commission has evaluated
4 geographic differences in program spending and service use
5 among beneficiaries in fee-for-service Medicare. For
6 today, we have largely repeated our previous analysis and
7 will present the results of this new analysis and compare
8 these results to those from our previous work.

9 An important point to understand is that spending
10 and service use are very different measures. We define
11 spending as monetary outlays by the Medicare program.
12 Geographic variation in spending is affected by geographic
13 differences in prices, special payments such as IME
14 adjustments, service volume, service complexity, and
15 beneficiaries' health status. Variation in service use is
16 affected by only by service volume and service complexity.
17 To obtain service use, we remove the effects of prices,
18 special payments, and health status from spending.

19 Because service use and spending are so
20 different, we find that areas where spending is high do not
21 always have high service use. For example, New York City
22 has per capita spending that is 26 percent above the

1 national average but per capita service use is 5 percent
2 below the national average.

3 Our discussion today includes separate analyses
4 of the variation in Part A and Part B of Medicare for all
5 fee-for-service beneficiaries and variation in Part D among
6 those enrolled in stand-alone prescription drug plans. We
7 also will compare our findings from this analysis to our
8 findings from the Commission's 2011 report on geographic
9 variation.

10 In our analysis of variation in Part A and Part
11 B, we obtained spending data for 2013 and 2014 from a
12 database that summarizes the spending on Medicare claims
13 into beneficiary-level spending amounts. We then obtained
14 service use by adjusting each beneficiary's spending
15 amounts for differences in prices, which meant removing the
16 spending effects caused by hospital wage indexes and GPCIs,
17 and special payments such as IME adjustments. We also
18 adjusted the spending for differences in demographics and
19 beneficiaries' health. The result is our measure of
20 service use for each beneficiary.

21 Then, we defined 484 geographic areas that we
22 based on metropolitan statistical areas. For areas that

1 were not in MSAs, we combined into statewide non-
2 metropolitan areas, and we refer to these as MedPAC areas.
3 We determined per capita spending and service use for each
4 MedPAC area. These per capita amounts are average spending
5 and service use from 2013 and 2014. Differences in service
6 use between areas reflect factors such as providers'
7 practice patterns and beneficiaries' preferences for care.

8 On this diagram, we show the distribution of Part
9 A and Part B per capita spending and per capita service use
10 over 2013 and 2014 across our 484 MedPAC areas. The green
11 bars represent the distribution of per capita spending and
12 the red bars represent the distribution of per capita
13 service use.

14 Along the bottom of the diagram, we've placed
15 categories that indicate per capita spending and service
16 use relative to the national average. This ranges from
17 less than 65 percent of the national average on the left to
18 more than 135 percent of the national average on the right.

19 The vertical bars indicate how many of our MedPAC
20 areas fit into each of the relative spending categories. A
21 vital point is that we weighted each MedPAC area by how
22 many fee-for-service beneficiaries are in that area. For

1 example, Los Angeles, with its 950,000 beneficiaries, has a
2 much larger presence on this diagram than does Corvallis,
3 Oregon, with its 7,000 beneficiaries.

4 We think the most important takeaway from this
5 diagram is that the distribution of service use illustrates
6 much less variation than does spending. For example, in
7 the 95 percent to 105 percent category at the very center
8 of the distribution, it indicates that 45 percent of
9 beneficiaries are in MedPAC areas that have per capita
10 service use that is within 5 percent of the national
11 average, but only about 24 percent of beneficiaries are in
12 MedPAC areas that have spending that is within 5 percent of
13 the national average.

14 We can also see that the green bars indicate that
15 spending is more spread to the ends of the distribution
16 than is service use.

17 Even though service use has less variation than
18 spending, substantial differences in service use remain
19 among our MedPAC areas. For example, we compared the
20 spending for the beneficiaries in the geographic area at
21 the 90th percentile to the spending for the beneficiaries
22 in the geographic area at the 10th percentile, and we did

1 the same 90th to 10th percentile comparison for service
2 use. We found the ratio of the 90th percentile to the 10th
3 percentile was 1.47 for spending and 1.24 for service use.

4 We have evaluated other measures of variation
5 that show much variation in service use but that variation
6 in spending is even higher.

7 Finally, an interesting result is that, on
8 average, per capita service use is nearly equal in urban
9 and rural areas. We found that urban areas, on average,
10 are 0.1 percent below the national average while rural
11 areas, on average, are 0.2 percent above the national
12 average.

13 Then we explored what factors underlie the
14 variation in service use. We started by evaluating service
15 use variation in three broad sectors: inpatient,
16 ambulatory, post-acute care, where inpatient combines acute
17 inpatient services with inpatient psychiatric services;
18 ambulatory is physician services and hospital outpatient
19 services; and post-acute care combines SNF, home health,
20 LTCH, and IRF services.

21 We found that the PAC sector has much more
22 variation than the other two sectors. For example, the

1 ratio of service use at the 90th percentile to the 10th
2 percentile is 1.88 in the post-acute sector, while the same
3 measure is 1.16 in the inpatient sector and 1.20 in the
4 ambulatory sector.

5 The high variation in the post-acute sector
6 appears to contribute more to the variation in Part A and
7 Part B services than do the other two sectors. Among our
8 484 MedPAC areas, we found that the correlation between use
9 of post-acute services and use of all Part A and Part B
10 services is 0.83, while the same measure is 0.65 for the
11 inpatient sector and 0.63 for the ambulatory sector.

12 Now I will turn things to Shinobu who will
13 discuss variation in Part D of Medicare.

14 MS. SUZUKI: A subset of fee-for-service
15 beneficiaries get their drug coverage through Part D. In
16 2014, about 25 million, or 62 percent of fee-for-service
17 beneficiaries, were enrolled in Part D drug plans or stand-
18 alone PDPs. We focused on this subset of fee-for-service
19 beneficiaries because we don't have drug data for the other
20 fee-for-service beneficiaries.

21 PDP enrollees differ somewhat from the overall
22 fee-for-service population. For example, they are more

1 likely to be female, disabled beneficiaries under age 65.
2 Among the elderly beneficiaries, they were less likely to
3 be younger cohort between 65 and 69, likely reflecting the
4 recent rise in beneficiaries choosing to enroll in Medicare
5 Advantage plans.

6 Compared with overall fee-for-service enrollees,
7 PDP enrollees have higher Parts A and B spending on
8 average, and higher prevalence of medical conditions.

9 Among the PDP enrollees, we found that drug use
10 varies less than drug spending. Similar to the method Dan
11 used to analyze Parts A and B spending, drug use is
12 spending adjusted for variations in prices, demographic
13 characteristics and health status. The dark blue bars show
14 the distribution of drug use relative to the national
15 average. Compared to the gray bars, you can see that it's
16 more concentrated around the middle.

17 About 51 percent of the beneficiaries were within
18 5 percent of the national average drug use, compared with
19 31 percent for drug spending. We also found that drug use
20 in high-use area, or at the 90th percentile, is 21 percent
21 higher than the low-use area, or an area at the 10th
22 percentile area, compared with a 38 percent difference for

1 drug spending.

2 Among the PDP population, we found that drug use
3 is somewhat more concentrated than medical service use and
4 that combined medical and drug use varied less than either
5 medical or drug use alone, though the difference was not
6 large.

7 In general, we do not find a systematic
8 relationship between medical service use and drug use
9 across geographic areas. That is to say that in many areas
10 that have very low or very high medical service use, we do
11 not consistently find correspondingly low or high drug use,
12 and vice versa.

13 Our regression analysis also did not show
14 statistically significant relationship between drug use and
15 medical use in a given geographic area, in total or when
16 analyzed separately for inpatient, ambulatory, and post-
17 acute care services.

18 Many of our findings are similar to our previous
19 study. For example, in both studies, we found that
20 areas with high or low spending is often different from
21 those with high or low service use. In the example that
22 Dan gave, the New York region had above average medical

1 spending, but once the spending was adjusted for
2 differences in prices and demographic characteristics and
3 health status, the average use was lower than the national
4 average.

5 Service use varies less than spending, but large
6 differences still remain, and for Parts A and B services,
7 much of the variation is due to variation in the use of
8 post-acute care services.

9 We also continue to find that medical service use
10 is positively correlated between sectors, but does not
11 appear to be correlated with drug use. We also found that
12 medical service use do not differ between urban and rural
13 areas.

14 There are some findings that are different from
15 our previous study. I'll just highlight a few here, and we
16 can address others on question.

17 Compared with the previous study, the current
18 study shows slightly lower variation in medical service
19 use. We also found this to be true for post-acute care
20 services, although the variation is still large compared to
21 non-post-acute care services.

22 Finally, we found lower service use in areas that

1 had the highest medical services use in our previous study,
2 though their service use is still higher than the national
3 average.

4 We would like your feedback on the material we
5 covered today and in the paper. Next step for us is to
6 include any revisions based on today's discussion and
7 prepare the paper for a standalone report to be published
8 later this summer.

9 With that, we are happy to take your questions.

10 DR. CROSSON: Thank you, Shinobu and Dan. We are
11 open for clarifying questions and I see Craig.

12 DR. SAMITT: So a two-part question. Great
13 report. Did you analyze service use difference based upon
14 the evolving penetration of CMS ACOs, and what impact the
15 ACO dynamic environment has on evolving service use
16 differences, by geography?

17 DR. ZABINSKI: We didn't tear it apart down to
18 that level, but I think there is probably some evidence
19 that, you know, that ACOs have had some impact. I think
20 Mark was thinking about McAllen and what happened there.
21 Right? Or do you want me to bring you into this?

22 DR. MILLER: So you're giving me the opportunity?

1 Thanks.

2 DR. SAMITT: Well, and it may be helpful for me
3 to add the second part of my question, because I think it's
4 all interrelated. You know, I think putting on my former
5 provider hat, you know, I think the phenomenon that the
6 provider community is experiencing is this notion of a foot
7 in two canoes. And there's still the volume world and
8 there's the evolving and growing value world.

9 And I guess the question is, is I would imagine
10 that the progressive value world, wherever that sits, is
11 motivating and evolving change in the way practice occurs,
12 across all payers. And so I'm interested in knowing and
13 studying sort of growing Medicare Advantage, because
14 growing Medicare Advantage could conceivably begin to
15 socialize the provider community with value, or the growing
16 commercial ACO world, CMS aside.

17 So if I am a provider and more and more of my
18 patients are either in MA programs or in commercial ACOs, I
19 may very well evolve my service use for fee-for-service
20 Medicare. And so I'm curious to know the correlation
21 between a payment for value for the providers and how
22 that's changing, and the spillover effect that would

1 frankly have in fee-for-service service use.

2 DR. CROSSON: Amy.

3 MS. BRICKER: I'm curious. Miami and McAllen, do
4 you have any idea as to why they improved, although still
5 above average?

6 DR. ZABINSKI: Well, just on nuts and bolts,
7 particularly in Miami, durable medical equipment dropped
8 substantially from the earlier study. They were way above
9 the average. In fact, they were way above the location
10 that was in second place on durable medical equipment, and
11 now they're below average on DME.

12 McAllen, it primarily looks like a decrease in
13 use of post-acute care, yet, you know, they're still well
14 above the average in post-acute care but much less so now,
15 in particular, the amount of home health dropped by a
16 substantial amount.

17 MS. BRICKER: So do you think it's like public
18 shaming, or like how did they, like, get in line?

19 DR. ZABINSKI: Um --

20 DR. MILLER: Well, I think that's what difficult
21 and in some ways not unrelated to Craig's question. It's
22 hard, at this level, even though it's disaggregating by

1 market, it's hard, still, to attribute cause. My
2 recollection, in the Miami situation, is there was a
3 specific program integrity effort on this front, wasn't
4 there?

5 DR. ZABINSKI: I think, you know, it could point
6 to some success in anti-fraud efforts.

7 DR. MILLER: And so that might -- and whether
8 that falls into your public shaming category, I'll leave it
9 to you to judge. But, you know, also, you know, the second
10 part of that story often is that the people who are engaged
11 in that activity move to different counties, and so I
12 wouldn't be surprised if you see some of this show up
13 elsewhere. But that was one piece of it.

14 In the McAllen instance, you know, we had this
15 conversation internally, post-acute care went down. There
16 was some sense that an ACO was created there, and if you
17 read -- and again, I want to be really clear that all the
18 following statements are just kind of connecting dots as
19 opposed to real analysis. If you remember kind of the Atul
20 Gawande stuff, where he said, you know, a set of
21 entrepreneurial providers kind of entered the market,
22 changed the dynamic there, and a part of that real change

1 in dynamic was post-acute care, in a big way, and there
2 were even issues of kickbacks and that type of thing. They
3 then formed -- or some of them have formed an ACO.

4 Now think about it. You have a giant -- you
5 know, you've kind of got it going up, and now somebody
6 shows up and says, "By the way, I'll reward you if you take
7 it down," so now they're into --potentially into that.

8 So internally, you know, around the, you know,
9 the lunch room, this is kind of the things. Maybe a
10 program integrity focus, and to some extent, maybe, but
11 not, you know, with a lot of analytical rigor, maybe some
12 effect from, you know, ACO type of activities, in these
13 couple of instances. But also, Dan, some compression in
14 the distribution overall.

15 DR. ZABINSKI: Yeah.

16 DR. MILLER: I'm sorry, and I'll stop. I swear.
17 The other thing to keep in mind is the other thing that
18 happened, I think, to data that we used previously and now
19 is also we're getting more of the effect of the slowdown in
20 utilization that started to occur around 2008, 2010, that
21 type of --

22 DR. ZABINSKI: Yeah, we picked that up as well,

1 and to the extent that the slowdown was greater at the high
2 ends, you're going to get some compression.

3 DR. MILLER: Right.

4 MS. BRICKER: So I know Miami is identified as a
5 heat zone. Is McAllen? Heat -- are you familiar with
6 this?

7 DR. ZABINSKI: No, I'm not.

8 MS. BRICKER: No? It's from a program integrity
9 perspective. They identify certain MSAs that have a high
10 propensity for fraud --

11 DR. ZABINSKI: Okay.

12 MS. BRICKER: -- so just curious. I know Miami
13 is that but I don't know if the other is.

14 DR. ZABINSKI: I'm not aware of it.

15 DR. CROSSON: Okay. Questions? Jack.

16 DR. HOADLEY: A couple of methodological
17 questions. When you're defining this concept of service
18 use, you're taking the overall spending and you're
19 adjusting out these various factors -- the wage indexes,
20 the add-on payments, and health status measurement, and so
21 forth -- but this is still a dollar measure so it's still
22 incorporating the price of the service?

1 DR. ZABINSKI: Hm -- I would say --

2 DR. HOADLEY: Or is it a true volume of service
3 measure?

4 DR. ZABINSKI: Yeah, it's going to -- Shinobu is
5 whispering. We have intensity yet. Yeah, it's intensity
6 of services. It reflects, you know, like the volume and
7 the intensity of the services with sort of a, you know --
8 basically, what it does is it says, suppose everyone was
9 paid at the same rate --

10 DR. HOADLEY: Okay.

11 DR. ZABINSKI: -- everybody had the same health
12 status. Okay?

13 DR. HOADLEY: So it does assume everybody is paid
14 at the same rate.

15 DR. ZABINSKI: Yeah.

16 DR. HOADLEY: It's not just adjusting out the
17 wage index kind of variation.

18 DR. ZABINSKI: Right. It adjusts out the
19 effects. Like everybody has a hospital wage index of 1 and
20 GPCIs of 1, is essentially what's going on here. And then
21 what it reflects is idiosyncrasies of the particular areas,
22 you know, like providers' practice styles, beneficiaries'

1 preferences, and that sort of thing.

2 DR. HOADLEY: Okay.

3 DR. MILLER: And the intensity point, which I'm
4 sure you get but just in case anyone else isn't following
5 it, is: Do I have more volume versus do I have more of
6 higher, you know --

7 DR. HOADLEY: Level 4 visits versus Level 2 or
8 whatever.

9 DR. MILLER: Yeah, MRI versus, you know, X-ray.

10 DR. HOADLEY: CT scan. And my second question,
11 in the text you talked about the difference between the A-B
12 analysis and the D analysis is the D includes the cost
13 sharing? Was there a particular logic to that or was that
14 just a byproduct of how you happened to run analyses?

15 MS. SUZUKI: So because D's benefit, as you know,
16 is very unique, to try to measure use, converting spending
17 to use, I think we had to include all of gross spending to
18 get at the use concept that's comparable to A-B.

19 DR. HOADLEY: Because of the doughnut hole and all
20 the --

21 MS. SUZUKI: Mm-hmm.

22 DR. HOADLEY: Okay. Thank you.

1 DR. CROSSON: Jon.

2 DR. CHRISTIANSON: On page 21 and 22, you talk
3 about the lack of correlation between spending in different
4 sectors. There's a bit of research that has been done on
5 that, on the private sector, often within single employer
6 groups. I think it would be useful to put that context
7 with that discussion, so maybe in the next version of this,
8 you could look at some of that research and compare your
9 findings to what other people have done that have tried to
10 do similar correlations.

11 DR. CROSSON: Bruce.

12 MR. PYENSON: Thank you. A question on NBSF. To
13 what extent -- I'm not familiar with NBSF. What do the
14 data fields look like?

15 DR. ZABINSKI: What do the what [off microphone]?

16 MR. PYENSON: Data fields. How summarized is it?

17 DR. ZABINSKI: Let's see. There is -- how
18 summarized. There's a number of ones that would be
19 classified under physician, you know, imaging tests, et
20 cetera, collected all those together, but there's ASC,
21 there's OPD. This is a number of different small
22 categories.

1 MR. PYENSON: The reason I'm asking is the
2 variation seems tighter than what I recall seeing, say, in
3 Dartmouth Atlas. And I'm wondering if that's -- I believe
4 they're using the 20 percent sample and looking at things
5 like an admission or days per -- you know, more granular.
6 And to what extent is your distribution of function of the
7 compression going on in NBSF?

8 DR. MILLER: Compression going on in what?

9 MR. PYENSON: In the data source, NBSF. NBSF is
10 a summarized --

11 DR. MILLER: Okay.

12 MS. SUZUKI: It's a beneficiary level file. So
13 if Dartmouth analysis is a bene level -- you know, they may
14 aggregate from the claim, but up to the beneficiary level,
15 whether it's six-month spending use or annual, NBSF is an
16 annual summary file at the bene level, so you have --

17 MR. PYENSON: But just maybe this is a technical
18 issue. So, for example, I don't know if ER is separate as
19 a line item.

20 DR. ZABINSKI: It's not, no.

21 MR. PYENSON: So the variation in ER just by
22 itself would be expected to be bigger than the variation in

1 OPPS, in --

2 DR. ZABINSKI: Sure, yes.

3 MR. PYENSON: That's kind of the question I'm
4 asking.

5 DR. ZABINSKI: Yeah, I mean, well, you know, we
6 aggregated -- we took everything from the NBSF and put it
7 together into a total for each beneficiary, all the
8 categories, all A and B, and then Shinobu will get Part D
9 with a different data set. So, yeah, there's going to
10 probably be canceling out from the different sectors and
11 get a little tighter distribution.

12 Perhaps also that, you know, they had a different
13 geographic unit. They use HRRs, and we were using these
14 MSA-based things. But I'm not sure how much that would
15 affect the variation or not.

16 DR. MILLER: But isn't there a much more -- and I
17 haven't reentered this debate for a while, but I thought
18 the big difference was that what we're adjusting for, we
19 adjust for more than Dartmouth does, and we did that
20 purposely because people were arguing over what the
21 variation represented in the Dartmouth Atlas. And so as I
22 recall the debate, the Dartmouth folks had a number that

1 was much more like a spending number. They did something
2 very different on their health adjustment. I'm not sure
3 they adjusted for prices, and -- I don't recall that. I
4 will leave that aside. And I don't think they did the
5 special payments thing.

6 And so we came in and said, look -- and at the
7 time when we did this the first time, there was a raging
8 argument on the Hill over what this data represented, and
9 so we came in and did the risk adjustment, the special
10 payment adjustment, and the price adjustments, the
11 conversation you just had, and said, look, it's imperfect,
12 but this is something that's closer to utilization. And if
13 you're talking about geographic variation, you shouldn't be
14 capturing differences in, you know, payment rates and that
15 type of things and try and get truly to practice variations
16 in terms of the services delivered.

17 Now, I think Dartmouth's big criticism of our
18 work -- and as always, we're right, they're...

19 [Laughter.]

20 DR. MILLER: Right okay. Their big criticism was
21 they're worried about the way we did the risk adjustment.
22 They think that there's a certain circularity between

1 utilization and getting more codes and, therefore, doing
2 greater adjustment like in the Miami area. And so if
3 anything, I think our error is we've probably understated
4 the variation a bit.

5 DR. ZABINSKI: That's correct. Yeah, I think so.

6 DR. MILLER: I think that's more what you're
7 seeing there.

8 DR. ZABINSKI: Another thing, Dartmouth was --
9 and they released a number of studies, and I think their
10 studies each have slightly different purposes. And from
11 one study to the next, their approach would be a little
12 different. So for one, you know, you'd have a variation
13 that could like quite wide and another one that would look
14 narrower. So that's probably adding some confusion.

15 DR. CROSSON: Okay. Questions? Kathy.

16 MS. BUTO: In 2011, did you put out a MedPAC
17 Atlas?

18 [Laughter.]

19 MS. BUTO: In other words, what I'm trying to get
20 at here is whether McAllen knew what its numbers were --
21 are, and Miami and so on. Was there -- back to Amy's point
22 about shaming, you would only be shamed if you and others

1 knew what you got, right?

2 DR. ZABINSKI: Yeah, there's a report 2011 --

3 MS. BUTO: With a table and --

4 DR. ZABINSKI: A table, yeah, and, you know,
5 explicitly pointing out your bad -- that sort of thing.

6 PARTICIPANT: Sad faces.

7 DR. GINSBURG: I think for the shaming, let's not
8 forget about the role that Atul Gawande played, who may
9 have been using the MedPAC numbers. But whatever he was
10 using -- or maybe he was using Dartmouth numbers.

11 DR. MILLER: He used ours.

12 DR. GINSBURG: Yeah, so I think -- you know, so
13 basically you're putting the numbers out, and then, you
14 know, getting the attention of Atul Gawande to put it out.
15 I think that's a big part of the story of why the variation
16 has shrunk somewhat.

17 DR. CROSSON: Okay. Brian.

18 DR. DeBUSK: First of all, I want to compliment
19 both of you for taking this issue on. This is a very
20 difficult analysis.

21 I had more of a methodological question. On
22 Chart 4, where you do your regression, you lay out the

1 HCCs, and then, for example, community versus
2 institutional, you know, dual versus non-dual, I think
3 disabled versus non-disabled were in the regression,
4 treated as regression variables.

5 If you look at the way CMS actually calibrates
6 the HCCs for, say, MA risk adjustment, they actually treat
7 those as separate compartments in eight different models.

8 Just for method consistency, would we want to
9 compartmentalize that just in case maybe you find something
10 down the road and it turns out to just be an artifact?

11 DR. ZABINSKI: I thought about that a little bit,
12 and I see benefits to both. I think ultimately, you know,
13 why we chose to have just one regression is just sample
14 size. You get, you know, very specific about who's in a
15 particular regression sometimes with CMS' method, and I
16 think on some occasions, you know, they have to do some
17 data massaging to get --

18 DR. DeBUSK: Just spreading your data too thin.

19 DR. ZABINSKI: Yeah.

20 DR. DeBUSK: Okay. Just curious.

21 DR. ZABINSKI: Yeah.

22 MS. SUZUKI: One thing we do, though, is to

1 assume that in each county the demographic characteristics
2 are representative of the national sample. So we're trying
3 to capture what's unique about each of the area. So to the
4 extent that there is more low-income or ESRD in any given
5 county, that shouldn't technically affect our analysis when
6 it's adjusted.

7 DR. CROSSON: Okay. One more question from Jack,
8 and then Paul.

9 DR. HOADLEY: Yeah, I had one more methods
10 question. You said you attached everybody's data to their
11 place of residence, not the place where the service was
12 delivered. I know at least anecdotally of cases where
13 people get their official address on file is at, you know,
14 their daughter's address or something like that. I assume
15 that we are basically stuck with using whatever zip code is
16 on file for the person. Has anybody ever looked into how
17 often you get these cases and whether that has any effect
18 on sort of studying these issues?

19 DR. ZABINSKI: Not that I'm aware of, and that's
20 a really good question. I hadn't even considered that
21 point. But that's a really good question.

22 DR. HOADLEY: I mean, it comes up because I know

1 people who -- you know, a person whose father lives in
2 Pittsburgh and the daughter lives here, and the daughter
3 gets all the records. So I assume all the records show up
4 as if that person lives in Washington, D.C. But, you know
5 -- and it seems like it wouldn't be totally rare, but I
6 don't know if there's any way even to study that.

7 DR. MILLER: You're really bringing the party
8 down here [off microphone].

9 [Laughter.]

10 DR. CHRISTIANSON: Let's assume [off microphone].

11 DR. HOADLEY: Maybe I'll offset it [off
12 microphone].

13 DR. CROSSON: Okay. We've got the last slide up
14 here. As you can probably see there, we're going to have a
15 standalone chapter published in the summer. The purpose of
16 the discussion now is to help improve the content of that,
17 sharpen it, emphasis, whatever anybody thinks would improve
18 what you've read, that purpose, so we won't be coming back
19 to it again. And Paul's going to start us off.

20 DR. GINSBURG: Sure. A really good job, and I
21 think it's very useful for MedPAC to be reporting on this
22 geographic variation. I think it goes into -- it's going

1 to go into policy areas we don't even imagine, you know,
2 like you think about the quartiles that Congress set up for
3 Medicare Advantage benchmarks, that would be probably very
4 well informed by this. I doubt it was when they did it.

5 And I like your analytic approach of separating
6 out use from spending. And I would be really interested --
7 and would suggest that you just add a chart to this -- in
8 having something on the variation in health status to just
9 give people some insight into how significant is this in,
10 you know, determining the different resource use in
11 different parts of the country. You know, people talk
12 casually about it, but this would be precise, or as precise
13 as we can do with the data.

14 You know, I found -- we've talked about the Miami
15 and McAllen results. Fascinating. And, you know, this is
16 not statistical regression to the mean. This is really
17 information getting out and various people in their own
18 ways acting on it, and I think that's a virtue of doing
19 this at a detailed level and getting some of these outliers
20 out.

21 I was also very surprised by the fact that urban
22 and rural as a group seemed about the same in service use,

1 and I think that will be a surprise to many people, because
2 I think the impression that many people have is that, well,
3 rural areas, they don't have the specialists, their
4 hospitals aren't capable of doing as much, and, therefore,
5 they have less service use. And, you know, that may not be
6 the case.

7 DR. MILLER: Can I just -- because I wouldn't
8 have brought this up but he said it. You are right.
9 Everybody walks around with that in their head. The
10 previous geographic analysis that we did a few years ago
11 showed it was relatively comparable. A bunch of work that
12 Jeff and others did on rural issues a few years ago showed
13 it was relatively comparable. And everybody walks around
14 with that perception, that it isn't. And so it -- at least
15 for the Medicare population, because I think sometimes
16 facts in other parts of the population get kind of
17 attributed to Medicare. So I'm glad that you picked upon
18 that. It is something that people miss.

19 DR. CROSSON: Okay. Further comments? We'll
20 start -- nowhere.

21 DR. CHRISTIANSON: Sue and Craig.

22 DR. CROSSON: Okay. We'll start down here again.

1 Craig. That's where the majority are.

2 DR. SAMITT: So, again, I thought the analysis
3 was wonderful. I think what I'm curious to understand is:
4 What is actionable now based upon what we've studied and
5 observed? And I think that's why I asked about, you know,
6 looking at ACO penetration, Medicare Advantage penetration.
7 It's why we ask about encounter data, to try to get to the
8 root causes of the differences in service use as opposed to
9 just knowing that there's geographic variation. So it
10 feels like we need to know more about the root causes to
11 truly make some additional policy recommendations, and so I
12 don't know how to go a layer deeper, because I think that
13 would be the natural next step.

14 MS. THOMPSON: Well, thank you for your work
15 here, because when I saw this chapter, I was really
16 excited, and I just wanted to dig into it. And as soon as
17 I did and started asking -- writing down questions I had, I
18 thought, "Oh, my gosh." I mean, we could go down many,
19 many rabbit holes here, and it felt like I wanted a whole
20 little set of folks just doing nothing but maintaining all
21 these analytics around variation. And, therefore, to your
22 point, I think this is going to be -- as a Commission, I

1 think it's going to be important for us to be disciplined
2 about -- I mean, we could go -- we could spend all of our
3 time doing nothing but studying variation and really never
4 understand what's the problem we're trying to solve. So
5 that's a point I just kind of like foundationally want to
6 make.

7 But at the same time, while we, you know, focus
8 on Miami and McAllen, I want to understand who are the best
9 performers and why can it work like that and where are they
10 and what does that look like, and better -- I mean, we tend
11 to kind of want to focus on the negative. But where's the
12 really good work going on?

13 And then to Kathy's point earlier about at some
14 point in time getting after appropriateness issues, I mean,
15 this does seem like a wonderful set of data to help guide
16 that discussion.

17 So my comment is thank you. I would love to see
18 a map. I'm looking for a map where we'd overlay where the
19 ACOs are and did that make a difference. But I could send
20 you down 14 rabbit holes pretty quickly. I just think it's
21 going to be important for discipline around how we use
22 this, and, of course, we love this stuff. So thank you.

1 DR. SAMITT: Fourteen aren't so many.

2 [Laughter.]

3 DR. CROSSON: David.

4 DR. NERENZ: A similar comment. I think this is
5 really good, and last night, actually, on the cover, when I
6 write down things I might say, I had the word "shaming." I
7 thought that was probably what was going on.

8 But as this moves forward to a report for the
9 summer, not a rabbit hole but you might want to just make
10 some passing mention to the relationship between any of the
11 patterns you see here and what we see on commercial
12 insurance. I'm going to look at Jon here, but it seems
13 like one of the interesting things we've seen in the past
14 is that Minnesota and Wisconsin are typically identified in
15 analyses like these as low cost, low utilization for
16 Medicare. But then you look at commercial insurance, and
17 it's completely reversed. They're up on top.

18 DR. CHRISTIANSON: On spending.

19 DR. NERENZ: Spending, yes, thank you. But it
20 seems like a dynamic that at least ought to, you know, get
21 a paragraph or two of mention, and maybe we draw some
22 conclusion from that, maybe we don't, but it's -- because,

1 otherwise, you look at this, and following on Sue's
2 comment, you say, well, there must be some places that have
3 really good, tight conservative practice patterns, and
4 maybe they actually do, but it's not reflected in
5 commercial insurance spending, and then you have to explain
6 why not.

7 So not a rabbit hole, just a little tiny hole in
8 the earth.

9 DR. CROSSON: A burrow.

10 DR. NERENZ: Not deep. Shallow. A little dig.

11 DR. CROSSON: Jack.

12 DR. HOADLEY: So my comments are sort of on this
13 notion of the standalone report and sort of follows on
14 Paul's comments. I mean it really seems like we have some
15 interesting findings, and to the extent that some of them
16 are against what persists as conventional wisdom, you know,
17 I'd really encourage you to try to find a way -- you know,
18 we have our normal sort of fine-print report that looks
19 like a nice MedPAC government report. But I know you also
20 sometimes put things into the blog and so forth, and I
21 think, you know, to be able to have things like five
22 interesting facts we learned from this analysis might be a

1 really useful way to subtly -- we don't have to hammer the
2 politics of it, but just sort of state that, gee, it turned
3 out that urban and rural have the same usage. And, you
4 know, you can go farther if you want, but if you want to
5 just stop at sort of making the observation. Same thing
6 with McAllen and Miami, to the extent that you've
7 identified this fact and, you know -- then, again, we can't
8 prove what all the reasons are, but to the extent that we
9 can comment on things, we think about why this may have
10 happened, I think that could be really effective in
11 communicating this to people.

12 The other piece I would say there is think hard
13 about trying to do certain aspects of the methodology in
14 some, you know, much more lay terms. So one of the things
15 that occurred to me after I asked my first clarifying
16 question is that this approach to the methodology kind of
17 works in Medicare because Medicare has a uniform payment
18 system. And for the moment, in my head I was still, you
19 know, thinking about the price variations that you might
20 see in a commercial analysis where you really would worry
21 about the fact that, well, the doctors here just charge
22 more than the doctors there. Oh, but in Medicare they

1 don't do that because we pay them based on a uniform fee
2 schedule once we take out those adjustments.

3 So I think if we can make sure that in writing
4 about the methodology, sort of walk it back to some of
5 those simple levels, then, again, you know, this is the
6 kind of document that could get a lot of use by a broader -
7 - not necessarily the general public, but a broader set of
8 journalists and policy folks and people on the Hill, and
9 just making sure that they completely get that we have
10 adjusted out and that might be why we're different than
11 something else you've seen. This really is about service
12 use with intensity and whatever the rights words to use
13 are.

14 So I would just pay a little more attention to
15 sort of simplifying it for readers and actually defending
16 why this is, in our view, the right way to look at these
17 things.

18 The only other comment I would make is in sort of
19 looking at the areas like Sue was saying that may be on the
20 low-use end is thinking about is there any possibility in
21 those that we're hitting areas that are underusing
22 services. There's always the issue, if, you know, we tend

1 to say they're high because they're overused, and when
2 we've controlled for health status and all that, you know,
3 let's look at the low areas, and if there's any way we can
4 think about a question like that, is there any potential
5 this is a low-income area where, you know, maybe there
6 isn't enough providers. That's the argument that people
7 make about rural, but we're able to show there that that
8 doesn't play out that way. So it's just one other little
9 element to think about.

10 DR. CROSSON: Okay. Kathy.

11 MS. BUTO: A quick question. I know this doesn't
12 include MA experience, but do we have a sense of how areas
13 with high MA penetration do in terms of both use and
14 spending versus high fee-for-service penetration areas?

15 DR. ZABINSKI: Haven't done it in this study, but
16 way back, the first time I think we ever did this, it was
17 like 2005, 2006, something like that, we did. And --

18 MS. BUTO: Is there a difference?

19 DR. ZABINSKI: There's an effect of -- we found
20 some effect of HMO penetration, yeah.

21 MS. BUTO: I don't think you can compare
22 spending, really.

1 DR. ZABINSKI: Right.

2 MS. BUTO: That's very hard, but use would be
3 interesting.

4 DR. ZABINSKI: Yeah. There was -- it was a long
5 time ago, but I think it was small but significant in a
6 regression.

7 DR. GINSBURG: I think what's so hard is that
8 when areas have high use, that attracts HMOs into Medicare
9 Advantage because of the payment. But then the Medicare
10 Advantage probably influences the fee-for-service part
11 through spillover effects. So it's pretty difficult to
12 sort it all out.

13 DR. CROSSON: Bruce.

14 MR. PYENSON: Just a thought to follow up on
15 Susan's comment, not about the rabbit holes, but
16 identifying what might be considered best practice or well-
17 managed areas. And that it could well be the case that
18 areas that are well managed for post-acute are not
19 necessarily well managed for inpatient or physician
20 services and so forth. So my recollection is you, in
21 effect, created a total index, use that for variability,
22 and I suspect separating out the major components of that

1 might -- I think you indicated relatively little co-
2 variance between the different categories.

3 DR. ZABINSKI: Right. That's correct.

4 MR. PYENSON: So from the standpoint of a
5 composite best practice, it may not be the same -- it's
6 unusual to find a place that does everything well.

7 DR. CROSSON: Okay. Good input. Seeing no
8 further comments, thank you, Shinobu and Dan. I look
9 forward to your report.

10 We'll move on to the final presentation of the
11 day.

12 [Pause.]

13 DR. CROSSON: Okay. Ariel is going to take us
14 through a re-look at the issue of low-value care.

15 MR. WINTER: Good afternoon. I want to begin by
16 thanking Aaron Schwartz and Michael McWilliams of Harvard
17 Medical School, as well as Dan Zabinski, for their help
18 with this work.

19 Rita originally encouraged us to examine the
20 issue of low-value services, and this is the third year
21 that we will be updating you on our work to measure low-
22 value care. We use this information every year for various

1 publications, including our data book and March report.

2 For today's presentation I'll start by defining
3 low-value care and discuss the development of claims-based
4 measures of low-value care. We applied these measures to
5 Medicare claims data from 2012 to 2014. I'll describe the
6 results of our analysis and conclude with some potential
7 policy directions

8 Researchers define low-value care as services
9 with little or no clinical benefit, or care in which the
10 risk of harm from a service outweighs its potential
11 benefit. In this presentation, we also use the term
12 "overuse" to describe low-value care.

13 Low value care is a concern for two reasons.
14 First, it has the potential to harm patients, both
15 directly. by exposing them to the risks of injury from the
16 service itself, and indirectly, when the initial service
17 leads to a cascade of additional tests and procedures that
18 contain risks but provide little or no benefit. It may
19 also displace higher value care. And second, it increases
20 health care spending.

21 I'll say a few words about our motivation for
22 exploring this issue. First, there is a growing literature

1 on the topic of low-value care. For example, analyses
2 sponsored by the Commission found higher-than-expected
3 rates of repeat diagnostic tests among Medicare
4 beneficiaries. In addition, practitioners are making
5 efforts to identify and reduce low-value services through
6 the Choosing Wisely campaign. Thus far, over 70 medical
7 societies have identified more than 450 tests and
8 procedures that are often overused.

9 As part of our recommendation in June 2012, on
10 redesigning the Medicare benefit, the Commission supported
11 value-based insurance design, in which the Secretary could
12 alter cost-sharing based on evidence of the value of
13 services. Under this approach, cost sharing would
14 encourage beneficiaries to use high-value services, and
15 discourage the use of low-value services. Therefore, CMS
16 would need information on how to define and measure low-
17 value care. Finally, when we measure quality, it's
18 important to look at overuse of services in addition to
19 underuse.

20 We have been using 31 claims-based measures of
21 low-value care developed by a group of researchers.
22 These measures were published in JAMA Internal Medicine in

1 2014 and 2015. The measures are based on Choosing Wisely
2 guidelines, recommendations from the US Preventive Services
3 Task Force, and the medical literature.

4 The researchers developed two versions of each
5 measure: a broader one with higher sensitivity and lower
6 specificity, and a narrower one with lower sensitivity and
7 higher specificity.

8 The broader version of a measure captures more
9 potentially inappropriate use, but also is more likely to
10 misclassify some appropriate use as inappropriate. The
11 narrower version of a measure is more conservative. It is
12 less likely to misclassify appropriate use as
13 inappropriate, but is more likely to miss some instances of
14 inappropriate use.

15 To explain this, I'll describe the measure for
16 inappropriate imaging or patients with nonspecific low back
17 pain.

18 The broader version of this measure includes all
19 patients who received imaging for low back pain and
20 therefore captures more inappropriate use, but also some
21 appropriate use. The narrower version of this measure
22 excludes patients with certain diagnoses, such as cancer

1 and trauma, and is limited to imaging provided within the
2 first six weeks of the diagnosis of low back pain. This
3 version identifies fewer cases of inappropriate imaging,
4 but is less likely to misclassify appropriate use as
5 inappropriate.

6
7 For the last three years, we have contracted with
8 the authors of the JAMA Internal Medicine articles to
9 obtain their measures and the algorithms to calculate them.
10 In prior years, we applied the 31 measures to 100 percent
11 Medicare fee-for-service claims data from 2012 and 2013,
12 and for the analysis we're presenting today, we added data
13 from 2014.

14 Here are the aggregate results from our analysis
15 for 2014. Based on the broader versions of the measures,
16 37 percent of beneficiaries received at least one low-value
17 service. A single beneficiary can receive more than one
18 service, which helps explain why there were 72 low-value
19 services per 100 beneficiaries. Medicare spending for
20 these services was about \$6.5 billion.

21 Based on the narrower versions of each measure,
22 23 percent of beneficiaries received at least one low-value

1 service, and there were 34 low-value services per 100
2 beneficiaries. Total Medicare spending for these services
3 was \$2.4 billion.

4 This table shows the aggregate results for the
5 low-value care measures for 2012 through 2014, and you can
6 see a modest decline in volume and spending during this
7 period. The first three rows show results for the broader
8 version of the measures. Aggregate spending declined from
9 \$7.5 billion in 2012 to \$6.5 billion in 2014, and the
10 number of services per 100 beneficiaries fell from 74.6 to
11 72.2.

12 The bottom three rows have results for the
13 narrower version of the measures, which also show a slight
14 decline. It is important to point out that despite this
15 modest decline, there is still a significant amount of low-
16 value care, which has the potential to harm patients and
17 increase Medicare spending.

18 We grouped the measures into six larger clinical
19 categories, using same categories as the authors of the
20 JAMA Internal Medicine articles. This table shows which
21 categories accounted for most of the volume and spending,
22 by type of measure.

1 Under the broader version of the measures, in the
2 first column, imaging and cancer screening accounted for
3 most of the volume of low-value care but cardiovascular
4 tests and procedures, and other surgical procedures, made
5 up most of the spending.

6 Under the narrower version of the measures, in
7 the second column, imaging and diagnostic and preventive
8 testing accounted for most of the volume, while other
9 surgical procedures and imaging made up most of the
10 spending.

11 Here are results for some of the individual
12 measures for 2014. Results for all individual measures are
13 in your paper.

14 The first row on slide shows back imaging for
15 patients with nonspecific low back pain, which I talked
16 about earlier. Based on broader version of measure, there
17 were 12 cases per 100 patients in 2014 and spending was
18 \$232 million. Based on narrower version, there were 3.4
19 cases per 100 patients and spending was \$66 million.

20 The second measure is PSA screening for men age
21 75 and older. The number of cases per 100 patients ranged
22 from 9 in the broader version of the measure to 5.1 in the

1 narrower version. These results show that the volume of
2 low-value care that we detected can vary substantially
3 based on the measures' clinical specificity.

4 Our results probably understate volume and
5 spending on low-value care, and thus they represent a
6 conservative estimate of the actual amount of low-value
7 services, and this is for following reasons. First, there
8 are a limited number of measures of low-value care that can
9 be calculated with claims data. It can be challenging to
10 identify low-value care with claims data because claims may
11 not have enough clinical information to distinguish
12 appropriate use from inappropriate use.

13 In addition, our spending estimates probably
14 understate actual spending on low-value care because they
15 don't include downstream services that may result from the
16 initial low-value service. For example, a PSA test with an
17 abnormal result can lead to prostate biopsies and prostate
18 cancer treatment.

19 We looked at a study that estimated Medicare
20 spending on PSA tests and downstream diagnostic services
21 related to the test. For men age 75 or older, average
22 annual spending for the PSA tests and the follow-up

1 diagnostic tests was \$145 million, but PSA tests accounted
2 for only 28% of the \$145 million. Half of the cost was
3 related to biopsies and about one-fifth was related to
4 pathology.

5 New for this year, we examined geographic
6 variation in the use of low-value services. We used a set
7 of geographic areas based on MSAs, and these are the same
8 areas that Dan and Shinobu used in the work they presented
9 earlier. We call these "MedPAC areas." We adjusted for
10 differences in the demographic characteristics and chronic
11 conditions of beneficiaries in each area.

12 The model estimates the adjusted number of low-
13 value services per 100 beneficiaries in each geographic
14 area. We used the narrower version of the measures for
15 this analysis because they represent a more conservative
16 estimate of low-value care.

17 We found that, even after adjusting for
18 differences in demographic characteristics and
19 comorbidities, there is still substantial variation in the
20 use of low-value services. The adjusted number of low-
21 value services was 61 percent higher in the area at the
22 90th percentile than the area at the 10th percentile. At

1 the extremes, the number was nearly two times greater in
2 the highest area than in the lowest area.

3 But it is worth noting that there is a
4 substantial amount of low-value care even in areas with
5 relatively less use of such care. For example, the area at
6 the 10th percentile had 25 low-value services per 100
7 beneficiaries.

8 We also explored the relationship between use of
9 low-value services and total Medicare service use, which is
10 the measure that Dan and Shinobu discussed earlier. We
11 found a modest positive correlation between the amount of
12 low-value services and total service use.

13 DR. MILLER: If I can hold you just for a second.
14 There is a little bit of a photocopying issue. You have
15 one copy that's 12 pages long and then you have a second
16 copy that's 16. We are now in the second copy, on page 13.
17 So if you are fumbling around, look at your second copy and
18 pick it up at page 13.

19 I'm sorry about that but it was Warner's fault.

20 [Laughter.]

21 MR. THOMAS: I stapled them in the right spot.

22 [Laughter.]

1 DR. MILLER: Sorry about that.

2 MR. WINTER: Okay. So moving on to Slide 14, we
3 want to give you a sense of which areas provide the most
4 low-value care. This table shows the 10 geographic areas
5 with the highest adjusted number of low-value services per
6 100 beneficiaries in 2014. As with the prior slide, these
7 are based on the narrower versions of the measures.

8 By way of comparison, the national mean across
9 all the geographic in our analysis was 32 low-value
10 services, and it is worth nothing that 5 of the top 6 areas
11 are in Florida.

12 The work we presented today raises the question
13 of whether changes in payment policy and delivery systems
14 can influence use of low-value care. In one of the
15 articles we mentioned earlier, Schwartz and colleagues
16 compared changes in the use of low-value care between
17 beneficiaries in Pioneer ACOs and a control group of other
18 beneficiaries. The study used the same 31 measures that
19 were in our analysis.

20 The authors found that Pioneer ACOs had a greater
21 reduction in volume and spending on low-value care,
22 relative to the control group. These results suggest that

1 changing financial incentives at the organizational level
2 can discourage overuse.

3 I would like to conclude by laying out some
4 potential policy directions for addressing low-value care,
5 for your discussion.

6 First, you could think about payment and delivery
7 system reforms, such as 2-sided ACOs. Second, quality
8 measurement at the population level could incorporate
9 measures of low-value care. A third issue to consider is
10 Medicare's payment and coverage policy. Kathy and Rita
11 have asked us to look into coverage policy, and we
12 anticipate coming back to you in the fall on this topic.

13 Finally, you could think about encouraging
14 greater beneficiary engagement through changes in cost
15 sharing or use of shared decision making. In shared
16 decision making, providers communicate with patients about
17 the outcomes and uncertainties of tests or treatment
18 options, and patients discuss their values and the
19 importance they place on risks and benefits.

20 This concludes my presentation. I would be happy
21 to take questions.

22 DR. CROSSON: Let me start off with one.

1 Ariel, were you able to look at the relationship
2 between the use of low-value care and beneficiary age?
3 Does it go up with age? Flat? What?

4 MR. WINTER: So we haven't looked at it using age
5 directly as a variable. However, what we've done is -- we
6 didn't show the results here or in the paper, but we did
7 segment it for beneficiaries who are over 65 only, and all
8 beneficiaries, whether they were over 65 or under 65. And
9 I think the results show a higher rate of low-value service
10 use for the over 65 population, but that's probably an
11 artifact as well as the way the measures are defined,
12 because some of the measures, for example, several of the
13 cancer-screening measures only apply to older
14 beneficiaries.

15 DR. CROSSON: Yes.

16 MR. WINTER: So it's really hard to say. But we
17 can go back and look at that for the future.

18 DR. CROSSON: Yeah. It might be interesting.

19 All right. Another question. Jon.

20 DR. CHRISTIANSON: I'd like to go back to Slide
21 8. I guess I was more impressed with, just looking at the
22 broader version of the measures with the declines than your

1 title of the slide implies -- modest. I mean, on the
2 spending it's like 15 percent or so decline in two years,
3 which, you know, any decline in health care spending for a
4 population is notable. Fifteen percent in two years is
5 seriously notable. And that's at the same time -- I think
6 that's not -- that's not a per capita, obviously. So it's
7 also a time when enrollment is going up in the Medicare
8 program, when you would expect to see exactly the opposite
9 happen. And then if you look at the count per
10 beneficiaries, that, of course, went down by not nearly as
11 much percentagewise as the spending.

12 So I think there is more to be said here about
13 this slide, and I can't, frankly, remember how much you
14 went into the discussion of that in the paper, but it
15 didn't strike me as being modest at all. It struck me as
16 something to really look at.

17 MR. WINTER: Right. The number that does stand
18 out, and said this in the paper, was the reduction in
19 spending for the broader version of the measures, which was
20 about 13 percent or so, and you don't -- the reduction in
21 counts per the 100 beneficiaries was much smaller in both
22 the broader and narrower versions of the measures. And a

1 lot of what's driving this was there was a really big
2 reduction in spending for the cardiovascular tests and
3 procedures category.

4 DR. CHRISTIANSON: It would have to be for high
5 cost --

6 MR. WINTER: It went down by over \$700 million
7 between '12 and '14, so that's driving about 70 percent of
8 the reduction.

9 The other categories, you know, there were
10 reductions but nothing as significant as that one, where
11 there's a lot of money to begin with. That's the highest-
12 spending category, when you look at it by type of clinical
13 category.

14 But the thing I want to caution you all about is
15 that we only have three years of data here, so things could
16 change. Things could start going up again in the future.
17 So I want to caution you about drawing too many conclusions
18 from this pretty short trend.

19 DR. CHRISTIANSON: Right. The only conclusion
20 I'd like you to draw is that it's a pretty big change in
21 two years.

22 DR. CROSSON: Other questions? Jack.

1 DR. HOADLEY: So my question relates to your
2 modest positive -- on Slide 13, where you're talking about
3 the positive relationship between the low-value care
4 estimate and the total service use. I'm thinking to the
5 last session. I wonder if there's an ability to sort of
6 say, well, how much of the variation that we were looking
7 at in the last session goes away when -- if everybody
8 achieved the level that, say, the best-performing areas
9 achieved, or something like that. It might be an
10 interesting way to --

11 MR. WINTER: I can talk to Dan about that. One
12 thing I'll show you -- we have a bonus slide, which Dan
13 created, so Dan gets all the credit. This shows you that -
14 - the simple regression that he ran, between total service
15 use, on the horizontal axis -- I'm sorry, the vertical axis
16 -- and low-value care on the horizontal axis. And you can
17 see that there is a relationship but it's just a lot of
18 unexplained variation between the two variables, and R-
19 square, as you can see, is 0.29. So we've begun to explore
20 this issue but just in the last couple of weeks, so we'll
21 think some more about your suggestion.

22 DR. HOADLEY: Thank you. You know, just the fact

1 that your biggest variation is in post-acute care, and I
2 don't know that any of those services are on the low-value
3 list --

4 MR. WINTER: They're not.

5 DR. HOADLEY: -- limits the degree of
6 correlation.

7 MR. WINTER: Right, and as Dan said, that's a
8 much bigger explanatory factor than low-value service use.

9 DR. CROSSON: Right. But you could remove post-
10 acute care and look at it again. Right?

11 Sorry.

12 MR. WINTER: He's nodding, yes.

13 MR. PYENSON: Just along the lines, I think of
14 this discussion. Looking at this in aggregate from Slide
15 7, roughly \$2 to \$6 billion, you know, a higher end, lower
16 end, which corresponds to roughly 1 percent of Medicare
17 spending, or half a percent of Medicare spending. And just
18 to emphasize, I think that this is not the only low-value
19 care around. Right? We expect ACOs, in order to get a
20 bonus, to do much, much better than that. And I think
21 we've looked at other measures, potentially readmissions,
22 potentially preventable admissions, things of that sort.

1 So I'm wondering how you put this into that context,
2 because just looking at the title, somebody assigned the
3 word "low-value care" to this set of specialty society CPT
4 codes, and there's lots more than that.

5 I don't know how -- that's sort of a context
6 issue, because I'm concerned that this gets lost.

7 MR. WINTER: Yeah, those are good points, and one
8 thing I'll point out is that the \$6.5 billion that was
9 captured by the broader versions, it's about 2 percent of
10 fee-for-service Medicare spending.

11 MR. PYENSON: Okay. Two percent of fee-for-
12 service.

13 MR. WINTER: So not -- it's still not huge.
14 Right, it's pretty small. And we've tried to caution
15 throughout the paper, and perhaps we should have done this
16 more in the presentation, that this is -- we are measuring
17 services that we can -- that could be defined pretty well
18 using claims data, by a group of researchers that have been
19 kind enough to let us use their measures, and it doesn't --
20 we're not -- we don't intend to capture the entire universe
21 of what might be considered low-value services within
22 Medicare.

1 And you mentioned PPAs and PPBs, and my
2 colleagues, Lydia and Nancy, have been doing a lot of work
3 in this area. And that, it's a little bit different
4 because they're looking at -- using that to assess the
5 quality of the ambulatory care system, where, was there
6 adequate access and was there adequate coordination to
7 present either ED visits or admissions that could have been
8 prevented. And we are not saying that each one of them
9 could have been prevented but it's more of a relative
10 measure. If you see a region of the country that's twice
11 as high as the national average, that might raise some
12 concerns. Whereas here I think they're trying -- these are
13 meant to be more precise, even though we have -- we
14 definitely have a range, you know, broad versus narrow, but
15 we're drilling down into specific kinds of services that
16 could be considered low-value.

17 MR. PYENSON: I wonder if we could somehow change
18 the title because it seems like measuring low-value care,
19 you're really measuring a subset of low-value care here,
20 and I think that's an important distinction.

21 But it's terrific work. I don't want to take
22 away from that.

1 DR. CROSSON: On this point, David?

2 DR. NERENZ: Yeah.

3 I appreciate it, but although I guess I would use
4 the words differently. If somebody has a bad infection and
5 then needs to be admitted, that's high-value care. So I
6 would think the two domains, although in both cases, there
7 are things you might not want to see, they're not sort of a
8 subset and then a remainder subset of the same concept.

9 The reason I like the term and what's under it is
10 that you're talking about services that either do no good
11 or do harm, but say a preventable admission, the admission
12 itself is of high value presuming --

13 MR. PYENSON: Well, no, but it --

14 DR. NERENZ: Yeah. We don't know for sure but at
15 least you don't presume up front that it's not. Here, we
16 do presume up front that it's not.

17 DR. REDBERG: For this list, I would say this is
18 no-value care or harmful care. It's not even low value.

19 MR. PYENSON: So I don't want people to say,
20 "Well, if it's not low-value care, then it's high-value
21 care; therefore, we're expecting ACOs to meet their targets
22 by getting rid of high-value care." Right? I think the

1 words are important.

2 DR. NERENZ: Well, except the discussion here is
3 not everything we think somebody might want to get rid of.
4 It's a specific thing put out with a label for a specific
5 region, was the point I wanted to make.

6 DR. CROSSON: I don't know if we need to change
7 the term, but we could modify it in some way, at least in
8 the text, to talk about selected areas, because after all,
9 this is sort of what we can measure, right, as opposed to
10 other areas of low-value care, which just represent
11 individual physician judgment for an individual patient,
12 which is just not the right decision, but it's non-
13 measurable or very difficult to measure.

14 So selected areas of low-value care, something
15 like that, would that help?

16 MR. PYENSON: Yep.

17 MS. BUTO: You might want to add in Medicare fee-
18 for-service, too, because it doesn't include --

19 DR. CROSSON: Right.

20 Could you come up with an acronym for all that?

21 [Laughter.]

22 DR. CROSSON: Alice, did I see you?

1 DR. COOMBS: Slowly.

2 DR. CROSSON: Slowly raise your hand, considering
3 your question.

4 DR. COOMBS: So this was a claims-based study.
5 It wasn't a medical record review.

6 MR. WINTER: Correct.

7 DR. COOMBS: So there's some inherent problems
8 with that, per se.

9 MR. WINTER: There are always going to be
10 questions about the accuracy of the claims in terms of the
11 diagnoses, procedures, the time frame, yes, and the measure
12 developers have acknowledged that in their publications.

13 DR. COOMBS: Right.

14 DR. MILLER: Well, and that's why there's kind of
15 a conservative and less conservative measure.

16 MR. WINTER: Right.

17 DR. COOMBS: And I think that's really important,
18 the narrow or broader division.

19 And then the other question is there are things
20 that I consider maybe not as valuable, but there is another
21 category that I don't think we really dealt with. And I'll
22 give you an example of Lyme disease. There's two different

1 specialties that are involved in the treatment of Lyme
2 disease. There's a Lyme Disease Society, and then there's
3 ID world, and they have very different ideas about
4 treatment. Some have proposed treating Lyme disease
5 chronically with antibiotics. The other group doesn't
6 believe in that. The cost is absolutely staggering with
7 one of the societies that propose it.

8 I think that duration of treatment can be low
9 value, so that inappropriate treatment with antibiotics for
10 prolonged periods of time can be low value, and there's
11 certain complications with that. So I think that's one of
12 the areas that I thought about in terms of low value.

13 I was happy to see that in the original paper,
14 they did discuss the U.S. task force. There's some
15 retraction with some of the recommendations originally in
16 terms of being able to recognize groups that are at risk,
17 i.e., African Americans with PSA monitoring. So I think
18 they did allude to that. I saw a brief statement.

19 MR. WINTER: Are you saying that the Preventive
20 Services Task Force has retracted its 2012 recommendation
21 against testing?

22 DR. COOMBS: Well, not so much retract, but there

1 is a qualifier, because I had talked about this, I think,
2 ever since we brought this up --

3 MR. WINTER: Yeah.

4 DR. COOMBS: -- about race being a consideration
5 that in an African American male, PSA is very valuable
6 because they are not going to have the same outcome as a
7 white male who has a positive PSA, just in terms of the
8 mortality by itself and how aggressive disease is.

9 MR. WINTER: So I've looked at the 2012
10 recommendation statement, and if there's something more
11 recent, then I'll be happy to look at that as well.

12 They looked at primarily two randomized trials of
13 PSA testing. In only one of them were African Americans
14 present, and there were too few of them for the task force
15 to draw conclusions about the balance of risks and benefits
16 for that population. If there's more recent information
17 that they've put out, I'd be happy to take a look at it.

18 DR. REDBERG: I don't know of any data, Alice,
19 that suggests that PSA testing is a value, even in African
20 Americans. If there are some references, I'd be interested
21 to see them.

22 The task force is doing an update on their PSA

1 recommendation. I will say the one in here is way -- this
2 one over 75, but as you know, in 2012, the task force said
3 PSA was a grade D for all ages.

4 MR. WINTER: Right.

5 DR. REDBERG: So this way underestimates the
6 overspend on PSA because none of it should be done.

7 MR. WINTER: Right.

8 DR. REDBERG: And there isn't any data to suggest
9 it's valuable in African Americans, but I suspect we're
10 going to see something on race in the next update because
11 they specifically say they're updating and looking at
12 subgroups, so I think that's what they'll look at,
13 probably.

14 DR. COOMBS: Just so we keep current with it.

15 MR. WINTER: One of the reasons we used the
16 earlier -- one reason the researchers who developed the
17 measures used the earlier Preventive Services Task Force
18 recommendation, which is age 75 or above, is because the
19 newer one came out in May 2012, and we're using 2012 data
20 as our baseline. So it wouldn't be fair to hold them to a
21 standard that wasn't yet out until the middle of 2012. So
22 that's why we're using the older recommendation.

1 DR. CROSSON: Okay. Let's see where we are with
2 the questions. I see no more here. Clarifying questions
3 coming up here?

4 [No response.]

5 DR. CROSSON: Okay. So, Rita, I believe you're
6 going to start off.

7 DR. REDBERG: Well, thanks, Ariel. It was really
8 a great chapter, and I think it's really important work
9 because it's really win-win.

10 I wasn't joking. This is harmful care. I mean
11 care that has no benefit and it only has harms, and so
12 besides the billions of dollars that Medicare is spending,
13 people are being hurt. I mean, there is nothing -- there
14 is no social redemption in this. It's like POD. There is
15 nothing fun about getting tests that you don't need and
16 aren't going to help you feel better.

17 And as I said, a lot of these, I think they were
18 pretty conservative because -- which is fine, and PSA was
19 just one example.

20 I do think -- and you talked about it -- it's
21 hard to separate our current fee-for-service system from
22 what's going on. I have a quote. George Bernard Shaw from

1 "The Doctor's Dilemma," 1911, said, "Having observed that
2 you could provide for the supply of bread by giving bakers
3 a pecuniary interest in baking, we go on to give a surgeon
4 a pecuniary interest in cutting off your leg." That's
5 essentially the kind of system we have.

6 I mean, the urologists and the spine surgeons,
7 they all vigorously protest that in their hands, they know
8 these things are better, but there isn't any evidence. And
9 it's very hard for -- it's like you don't ask the barber if
10 you need a haircut. I mean, those are not the groups that
11 should be passing on this, and it should be -- and we know
12 for a fact that your treatment, because -- and the other
13 reason they way underestimated the cost of PSAs, I mean,
14 you showed the data on biopsies. It's not the biopsy.
15 It's the surgery. It's the IMRT, the proton beam therapy.

16 I mean, there was that new article in the Times
17 last week about some other kind of radiation therapy for
18 prostate cancer. None of it ever has any evidence, and
19 it's always very expensive. And I look at it and I think
20 this has all started because men keep getting PSA testing.
21 Why is Medicare paying for PSA testing at all? We pay for
22 Grade A and B. That's great, but this is harmful, but

1 Medicare is still paying for it.

2 If people want to get tests that aren't in your
3 best interest, you can pay out of pocket for them, but I
4 don't see why the program is paying. So it's not the tests
5 or the biopsies. It's all of these treatments. It leads
6 to incontinence, erectile dysfunction. There are a lot of
7 very unpleasant things from PSA.

8 The other thing here, imaging for non-specific
9 low back pain, I suspect most of the Commissioners, but
10 maybe not a lot of other people remember the Office of --
11 was it OTA? No. Agency for Health Care Policy and
12 Research, which did the technology assessment looking at
13 back pain, and said that conservative treatment, you did
14 better than with surgery for back pain. But the orthopedic
15 surgeons got very upset with that and got together with Tom
16 DeLay and threatened to zero-fund the agency, and then it
17 sort of went away and came back as AHRQ, which stayed away
18 from making any kind of statements that would have got the
19 medical groups concerned that they would interfere with the
20 practice of medicine, which wasn't, of course, what they
21 were doing. They were stating that there was no evidence.

22 But there are a lot of -- I see patients every

1 week who have had spinal surgery, and I feel very badly
2 because I know that there isn't any evidence that they are
3 better off. And a lot of our device discussion was over
4 spinal fusions.

5 So getting to what we can do, I think certainly
6 changing -- getting away from fee-for-service and getting
7 away from paying for services, I mean, some of these are
8 quite clear. A lot of it is in cancer screening, and you
9 can use billing data because you're just looking at age. I
10 mean, it's not recommended for people over 75 because you
11 need a long lead time in order to see a benefit from cancer
12 screening. So there are a lot of things we could do even
13 without medical records data.

14 So I think Medicare can -- it takes political
15 will, but not pay for things that are harmful for
16 beneficiaries, that seems pretty reasonable to me.

17 Moving towards ACOs and alternative payment
18 models that don't reward this is certainly an improvement.

19 You mentioned quality, because all of our quality
20 measures are -- or towards things we're not doing, but
21 certainly overuse as a quality measure, I think is a very
22 effective mechanism.

1 And I think -- so those were all, and I want to
2 see if there's anything from the discussion. Quality
3 management, payment and coverage policy, we talked about --
4 and beneficiary engagement. You know, that's an
5 interesting question. I'm just not sure how much shared
6 decision-making. It's a good idea. I don't think it's
7 actually happening. It's very hard for beneficiaries to
8 understand all the numbers, and I don't think that a lot of
9 doctors are taking the time to explain, especially in the
10 system where people are going through very quickly, and
11 honestly, financially, doctors are rewarded for doing more
12 things, not for explaining to patients why they don't need
13 particular tests.

14 So while I think shared decision-making should
15 happen, I don't think it's going to be a major factor in
16 decreasing overuse. But I'm glad that we're looking at
17 this work, and I look forward to my fellow Commissioners'
18 comments.

19 DR. CROSSON: Okay. Thank you, Rita.

20 So Rita has touched on the four potential policy
21 directions that are up there. It's not the first time
22 we've discussed them.

1 So what I'd like to do is -- and we can do this
2 fairly -- in a fairly time-efficient manner -- is to say
3 which of these four -- and some have more components, cost
4 sharing, shared decision-making, for example -- where
5 should we be putting our policy development energy over the
6 next year or two? What are your favorites? Which ones do
7 you think are a blind alley? That's the point, I think,
8 we've got here.

9 I can't remember now. I think I've been going
10 this way every time, so I'm going to start over here.

11 Paul.

12 DR. GINSBURG: It's really good to put these four
13 options, but even though I suspect that when you think
14 about what Medicare can do well and what Medicare can't do
15 well, probably coverage policy is not a strength of
16 Medicare, just given the political environment it does, and
17 just the difficulty of using well the recommendations that
18 come from the Preventive Services Task Force when Congress
19 gets hold of them. That may not be the area.

20 To me, payment delivery system reform, in a
21 sense, gets at this indirectly by providing, you know,
22 frameworks and incentives for an organization to act in

1 this way, which is something that Medicare can do much
2 better, and I think the dollar potential in that one is
3 probably strongest. So this motivates me to work more on
4 delivery system reform payments.

5 DR. CROSSON: Bruce.

6 MR. PYENSON: I think one of the things that we
7 could do in this piece that would be helpful is to avoid
8 some of the controversies that are in the health care
9 system. For example, on page 5, there's the statement
10 about the risks of injury from radiation exposure from CT
11 scans. I and others believe that's a myth.

12 I have a quote from the American Association of
13 Physicists and Medicine to that effect, perhaps not as
14 eloquent as George Bernard Shaw, but it says, "Predictions
15 of hypothetical cancer risks and deaths in patient
16 populations are hypothetical and probably nonexistent and
17 should be avoided because they lead to sensational articles
18 that cause patients and parents to refuse needed medical
19 treatment."

20 It's the same -- so, in my opinion and others, a
21 safer example would be the harms from -- the well-known
22 harms from, for example, perforation, from optical

1 colonoscopy, which is somewhere between 1 per 1,000 and 5
2 per 1,000 -- I'm sorry -- 1 per 1,000 and 1 per 5,000. So
3 I think focusing on really the strong evidence would be
4 helpful.

5 I heard what Paul said about the challenges with
6 coverage, but perhaps I'm not as pessimistic or as smart.
7 But I would hope for coverage policy changes that would
8 help, in particular, with the relatively focused subject of
9 this paper.

10 DR. CROSSON: We have a comment on your comment
11 from Rita, and then I'm not sure if Kathy wants to get in
12 on that one too. So, Rita, Kathy, Alice.

13 DR. REDBERG: Yeah.

14 DR. CROSSON: You're getting it now. Look out.

15 DR. REDBERG: I've been practicing medicine for
16 35 years, and that's the first time I've heard someone say
17 that there was not a cancer risk from radiation. I think
18 there's extensive evidence that links exposure of ionizing
19 radiation to increased risk of cancer. There's diagnostic
20 CT. There is studies showing DNA damage. There's
21 epidemiologic studies. We have all the Hiroshima data. I
22 mean, I could give you just lists.

1 I wrote a New York Times op-ed on the risks of CT
2 scans, and we published articles in Archives, when it was
3 Archives of Internal Medicine from the National Cancer
4 Institute, estimating there would be 60,000 additional
5 cases of cancer, 30,000 excess deaths just from the CT
6 scans done in 2007 alone. There have been studies and
7 studies. There have been hearings. I have to disagree,
8 that there is definitely a radiation -- there's cancer risk
9 from radiation exposure.

10 MR. PYENSON: You heard it from me before, but as
11 an actuary, I can calculate the risk of a 10-mile car trip
12 to go to an office visit. I can't extrapolate from the 500
13 -- the lethal dose at Hiroshima to the kind of
14 millisievert, one millisievert, five millisieverts doses
15 that occur today with modern CT scans.

16 So I know there's been a lot of things said
17 around that, but frankly, the methodologies aren't
18 something that has been widely accepted, the linear
19 extrapolation.

20 DR. CROSSON: Okay. It's getting a little
21 radioactive here. Kathy?

22 [Laughter.]

1 MS. BUTO: It's the end of the day.

2 So the first bullet, which is payment delivery
3 system reform, I think we all feel comfortable in that
4 space.

5 I don't think it works very well, though, without
6 clinical guidelines or some other mechanism to help inform
7 the judgments made by well-meaning payment systems. So I
8 think there is a responsibility or an opportunity there to
9 go forward or to promote a greater role for Medicare in
10 getting -- pulling that information together, whether it's
11 through outside bodies or whatever it is, in order to help
12 inform that decision-making.

13 I know Paul is pessimistic about coverage policy,
14 but it has been effective in limiting coverage, sometimes
15 after the fact where evidence suggests that a procedure or
16 an approach is not advisable. And it doesn't happen very
17 often, but when it does and claims get pulled or denied as
18 a result, it's pretty effective.

19 So I think when we get around to looking at
20 coverage policy, maybe in the coming year, one of the
21 issues will be is there a way that it can be a little more
22 nimble in addressing these kinds of questions. It has a

1 number of problems right now that make it difficult to --
2 and one of them is trust. A lot of beneficiary groups and
3 other groups do not trust the process. So I think it's got
4 to be looked at and made potentially -- brought up to
5 modern times. But I think there is a potential there.

6 DR. CROSSON: Alice.

7 DR. COOMBS: I just wanted to speak to some of
8 the items there, and also to say that -- you know, I think
9 I circulated the article on cancer mortality -- I sent it
10 out to a few people around the table -- in which there is
11 20 percent reduction in mortality, and in that article in
12 JAMA, January 2017, this year, they allude to the fact that
13 what has happened with colon cancer, how do you get a 20
14 percent reduction without the identification and the
15 diagnosis? Well, that's for the general broad population,
16 but they do break out age groups in that, and they also
17 look at geographic distribution. Very persuasive article.

18 So something we're doing is okay with screening,
19 and so I'm not saying that an octogenarian needs to have,
20 you know, the full cart-plus in terms of workups, but
21 there's something we're doing in this country that has
22 resulted in good results for that article, and they allude

1 to screening. And that's in the Journal of the American
2 Medical Association.

3 First of all, I agree --

4 DR. REDBERG: The recommendation is to stop at
5 age 75. It's not --

6 DR. COOMBS: Yeah, so I just mention I'm not
7 talking about octogenarian, but I am talking about
8 screening tests in general in terms of the individual
9 tumors that they allude to. It's a great article.

10 So the first part is that I agree with Paul
11 regarding system reform. We are in the midst of MACRA and
12 MIPS. I mean, what do we think we're doing if we're not
13 doing quality and we're not looking at how we're impacting
14 providers, physicians, nurse practitioners, and PAs? And I
15 would think that we need to sit back and consider that we
16 already have something that is actually hopefully changing
17 patterns through the MIPS. And that in and of itself
18 actually addresses some of this in terms of -- and it's
19 looking at cost, it's looking at resource utilization.

20 So why do we have to layer yet another layer on
21 top of providers for some of the other things? Why don't
22 we wait and see or wait and look at how we best change

1 patterns of low-value services through what is already on
2 the table? I mean, it sounds like we're trying to -- I
3 mean, I'm okay with saying that it actually deals with all
4 the specific areas that we would like to see in terms of
5 low-value services.

6 DR. MILLER: But there is one thing on MIPS that
7 I've got to say. There was a lot of discussion over the
8 last few months -- I can't remember the specific months --
9 where we kind of came back to the MIPS and the APM
10 framework, raised a whole host of issues around the amount
11 of data collection and burden and how much given the
12 precision fact that you choose your own measures, that
13 they're small, and the way the system is designed, whether
14 you're actually going to really be able to distinguish
15 among physician performance, and started to have those
16 questions and started to raise questions about whether you
17 could use more of a population-based approach to it, of
18 which a low-value measure could be slotted into that.

19 Now, you could do it certainly for an APM or an
20 ACO when you have a population base. And then we talked
21 about the notion of individual physicians saying, "I want
22 to choose the physicians I get measured with" so that

1 there's enough measurement that you could use a population
2 base for. And it would relieve, you know, the burden and
3 then measure, like I said, on a population basis.

4 There is a concern that the current methods and
5 the measures that are being collected are not going to
6 really give a lot of information to distinguish the
7 performance of --

8 DR. COOMBS: And I agree with that, but that
9 argument and discussion, especially around the specialties,
10 the 5 percenters, the radiologists, anesthesiologists,
11 pathologists, and ER physicians, because they didn't have
12 consistent benchmarks, qual. metrics to look at, so they're
13 trying to meander their way through this whole process.
14 But some of these things are more skewed toward primary
15 care, family practice, and, you know, just in terms of the
16 generalists. And I think if you were to analyze any
17 internal medicine practice -- and, Craig, you can say so --
18 there's inculcated within their practice those quality
19 parameters that people actually look at already.

20 So I think the point you bring up is very good,
21 but I think right now, for primary care doctors, they're
22 including all of those things, and I'm not sure that having

1 another layer of yet something else that we're requiring of
2 providers is going to help them in the big picture. I
3 would like to see how this works out first rather than to
4 layer something else on top of providers.

5 DR. MILLER: The only thing I'll say -- because I
6 don't want to get into an argument -- I do want to get into
7 the CT thing you guys --

8 [Laughter.]

9 DR. MILLER: In our approach, this wouldn't be an
10 additional layer. It would be a removal of the current
11 requirements, and then the calculation would be done on a
12 population basis and would remove the burden from the
13 physician entirely. So we can, you know, potentially
14 disagree on what's the right approach, but I do want you to
15 understand we're not proposing this as another layer. That
16 at a minimum I do want to be clear on. But, you know, we
17 may have a different view of -- you know.

18 DR. CROSSON: Okay. Let me see where we are.
19 Who wants to get in on this point right now? Okay. Paul
20 and Brian. Then, Bill, you have another point?

21 DR. HALL: Well, yeah [off microphone].

22 DR. CROSSON: Okay. Let's do Paul and Brian

1 first.

2 DR. GINSBURG: When I suggested that payment
3 delivery system reform was perhaps the best way to go, not
4 necessarily the path we're on now, and really reflecting a
5 lot of what I've learned here, I'm not very optimistic
6 about what MACRA is going to accomplish in its current
7 form. I think the ACO model that Medicare has chosen is
8 not the best way to pursue that concept of global payment.

9 So, basically, the path, which I think has high
10 reward, is also high risk, that we could fall on our face
11 and not accomplish much. So I wouldn't -- in saying that I
12 think that the greatest opportunity is there, I wouldn't to
13 rule out working in other areas. And, you know, coverage
14 policy is something that where there's lower potential,
15 there might be some low-hanging fruit there to get at.

16 DR. CROSSON: Brian.

17 DR. DeBUSK: The last time we met, we talked a
18 little bit about reforming MIPS and some of the limitations
19 in PQRS and all that. Could this methodology, if it were
20 packaged and refined, could this produce a virtual PQRS
21 measure, I mean, something that -- it would work like a
22 PQRS measure but it would be passively derived from claims

1 data, so you wouldn't actually have a physician-reported
2 measure at all. That's to Mark's point earlier.

3 DR. CROSSON: As I listen to Mark, that's what I
4 thought --

5 DR. DeBUSK: Yeah, it's a virtual PQRS measure.

6 DR. CROSSON: Essentially, because we've talked
7 before about getting out of the granular MIPS measurement
8 process because of the burden that that creates for
9 physicians. And yet we have to have something to hold
10 physicians at some level of collective responsibility
11 accountable. But that should be a small number of
12 measures, and it should be, as much as possible, measures
13 that don't require extra work on the part of the physician.
14 So you could imagine just what I think -- that's what I
15 thought it meant. What Brian was saying was you could
16 develop a global measure of the use of low-value services
17 at an aggregate practice level of some sort. It wouldn't
18 require any direct work or reporting by the individual
19 physician but still would represent, you know, for
20 comparison purposes how one practice of collection of
21 physicians is going about the practice of medicine versus
22 another. I think that's -- okay. Bill.

1 DR. REDBERG: Can I just comment --

2 DR. CROSSON: You want to comment on this? Okay.

3 DR. REDBERG: I just wanted to say on the
4 colorectal cancer -- and I agree that with screening
5 between the ages of 50 and stopping at 75, but the article
6 -- and it was Gil Welch's article -- I just pulled it up --
7 in the new England Journal called "Colorectal Cancer on
8 the" --

9 DR. COOMBS: It was a JAMA article [off
10 microphone].

11 DR. REDBERG: I'll just finish my sentence,
12 thanks. "Colorectal Cancer on the Decline: Why Screening
13 Can't Explain It All." And it's just about how the decline
14 started way before we started screening, and it is
15 attributed to changes in American diet, which is a good
16 thing.

17 DR. CROSSON: Okay. We have gone from
18 radioactive to scatology, and I'm going to now --

19 [Laughter.]

20 DR. COOMBS: It was a different article, just so
21 everyone knows [off microphone].

22 DR. CROSSON: Bill.

1 DR. HALL: I don't have a solution for this, but
2 just a couple of observations.

3 Number one, the most important one is that
4 medicine is not a precise science -- and we don't like to
5 admit this very often -- so you're always going to have
6 controversy about screening or therapeutics among well-
7 meaning, well-educated physicians. I think this is very
8 difficult.

9 The other thing, I haven't mentioned this for a
10 long time, but the very powerful influence of direct-to-
11 consumer advertising that really blew this out of the
12 water, so on my very modest and on-time flight down here
13 yesterday -- it takes one hour -- I went through the
14 American Airlines book that's there, and it talks about
15 Florida vacations and all that sort of thing. I found -- I
16 wasn't looking for it, but I guess I was in a way. I found
17 maybe six or seven ads all related to prostate screening or
18 therapeutics that implied magic. Half of them were put in
19 there by major medical centers in the United States. This
20 wasn't some fly-by-night person doing this.

21 DR. COOMBS: American Airlines [off microphone]?

22 DR. HALL: American Airlines, well, yeah, so they

1 change it every month. So this is a big problem, and I
2 don't think there's going to be one solution. We talked in
3 the presentation about "Choose Wisely," which was a heroic
4 effort by dozens of medical societies. It's almost fallen
5 off the map two years later. You don't hear much about it
6 anymore. So it didn't lead to something that was
7 actionable over a short -- or a long period of time.

8 So I think it's multifactoral, but I think the
9 one thing that comes out of this is that there's got to be
10 some effective consumer education, and I don't really know
11 how that's going to happen. We went many years about
12 perimenopausal use of estrogens in women. I don't know how
13 many thousands of women were harmed, killed, before we --
14 it wasn't just overnight that people discovered this. So
15 in terms of high-risk things, I think if we say this is the
16 one thing that's going to do it, MIPS or whatever, I think
17 we're going to be -- we're going to fail.

18 But a lot of things I think as we go forward in
19 Medicare, at least one approach that might be better is, as
20 much as we can, to have a much higher educated Medicare
21 population. I don't think this is all legislation and
22 knocking on the doors of physicians and saying, "You were a

1 naughty boy or girl." But this isn't going to go away. I
2 think I's going to get much worse with time -- well, it is
3 getting worse with time.

4 So I think we should be very careful before we
5 say this is the magic bullet that's going to change this
6 behavior.

7 DR. CROSSON: Bill, I usually travel on United,
8 and they try to send me on cruises.

9 [Laughter.]

10 DR. CROSSON: The other thing is, to your point,
11 I have seen on TV fit testing advertisements with some
12 really interesting graphics, if you are not seeing the
13 commercial. I won't go any further on that.

14 DR. HALL: Is that right next to the page where
15 you have 30-minute dating for older people [off
16 microphone]?

17 [Laughter.]

18 DR. CROSSON: Right. Yeah, well, that's a thing
19 of the past. Who's up next?

20 DR. REDBERG: Can we please get back to radiation
21 [off microphone]?

22 [Laughter.]

1 DR. MILLER: Please change the topic.

2 MS. BRICKER: I'll be brief. I was going to
3 highlight the importance of thing 4, increase beneficiary
4 engagement. You know, Bill, you said a lot to cover what I
5 was going to reiterate. I don't think it can be done in
6 isolation, but I'm absolutely a proponent of ensuring that
7 folks have, you know, a balanced view. If you believe that
8 you can't ask the barber about the haircut, then we've got
9 to figure out who they can ask about their haircut.

10 And, you know, I think to your point about
11 estrogen and the harmful effects of, I think it's going to
12 take, you know, quality measures -- right? So when someone
13 comes into the office and says, "I just saw this thing in
14 American Airlines about getting the screening," and you
15 know as a physician that you're going to be dinged from a
16 quality perspective and you're held to a standard that you
17 must educate the beneficiary on that decision, and maybe
18 they share in some of that cost -- I don't know, weaving
19 some of these things together -- maybe then the outcome is
20 different. But to do it not in consultation with the
21 beneficiary I think is a missed opportunity.

22 DR. CROSSON: Thank you. Jack -- David.

1 DR. HOADLEY: I do want to get in [off
2 microphone].

3 [Laughter.]

4 DR. CROSSON: And I do have eyes in the back of
5 my head.

6 DR. NERENZ: That's good. I'll also try to be
7 brief. I would, first of all, say that I'm so glad this is
8 on our agenda. I think it's important. I think it's
9 crucial. You've done a really nice job. I've tried to
10 support Rita's interest in this, so I want this to stay in
11 front of us.

12 You know, when I think broadly about this, I do
13 have this from the heart sense -- and Rita expressed it
14 eloquently -- Medicare shouldn't pay for things that hurt
15 people, and that leads me to the third and fourth bullet
16 there, but then I am cautioned, and appropriately, by
17 Paul's comment that it's okay to say that in this room.
18 But you try to run that through Congress and ultimately out
19 through CMS, and it's a way harder process.

20 I would by instinct say, well, we should just say
21 Medicare doesn't pay for this, or the cost sharing is
22 kicked up to a high level, so at least Medicare isn't

1 paying very much for it. But I appreciate the difficulty
2 in implementing that.

3 So that leaves us with the top two bullets. I
4 think there are things to like there. I'm a little curious
5 on the top one that we highlight ACOs, which I think aside
6 from that one little example of the Pioneers, over on the
7 much larger MSSP program, I don't know of any evidence that
8 they've done much in this space. In fact, they're having
9 trouble saving money in any -- doing anything. So I don't
10 know the answers there, but we didn't talk about MA. And
11 I'm a little surprised because MA has stronger incentives
12 to do this and better tools, and a dollar saved drops right
13 to their bottom line.

14 Maybe there just aren't examples there to talk
15 about, but at least I'd like to sort of perhaps highlight
16 that a little more.

17 Do you have a response?

18 MR. WINTER: Just quickly, we do cite an article
19 in the paper by Culhane and colleagues from 2013 which does
20 say there is low-value care in managed care arrangements in
21 addition to fee-for-service. I don't recall if they were
22 looking at MA specifically or general managed care, but we

1 can get back to you, get some more details to you about
2 that article. And the low-value care that they were
3 looking at is different than these 31 measures. I don't
4 remember exactly what they were, how they were measuring
5 it, but they were using a different set of metrics.

6 DR. NERENZ: I imagine there are lessons out
7 there sort of in managed care in general. I just mentioned
8 MA because that's our territory. We could learn from --

9 MR. WINTER: And if we ever get the full set of
10 encounter data for 2014, which Andy and Jennifer talked
11 about last time, we could try to look at applying some of
12 these 31 measures to the encounter data. We've begun to
13 explore this a little bit within the last year, and it's
14 going to be difficult. So I don't want to get your hopes
15 up too much, but we are continuing to think about that.

16 As well, there is at least one HEDIS measure that
17 is comparable to one of these measures, which measures on
18 prostate cancer screening using PSA tests. So we're going
19 to see about whether we can make those two measures more
20 comparable so we can compare MA to fee-for-service, at
21 least on that one dimension.

22 DR. CROSSON: Okay.

1 DR. NERENZ: And then just quickly, the last
2 thing on the quality measurement, I would like to see us
3 take a favorable stance on moving this into MIPS or perhaps
4 in other quality measurement programs, depending on where
5 we think the accountable entities are. You know, that's,
6 again, easier said than done. Measures have to be
7 developed. They have to go through NQF endorsement. They
8 have to -- you know, it's kind of a long path. But that's
9 there. And I don't think I'll surprise anybody at the head
10 of the table. I don't think what I would do is just make
11 one big global indicator, because I'm not sure the entities
12 that are high on one thing or high on another thing. I'm
13 just afraid by aggregating, you're just going to wash it
14 all out, and nobody's going to be different.

15 Also, my instinct, as I've said in other meetings
16 and other contexts, would be to try to focus the
17 measurement and its eventual financial implications much
18 more tightly on whichever entities or actors it is that are
19 actually driving these decisions. I would not do it on a
20 region basis. I wouldn't do it on a big global basis. But
21 we just differ in that view, so I'll just -- for the
22 record, I would do it differently. But it's favorable to

1 this concept. I think the execution in my view would be a
2 little different.

3 DR. CROSSON: Okay. Comments? I have Warner,
4 Craig, Jack.

5 MR. THOMAS: I'll be very brief. I just would
6 encourage us -- I know there's a lot of controversy around
7 the issues we've been talking about. I think ultimately
8 changing the payment model in the ACO arena is the way to
9 get folks to be more creative and to look at this in a much
10 more disciplined way. I would encourage us to spend more
11 time looking at how we can continue to refine and improve
12 the ACO model to get more folks into it and to improve the
13 incentives and improve the alignment of those programs.

14 DR. SAMITT: So I want to go back to the
15 discussion about radiation. Should I be worried about all
16 the air travel that I'm doing?

17 [Laughter.]

18 DR. CROSSON: Don't even think about it.

19 DR. SAMITT: So I'm going to put back on my
20 provider hat as we think about this, and, frankly, of all
21 of these four policy directions, similar to what others
22 have said, I would focus on the first. And I think it's

1 mostly because I'm not sure the other three are going to be
2 powerful and effective enough. You know, the reality is
3 whether it's CMS is not very good at coverage policy or,
4 frankly, providers aren't incredibly receptive to policy as
5 a means of driving change and adoption of evidence-based
6 medicine, I'm not sure that's so effective.

7 Shared decisionmaking, you know, I've studied in
8 multiple prior lives, and I think it's still early and it's
9 still even a bit unproven in terms of changing consumer and
10 patient behavior based upon those levers.

11 And then quality measurement, at least in
12 isolation, has problems as well. As Rita knows, we
13 published a piece in 2015 about "Choosing Wisely" and found
14 that, despite sort of avid measurement and communicating
15 evidence-based best practice, it didn't translate into
16 practice, that communication and reporting on sort of non-
17 adherence to "Choosing Wisely" didn't change prescribing
18 and ordering behaviors.

19 And so for all these reasons, it feels like the
20 concept of ACOs and delivery system reform, which is to
21 drive accountability at the provider level, is the one
22 that's likely going to generate the most significant

1 change.

2 One other thing about quality measurement as
3 well, we talked about -- I'm not opposed to a population
4 health measure for "Choosing Wisely," but we already talked
5 about the fact that we measure too much, and it's kind of
6 hard to follow. What we haven't talked about lately is
7 maybe we should be rewarding cross-cutting measures. So,
8 for example, you know, there are systems out there that are
9 offering "Choosing Wisely" decision support. So, in
10 essence, you're prompted when you're ordering things,
11 whether you're adhering to "Choosing Wisely" guidelines or
12 not. You know, maybe our quality measure is: Do you have
13 a "Choosing Wisely" decision support tool, and are you
14 using it and adhering to it?

15 And the same would be true of other quality
16 measures, but, you know, assuring that ACOs are using some
17 of these tools is another way of sort of raising all boats.

18 And then, finally, I think it has already been
19 mentioned, you can sort of extract my comments from the
20 last chapter to this chapter, you know, which is: Have we
21 looked at differences at low-value care deeper beyond just
22 the Pioneer ACO pilot? I'm interested in looking at

1 commercial ACOs. Commercial ACOs seem to be getting
2 differential results than Medicare ACOs. Do we see
3 differences in low-value care use? Do we see differences
4 in Medicare Advantage? And, remember, not every Medicare
5 Advantage plan looks the same. So when you look at
6 Medicare Advantage plans where the shift of accountability
7 has actually occurred to the provider groups, do you see
8 differences? I'm curious to know that.

9 And also going back to the last discussion, where
10 do we see the lowest use of low-value care? And what have
11 they done to achieve that performance? Because that could
12 give us the road map in terms of policy directions. If we
13 find that X organization or Y market has very low
14 utilization of low-value services, what levers have they
15 pulled to actually achieve that result? And it may sort of
16 give us -- shine some light on the direction for us as
17 well.

18 DR. CROSSON: Thank you. On this point?

19 DR. REDBERG: So I liked almost everything you
20 said, Craig.

21 About the clinical decision support tools, I
22 think it would be good for companies that make clinical

1 decision support tools, but we see so many papers on this,
2 and I have seen a lot of literature. Mostly -- maybe
3 people check off they have them. It doesn't really change
4 anything.

5 And the data that I've seen shows you can put a
6 decision support in, and then people will check the right
7 boxes, but the overall volume of what they're -- so it
8 looks good as what you're supposed to do, like people --
9 all of a sudden, everyone had acute chest pain instead of
10 no symptoms. But the volume doesn't change at all. So I
11 think it just -- unfortunately, I think there's a lot of
12 gaming. I don't think it changes practice.

13 DR. SAMITT: And I think what I should say is
14 they kind of go hand in hand. If they're offered within a
15 setting of an ACO, I think you tend to see more appropriate
16 and effective adoptions of these tools as opposed to just
17 teaching to the test. So, to some degree, I could be
18 convinced to say the first and the second together are
19 going to be much more effective than, I would argue, the
20 third and the fourth.

21 DR. REDBERG: Maybe as part of a big picture, but
22 I also think there's a lot of electronic record fatigue. I

1 mean, I turn off every -- and most people turn off every
2 alert you get because there are just too many of them.

3 DR. MILLER: And for future discussions, what I
4 want you to think about is, on those two things, which is
5 the responsibility of the program and which is the
6 responsibility of the entity. So, in a sense, you are
7 saying you can't -- this prompting thing, notwithstanding
8 the disagreement right at the moment, let's just say it
9 does work.

10 Rita, hang with me.

11 You know, should the -- or whatever. You know,
12 should the government and Medicare be tracking that and
13 scoring on that basis or saying to, in your example, the
14 ACO or whatever example, you were using, "Look, we're going
15 to judge your performance. You are free to pursue at a
16 disaggregated basis how you get to that performance." If
17 you want to use your prompting and Rita is saying in our
18 group, that just doesn't work, there is some flexibility
19 there.

20 When we go on with these conversations, I am
21 going to focus you constantly at what's the Medicare role,
22 what do you want to leave as the flexibility for the

1 organization or the accumulation of physicians.

2 DR. CROSSON: Okay. Jack.

3 DR. HOADLEY: So, actually, one of my comments
4 dovetails nicely on this last conversation, which is if
5 we're able to identify by whatever means, ACOs, MA plans,
6 organizations, or whatever that have had some greater
7 success in this, whether we can do that from the data or
8 more from just other kinds of reporting, it seems like
9 there might be value in trying to find out what they think
10 is working for them, if they think anything in particular
11 is.

12 And it's like your example. Whether it prompts
13 one place or some other device -- and I don't know whether
14 -- if we're able to find that X organization that is MA or
15 X organization that is ACO, do some interviewing, do some
16 qualitative research, and get a sense from them of what
17 they think they are doing, or even if there is no data, to
18 start out and go in, "Do you think you've made any inroads
19 on this, and if so, what have you done? What works?"

20 And then maybe it's to your question, Mark.
21 Maybe it's more circulating best practices and highlighting
22 some things, especially if there is not an obvious -- if

1 everybody points to the same thing, then obviously that
2 leads us to a different place than if, well, if this worked
3 here and that worked there, but having some of that kind of
4 dialogue.

5 I am very much, I think, in agreement with the
6 political challenges of the coverage policy, but I do
7 wonder if there are examples out there, again, sort of
8 trying to build this case study kind of notion. It seems
9 like there are cases where at some point in time, practice
10 changed. So whether it's the estrogen treatments or
11 something like that, you can see certain things where there
12 actually was a big shift in practice on something or other.

13 And, again, maybe trying to look back -- and this
14 might not be Medicare-specific as much as society-specific
15 -- what changed the dialogue on that? "Choosing Wisely," I
16 think was premised on that notion, that if there's a
17 conversation about some of these things, it will change the
18 dialogue, and then people will think differently. If
19 people are saying that didn't happen all that much, that's
20 one thing.

21 I mean, I remember, now probably several decades
22 ago, the videos, I think, Jack Wennberg had on "Watchful

1 Waiting" versus other treatments for prostate, and it seems
2 like that's something that's kind of known out there now is
3 that things like "Watchful Waiting" can be a good
4 alternative for certain things. I don't know if that's
5 right, but, I mean, if there are examples of where the
6 dialogue really did change or the practice really did
7 change, trying to go back and figure out what changed that
8 dialogue -- was it dramatic safety? I mean, obviously, if
9 something went to a black box and it got taken off the
10 market, that's one thing. But in cases where there isn't
11 the case, can we go back and look at? And then that goes
12 to is it going to be only those rare examples where we can
13 intervene with coverage policy.

14 Same thing with the beneficiary cost sharing.
15 For any of these subjects where the evidence at least is
16 controversial or there is some disagreement, it's a tough
17 thing to go to the beneficiary and say -- even if you
18 politically could get to that point to say, "You're going
19 to get higher cost sharing," because at least some people
20 think that's a bad thing to do. And in many of these
21 cases, the "don't do it" is contingent upon various
22 criteria. Okay. Don't get this if you're in a certain age

1 group, but there's an exception if you have this kind of
2 medical history or whatever. And if you're going to have
3 to write all that into cost-sharing rules, we're going to
4 go crazy. So, again, that's hard.

5 The only other thought I was going to throw out
6 is we've now done a nice job, I think, of exploiting this
7 particular analytical tool of these 31 or whatever items it
8 is. Are there other lists out there that we could do
9 similar things with? And I'm wondering whether there are
10 some examples in the drug world, whether it's Part B or
11 Part D drugs, where there are certain drugs that there's
12 fairly strong evidence that moderate use is unnecessary.
13 And, again, it's like your different levels of evidence.
14 It doesn't have to be one where it's absolutely this should
15 never be done, but if there's at least a significant thing
16 and if there's other kind of medical procedures where we do
17 this -- and, again, this is just a matter of doing analysis
18 and saying -- you know, shedding some light on it, and if
19 there is some shaming effect or whatever else is going on
20 that's leading to a change, just identifying this on some
21 other categories of services might be something else where
22 we could do it, which is less fraught with some of the

1 controversy than some of these other policy solutions that
2 we're talking about.

3 DR. CROSSON: Just to combine two of your ideas,
4 Jack, that sort of second level could potentially, I think,
5 be derived from that interview process with delivery
6 systems managing population risk, and I would imagine -- I
7 don't know, but I would imagine that you'd find a lot of
8 similarities, particularly if you're looking at ones that
9 have been successful over time. And then that could work
10 as an adjunct here.

11 I know how the "Choosing Wisely" -- the selection
12 process for the "Choosing Wisely" measurements took place.
13 I would just say -- in not all circumstances. In many
14 circumstances, they were not on the most aggressive end of
15 the spectrum, whereas I think you would find a more
16 balanced spectrum if you actually looked at what clinical
17 guideline processes or other collective physician
18 educational processes were going on in certain
19 organizations that had the incentive to do that.

20 DR. HOADLEY: I mean, I would wonder, in
21 particular, Group Health Puget Sound. We used to hear
22 Scott talk about some of the kinds of ways. They just saw

1 medicine differently and now obviously part of Kaiser.
2 What is a place like Kaiser doing? What are some of the
3 other organizations doing? Or if we think there's some
4 successful ACOs out there, ways to target what they might
5 be doing.

6 DR. CROSSON: Alice.

7 DR. COOMBS: I just want to say, as Jack was
8 talking, I was thinking about a couple things. One is how
9 certain robust health care systems say, "We want IHI to
10 come in, and we want to implement some of the things that
11 they've done." And even with the changes that I've seen in
12 the ICU, Xigris is a \$3,000 drug that was used for sepsis.
13 We stopped using it, and it was a process of several
14 specialty groups saying, "This is no good, and it's a waste
15 of money." But that in and of itself took probably 12
16 months, 12 to 18 months.

17 PA lines are not used anymore because people have
18 looked at the literature, as is right now hypothermic
19 protocol for a post-arrest is being assessed, which is
20 really a costly venture. And so it's not proven to help
21 patients.

22 So I think there are some things that you could

1 say this is a marker, leap frog coming in saying, "Do you
2 have 24-hour ICU coverage?" and how that makes a difference
3 in the quality.

4 So I almost think that even an emphasis on high-
5 value care might be as productive as looking at low-value
6 care.

7 DR. CROSSON: I have Amy and Kathy. Amy?

8 MS. BRICKER: Just quick, back on your point,
9 Jack, so the Beers List exists, medications you shouldn't
10 use in the elderly, and star ratings look at those certain
11 metrics of MDs. So you are thinking about something beyond
12 that?

13 DR. HOADLEY: Yeah. I mean, part of this -- I
14 mean, the Beers List goes at sort of a collective measure
15 of the list of drugs. If there are -- I mean, I could
16 imagine things like overprescribing of opioid. Well,
17 opioids may be a special case, but even use of PPIs beyond
18 what they are indicated for cholesterol drugs for people
19 over a certain age. Again, I am not the clinician, so I
20 don't know quite what to put on the list, but it could be
21 individual drugs, like this drug is contraindicated for the
22 age, so that's the sort of Beers List kind of thing, and I

1 know that's been controversial. What's the right list
2 there?

3 MS. BRICKER: You're saying more clinical
4 appropriateness?

5 DR. HOADLEY: Clinical appropriateness. Again,
6 I'm just sort of trying to take this notion that there are
7 things that there was some consensus on that had issues,
8 and can we find some other categories just to sort of push
9 this exercise further?

10 DR. CROSSON: Kathy.

11 MS. BUTO: Mine is going to be very short.

12 Payment policy is hard, and depending on how
13 dramatically we want to tinker with it, it may require
14 legislation.

15 Coverage policy is hard, but you don't need
16 legislation.

17 So if we can get our minds around what might be
18 appropriate and a better way to approach low-value care,
19 coverage policy is a definite avenue. If it's clear what
20 you want to do and the criteria are basically accepted, you
21 can go forward more easily.

22 DR. CROSSON: Okay. Very good comments.

1 Ariel, I hope you have got some good ideas here.
2 I think there were many, and I think we are finished with
3 this presentation and discussion.

4 So we now have time for the public comment
5 period.

6 [Pause.]

7 DR. CROSSON: I'm just going to wait and see who
8 is lining up here. If you are going to make a public
9 comment please line up so we can see who you are. We've
10 got a couple of individuals here.

11 So we will -- I think you may remember the
12 admonitions from this morning, but I'll have to repeat them
13 for you colleague behind you, which is we would ask you to
14 state your name and your institution, if any, and then give
15 us your comment. We'd ask you to limit your comment to two
16 minutes, which you will know are up when this red light
17 comes back on again, and then we'd ask you to sum up.

18 Please begin.

19 DR. DUPREE: Great. So my name is still Jim
20 Dupree. I work at the University of Michigan.

21 I wanted to talk a little bit about beneficiary
22 choice -- I mean, it's sort of a foundational principle of

1 Medicare -- and express some concerns, from my perspective,
2 about the use of sort of broad strokes of federal health
3 policy to influence what are ultimately, in these uncertain
4 situations, admittedly very controversial but also very
5 personal and complicated decisions between a patient and,
6 in the case of PSA, his doctor. PSA got a lot of attention
7 today so I'd like to, if I may, just speak about PSA for a
8 second.

9 It is absolutely controversial. I think there is
10 a diversity of very well-learned and very well-intentioned
11 opinions on the subject, but it is not a clearly -- and I
12 would respectfully disagree with the statements that were
13 made, that it is universally harmful.

14 The biology of the disease is very important to
15 consider. Age is not a strict cutoff. The biology of the
16 disease does not recognize age. Instead it recognizes
17 longevity.

18 So I would like to offer two examples to bring
19 that to people's attention. The first is, for example, a
20 76-year-old patient with newly found metastatic disease in
21 the lungs, and an exhaustive search needs to be done to
22 find the primary source, to guide further therapy. That

1 patient might receive a very high-value PSA and diagnostic
2 biopsy to find out if these are metastatic prostate cancer
3 nodes in the chest.

4 Another example would be a very health and fit
5 76-year-old, who has a longevity of at least 15 years, for
6 whom PSA screening would absolutely offer a benefit.

7 Since the introduction of PSA screening there has
8 been about a 40 percent reduction in mortality for the
9 disease. Certainly not for patients with short life
10 expectancies, but I think using strict ages and cutoffs
11 really risks removing choice from patients for whom this
12 would be quite beneficial.

13 That being said, there are absolutely
14 inappropriate surgeries that are being done for prostate
15 cancer. There are urologists who are as offended and
16 appalled by the advertisements in American Airlines, as you
17 certainly expressed. And there were several comments, I
18 believe from Craig and Jack, who asked about case studies,
19 about places where we can find examples of how care is
20 being improved, and I would offer to invite you to come to
21 Michigan. There is the Michigan Urologic Surgery
22 Improvement Collaborative, a group of empowered physicians,

1 together with patient advocates, who are working on
2 reducing low-value services.

3 So please come to Michigan. Please come and see
4 another way, other than sort of broad strokes of federal
5 policy to empower physicians and empower patients to make
6 these complicated decisions together.

7 Thank you.

8 DR. CROSSON: Thank you.

9 MR. MAY: Hi. Thank you. Don May with the
10 Advanced Medical Technology Association. We represented
11 medical technology companies, device manufacturers, and
12 diagnostic manufacturers.

13 I really appreciate the discussion today on
14 medical technologies. It's a really important issue and
15 glad that you're taking it up. I really enjoyed hearing
16 the conversation and the dialog here today.

17 I wanted to highlight a couple of things that I
18 think are important to remember. One is that technology
19 has got to be part of the solution as we look forward into
20 the policies that we want to think about, our policies that
21 should be about making sure that patients have access to
22 new innovations, have access to technologies that will

1 improve care.

2 If we look at the changes in health care that
3 have occurred over the last several years, whether that's
4 less invasive care or precision medicine, we are able to be
5 able to target lower costs and improve care, because of
6 what technology is allowing physicians and hospitals and
7 caregivers to do.

8 You've talked about a lot of important policies,
9 whether that's how to collect information using UDI, which
10 is really important. You had a lot of good discussion
11 about the benefits and costs, and what is the best way of
12 getting that information for safety and surveillance
13 issues. We'd really like to engage with you on that.
14 We've got some ideas and we can reach out to you.

15 On gainsharing, that's another issue I think
16 that's real important. But as you were talking here in
17 this last discussion, in particular, about the changes to
18 the payment system, and incentives that have already
19 brought physicians and hospitals together, you know, I
20 think a lot of focus around gainsharing should really be
21 around how do you improve quality, how do you reduce costs,
22 how do you make sure that there's appropriate use. And

1 technology can be a part of that but a lot of that's
2 happening already, through these payment mechanisms that
3 have been in place in APMs.

4 On the PODs issue, I absolutely agree with you.
5 There are a lot of issues there to be concerned about.

6 And then I think I just wanted to highlight
7 another policy option for you to consider, finally, and
8 that is this whole idea of risk contracting, or value
9 contracting, and opening up new ways for technology
10 companies to engage with hospitals, with physicians --

11 DR. CROSSON: Please sum up. Please sum up.
12 You've gone over your time.

13 MR. MAY: -- with creative contracting ideas, and
14 that gets at removing safe harbors.

15 So thank you again, and we'll be reaching out to
16 you as well with some more ideas.

17 DR. CROSSON: Thank you.

18 MS. McDONOUGH: Good afternoon. I'm Susan
19 McDonough, a senior director at DataGen. DataGen helps do
20 Medicare and policy analytics for 47 state hospital
21 associations throughout the country, and I appreciate all
22 the work and commitment that each of you have.

1 I wanted to just mention that participants, as
2 you know, in the Medicare Shared Savings Plan, the Bundled
3 Payment Care Collaborative, Pioneer ACO, the Comprehensive
4 Joint Replacement Program, all have access to patient-level
5 data that spans across time and care settings. And this
6 has really enabled providers throughout the country to
7 pinpoint deficiencies in care and to try to identify
8 opportunities for improvement. And the level of data that
9 they have includes 100 percent physician carrier file data,
10 that's only available to providers that participate in one
11 of these programs.

12 However, we find hospitals throughout the country
13 clamoring for that level of data, from the 100 percent
14 carrier file, so they can better understand and prepare
15 themselves for the MIPS program that you discussed this
16 afternoon, for the Oncology Care Model program that some of
17 them are trying to ascertain should they participate in
18 that program.

19 So I ask you today to go to Congress, or to
20 recommend to Congress and to CMS that they provide access
21 to that 100 percent carrier file to the industry, not
22 simply just the 5 percent carrier file, which is

1 insufficient in order to do the total analytic work that is
2 necessary to improve care in the industry.

3 Thank you.

4 DR. CROSSON: Thank you. Seeing no other
5 individuals at the microphone, we are adjourned until 8:30
6 tomorrow morning.

7 [Whereupon, at 5:25 p.m., the meeting was
8 recessed, to reconvene at 8:30 a.m. on Friday, April 7,
9 2017.]

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MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, April 7, 2017
8:31 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
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

B&B Reporters
4520 Church Road
Hampstead, Maryland 21074
410-374-3340

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Provider consolidation: The role of Medicare policy - Jeff Stensland, Kate Bloniarz.....	71
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P R O C E E D I N G S

[8:31 a.m.]

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DR. CROSSON: Okay. Perhaps we can sit down and we can begin this morning. Welcome, everyone.

This morning, we're going to begin a return to our discussions with respect to Medicare Part D, and we're going to have a presentation on plan incentives, and I think we have got Shinobu and Rachel here. Who is going to start? Shinobu? Shinobu's going to start. You have the floor.

MS. SUZUKI: Good morning. The Commission has been concerned about the growth in catastrophic spending. Last June, the Commission made recommendations to address the issue through changes in incentives plans face. Today Rachel and I are going to talk about a couple of issues that came up out of that discussion.

One of them is related to biosimilars, which we discussed in October. It seemed that there was enough Commissioner interest, so we are coming back to it.

The other issue is related to rebates that plan sponsors receive and how that affects prices faced by different actors.

1 Another issue that we'll return to in the fall is
2 exceptions and appeals in Part D.

3 In this presentation, we'll discuss changing
4 distribution of Part D spending, factors behind the
5 expansion in catastrophic spending, and concerns around the
6 growing gap between gross and net prices.

7 We'll review the Commission's 2016
8 recommendations that could help address issues around plan
9 incentives. We'll also discuss Part D policy with respect
10 to biosimilars and the coverage gap discount.

11 You may remember this from our January
12 presentation. Medicare defines a standard benefit; the
13 amounts shown are for 2017.

14 Working our way up from the bottom, there's a
15 deductible, and after that there is a 25 percent cost
16 sharing.

17 At \$3,700 in total spending, they are in what's
18 known as the coverage gap, and that lasts until the person
19 reaches the out-of-pocket threshold.

20 How long a beneficiary stays in this phase
21 depends on whether that person uses brand or generic drug.
22 This is because of the 50 percent manufacturer discount

1 that applies to brand-name drugs, but not to generics, and
2 that discount counts as enrollees' out-of-pocket spending
3 that's used to determine when a person reaches the out-of-
4 pocket threshold.

5 As you'll see shortly, this discount makes a
6 pretty big difference. Above the out-of-pocket threshold,
7 the cost sharing goes down to 5 percent, the plan pays 15
8 percent, and Medicare picks up 80 percent in individual
9 reinsurance, which is shown in white.

10 The combination of the 50 percent brand discount
11 and the rising prices has resulted in double-digit growth
12 in Medicare's payments for reinsurance. And because the
13 discount continues even after the coverage gap is fully
14 phased out, without a policy change this trend is likely to
15 continue.

16 This chart shows that high-cost enrollees' share
17 of spending grew from just under 40 percent in 2007 to 53
18 percent in 2014.

19 It's particularly notable among the non-LIS
20 enrollees. Their share of spending more than doubled from
21 7 percent in 2007 to 18 percent in 2014.

22 Some of this is because more people are reaching

1 the catastrophic phase of the benefit. In 2007, there were
2 2.3 million people reaching the catastrophic phase. That
3 number was 3.4 million in 2014.

4 But high-cost enrollees as a share of Part D
5 enrollees has been stable -- 8.8 percent in 2007 and 8.6
6 percent in 2014. So one of the main reasons high-cost
7 enrollees are accounting for larger share of Part D
8 spending is higher prices.

9 Multiple factors are behind the expanded
10 catastrophic spending. One is enrollment growth. Part D
11 enrollment has grown pretty rapidly since 2010,
12 particularly among the non-LIS enrollees. More people
13 generally means more spending in the aggregate.

14 The problem is in Part D there's an interplay
15 between enrollment growth, benefit structure, plan
16 incentives, and market dynamics.

17 The brand manufacturer discount in the coverage
18 gap pushes more people through the gap phase into the
19 catastrophic phase. In a few minutes, Rachel will go over
20 this in more detail.

21 Another factor is higher drug prices. It
22 reflects both growth in prices for existing products and

1 new drugs with high launch prices. Going forward, the drug
2 pipeline includes many specialty drugs and biologics that
3 are likely to command high prices.

4 A related issue is the growth in direct and
5 indirect remuneration, or DIR. It refers collectively to
6 manufacturer rebates, pharmacy fees, and other payments
7 that plan sponsors (or their pharmacy benefit managers)
8 negotiate to reduce benefit costs.

9 Growth in DIR alone would be beneficial to the
10 program and to beneficiaries, but when it's growth in both
11 prices and DIR, it's not always beneficial to all parties,
12 which I'll talk about in just a minute.

13 DIR is related to gross and net price -- terms
14 you may have heard about a lot recently. Gross price is
15 the amount paid at the point of sale, usually at the
16 pharmacy counter. Net price is the gross price net of
17 rebates and discounts, or DIR.

18 DIR, or the gap between the gross and net prices,
19 has grown by 20 percent per year between 2010 and 2015,
20 which is much faster than the 12 percent growth in overall
21 spending.

22 Back to why we're concerned about the growing gap

1 between gross and net prices. It is because certain
2 beneficiaries and Medicare payments are based on gross
3 prices which are higher than net prices. These include
4 higher beneficiary coinsurance and low-income cost-sharing
5 subsidy that Medicare pays on behalf of LIS enrollees.
6 More beneficiaries are reaching the out-of-pocket threshold
7 than if the prices reflected rebates and discounts. And
8 because more people are reaching the catastrophic phase,
9 Medicare's payment for reinsurance is also higher.

10 Another concern is that the current risk
11 adjustment may overcompensate plans for conditions treated
12 with medications that tend to have high gross-to-net price
13 differences.

14 For certain drugs, the large gross-to-net
15 difference may provide financial benefit to both plan
16 sponsors and manufacturers, and this arises because of the
17 way the benefit is structured -- the coverage gap, the
18 discount, and reinsurance provided by Medicare -- and the
19 market dynamics, including higher prices.

20 The resulting financial incentives may affect
21 plan formulary decisions. In such cases, plan incentives
22 would not be aligned with beneficiaries and Medicare

1 because higher gross prices generally means higher costs
2 for beneficiaries and Medicare's reinsurance.

3 As DIR grows in size, its importance also grows
4 for both plans and Medicare. Plan sponsors report how much
5 DIR they received to CMS, and then CMS retains some of it
6 to offset part of the cost of Medicare's reinsurance.

7 CMS recently noted that plans get to keep most of
8 the DIR, and we think that perhaps CMS' formula may be too
9 generous to the plans. I'm going to walk you through how
10 CMS currently determines how much to keep, and then I'll
11 show you an alternative.

12 In 2015, gross Part D spending totaled about \$137
13 billion. Cost sharing was about \$54 billion, and benefit
14 spending was about \$84 billion, which was split almost
15 equally between Medicare's payments for reinsurance and
16 plan liability.

17 DIR, which consists mostly of manufacturer
18 rebates, totaled about \$25 billion. Current formula sets
19 Medicare's share as its spending divided by total gross
20 spending, or \$137 billion. That comes out to about 30
21 percent. So Medicare keeps 30 percent of the DIR, or \$7.6
22 billion. The remainder, \$17.5 billion, is retained by

1 plans.

2 Because this is an administrative decision, not
3 in law or regulation, CMS could use a different allocation
4 method that would result in a more equitable distribution
5 between plans and Medicare.

6 For example, CMS could set Medicare's share as
7 its spending divided by total benefit spending, or \$84
8 billion. Under that formula, Medicare keeps half, or \$12.5
9 billion of the DIR. The remainder would be retained by
10 plans.

11 DR. SCHMIDT: So Shinobu just described one
12 approach that could reduce the rate of growth in Medicare's
13 reinsurance spending. However, it would not fundamentally
14 change incentives in Part D. Medicare would still pay 80
15 percent reinsurance above the benefit's out-of-pocket
16 threshold and, in turn, there may be less incentive for
17 plans to manage the spending of high-cost enrollees. We
18 think that's a key reason for the trend you see on this
19 slide -- the steady increase of reinsurance as a component
20 of spending for Part D benefits over time.

21 You can see that back in 2006, Medicare's
22 reinsurance -- shown in red -- and enrollee premiums -- in

1 blue -- each made up about one-quarter of the financing,
2 while Medicare's capitated payments to plans made up the
3 other half. By 2015, the positions of reinsurance and
4 capitated payments had flipped. With capitated payments,
5 plans bear risk because if the combination of the fixed-
6 dollar payments from Medicare and enrollee premiums doesn't
7 cover benefit spending, the plans lose money.

8 Reinsurance payments are open-ended and based on
9 plans' costs. So Part D has gotten to a point where about
10 half of the financing is cost-based, which does not seem in
11 keeping with the original intent for the program.

12 Because of that trend and concerns about the
13 financial sustainability of Part D, last year the
14 Commission recommended significant changes to the program.
15 A key recommendation was to phase in a reduction in
16 Medicare's reinsurance from 80 percent of costs above the
17 out-of-pocket threshold to 20 percent. At the same time,
18 Medicare would increase its capitated payments so as to
19 keep the overall subsidy the same. Medicare would continue
20 to pay about three-quarters of the cost of basic benefits.
21 This would put more insurance risk on plan sponsors so that
22 they would have greater incentive to negotiate over prices

1 and rebates. In return for bearing more risk, plans would
2 have more flexibility to use formulary tools.

3 Another recommendation was to discontinue
4 counting the coverage gap discount towards the enrollees'
5 out-of-pocket threshold. We'll pick up on this again in a
6 minute, but the general idea was that counting the discount
7 as the enrollees' spending was similar to the effect of
8 using copay coupons. It lowers enrollee cost sharing, but
9 also makes brand-name drugs look less expensive than they
10 really are.

11 We recognized that this would lead some
12 beneficiaries to have higher out-of-pocket spending, but
13 the Commission also recommended adding a hard out-of-pocket
14 cap rather than the current 5 percent coinsurance. The
15 package also included changes to low-income subsidy cost
16 sharing to encourage LIS enrollees to use generics and
17 biosimilars when clinically appropriate.

18 An issue that was not part of our recommendation
19 last year has to do with biosimilars. Part D law excludes
20 biosimilars from the coverage gap discount and, in turn,
21 that policy may discourage plans from putting biosimilars
22 on their formularies.

1 This chart depicts a \$30,000 reference biologic
2 on the top bar and a biosimilar priced 15 percent lower on
3 the bar beneath it. Look at the top bar first -- the
4 reference biologic under current law. The different colors
5 within the bar show you the phases of the benefit, and the
6 key pieces here to focus on are the coverage gap and the
7 phase above the out-of-pocket threshold on the far right.
8 Remember, that's where Medicare pays 80 percent of the
9 costs.

10 Notice that the coverage gap is shorter in the
11 top bar. That's because the manufacturer provides a 50
12 percent discount, and that discount counts as though it
13 were the enrollee's own spending. So under current law,
14 the out-of-pocket threshold for this reference biologic
15 begins at about \$8,700 in gross spending.

16 In the bottom bar, you can see that the
17 biosimilar has a lower price because the far right of the
18 bar only goes to \$25,500. But under current law, there is
19 no coverage gap discount on the biosimilar, so the out-of-
20 pocket threshold is farther to the right. This means that
21 the plan is responsible for covering 75 percent of the
22 costs much longer. So from a plan sponsor's perspective,

1 even if the biosimilar has a lower price, it might make
2 sense for them to put the reference biologic on their
3 formulary.

4 Now let's look at two more bars -- again, a
5 reference biologic on the top and its biosimilar underneath
6 it. Part of last year's recommendation was to change the
7 law so that the coverage gap discount would not count as
8 the enrollee's own spending. That's depicted in the top
9 bar, so the out-of-pocket threshold happens at a higher
10 level of spending than under current law. However, once
11 the enrollee reached that threshold, there would be a hard
12 cap on what he or she pays.

13 For the lower bar, the biosimilar, an alternative
14 policy would be to change the law to apply the coverage gap
15 discount. And to be consistent with last year's
16 recommendation, the coverage gap discount would not count
17 towards the out-of-pocket threshold for either type of
18 product. With that approach, when the plan sponsor was
19 deciding which product to put on its formulary, it would
20 face higher costs if it chose the higher-priced product.

21 To summarize, there are a number of reasons we
22 expect continued upward pressure on Medicare program

1 spending: growing enrollment, the coverage gap discount, a
2 development pipeline that includes lots of specialty drugs
3 and biologics, growth in drug prices and in DIR. Part D's
4 unusual design and the way in which Medicare pays
5 reinsurance may affect plan incentives and reduce the
6 imperative for plans to manage enrollees with high costs.
7 And, increasingly, those 9 percent of enrollees that reach
8 the out-of-pocket threshold are driving overall Part D
9 program spending.

10 The Commission's recommendations from last year
11 would give greater incentive for plans to manage high-cost
12 enrollees, but it may be difficult or take a while to make
13 those changes. Short of that, CMS could administratively
14 change the way in which it allocates DIR between plan
15 sponsors and the program. We think this would be a short-
16 term fix, though. There would still be a need to make more
17 fundamental changes to incentives.

18 In addition, last year's recommendations did not
19 address the issue of biosimilars and the coverage gap
20 discount. Given that biologics make up more and more of
21 overall spending, that may also be an important change to
22 make, but it would require a change in law.

1 We'd like your feedback on what we've presented
2 today. The goal is to incorporate this material within
3 next March's report. If any Commissioners are interested
4 in further pursuing the change to biosimilars that would
5 require legislative action, let us know. And at this
6 point, we're happy to take your questions.

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

8 We're open for clarifying questions. Can I see
9 hands? Amy, Kathy.

10 MS. BRICKER: You referenced the term "gross
11 versus net," and just as a point of clarification, gross
12 does include the discount at point of sale that's
13 negotiated with retail.

14 MS. SUZUKI: Yes.

15 MS. BRICKER: So I think it's a bit misleading
16 because I would think any retail pharmacy that would have
17 interest in this topic would, you know, be somewhat
18 offended to believe that we think that that's a gross
19 price. There's a significant discount that's applied at
20 point of sale. So we might just want to make that
21 clarification going forward.

22 You mentioned, too, that there would be some more

1 flexibility to use formulary tools. Specifically, what
2 were you referring to?

3 DR. SCHMIDT: So there were a number of things
4 that we referred to in our June 2016 report. One thing was
5 to allow more flexibility for making formulary changes,
6 both midyear and kind of at the start of a new formulary --
7 benefit year.

8 Another was we looked at the protected classes,
9 and part of that was to follow a CMS recommendation that
10 never became an actual rule to exclude two of those
11 categories from protected status. We also called for
12 allowing a little bit more flexibility in terms of using
13 tools for specialty pharmacy, for example, allowing 15-day
14 fills rather than 30-day if that's how the doc wrote the
15 script and -- thank you, Shinobu -- the last one was asking
16 physicians, if they're applying for an exception on behalf
17 of a patient, to put a little more clarity behind the
18 justification for that exception, so tried to standardize
19 that approach, because right now we're hearing from plans
20 that it's rather easily overturned.

21 MS. BRICKER: Okay. Thanks so much.

22 DR. CROSSON: Kathy. Microphone.

1 MS. BUTO: [off microphone] reference in the
2 paper, but I think somewhere you refer to the midyear price
3 changes and the fact that DIR is the tool that's used to
4 lower or make it not a huge cost or any cost additional to
5 the plan. Beneficiaries, however, pay the coinsurance
6 based on the midyear price changes.

7 Is there something -- I'm trying to understand
8 whether there's any flexibility to provide beneficiary
9 protection, sort of having their coinsurance held at the
10 same level before the midyear change, or whether that's
11 something that would have to be done, you know, either
12 through statute or regulation. Is it a big change, or is
13 that really just a plan decision?

14 MS. SUZUKI: So we're talking about the drugs
15 that have coinsurance rather than copay in the initial
16 coverage phase.

17 MS. BUTO: Right.

18 MS. SUZUKI: But right now, there are rules
19 around what the cost sharing is in different phases of the
20 benefit. So if it's a coinsurance, plans have submitted
21 the formulary, and they have to use that formulary to apply
22 cost sharing.

1 MS. BUTO: Okay. And if there's a price increase
2 midyear, they have to apply that to coinsurance.

3 DR. SCHMIDT: They do. I mean, I think maybe
4 some future work could look into the decisions plans are
5 making on coinsurance versus copays. There's a specialty
6 tier for which, you know, plans are absolutely using
7 coinsurance.

8 MS. BUTO: Yeah, yeah.

9 DR. SCHMIDT: But more and more we're seeing
10 coinsurance in some of the other tiers as well. And it's
11 possible you could use some of the rebate to turn some of
12 that more into co-pay versus coinsurance. But that's
13 partly a plan decision, but they also have to abide by some
14 checks that CMS has for the value of that benefit.

15 MS. BUTO: Yeah. My thought is just that if the
16 plan is protected from price increases, there ought to be
17 some way of looking at ways to protect the beneficiary --
18 from some of that, anyway, if not all of it.

19 DR. CROSSON: Craig. Did you have your hand up?

20 DR. SAMITT: Yeah, I did. Thanks.

21 I'm curious about the intersection of the DIR
22 recommendations with our prior June recommendations for a

1 transition of reinsurance from 80 to 20 percent, that
2 whether we feel that they're complementary or additive or
3 whether we would not do them both simultaneously.

4 So on Slide 8, how would this example change
5 should the June 2016 recommendations be accepted?

6 MS. SUZUKI: So we were thinking this DIR
7 reallocation as sort of a short-term fix.

8 As Rachel mentioned, the recommendation would
9 take a change in law, and that may take a while to actually
10 happen.

11 But in the short term, this is something that CMS
12 can do administratively, and it would help with offsetting
13 the cost of reinsurance.

14 DR. SCHMIDT: But we think you wouldn't need to
15 do this reallocation if you had the 80/20 in place, the
16 recommendation from last year. We think that that would
17 really take care of that.

18 DR. SAMITT: That would solve the long-term
19 problem, and the DIR recommendation is a short-term fix.

20 DR. CROSSON: Bruce.

21 MR. PYENSON: Yes. Shinobu and Rachel, excellent
22 report, really terrific.

1 I have a very granular question and a bigger-
2 picture question. The granular question is there is a
3 phenomenon known as transitional scripts that get a patient
4 one script was a formulary change at the year. That can
5 be, I think, up to three scripts for people in long-term
6 care.

7 Have you looked at that, or do you think that's a
8 fruitful policy to look at as a -- whether that policy
9 should continue?

10 DR. SCHMIDT: We have not looked at it in depth,
11 and I'm sure I've heard you say before, in fact, Bruce,
12 that you think that there's some issues perhaps, in
13 particular, around long-term care.

14 MR. PYENSON: And I'm wondering if you could
15 quantify. I think it's on the PDE. You can identify those
16 scripts and quantify how much of an issue that is?

17 MS. SUZUKI: We can go back and look. I don't
18 remember whether a specific claim is flagged as being a
19 transitional supply versus just a claim that's filled, but
20 we can go back and check.

21 DR. MILLER: I just want to understand the
22 motivation here. Is this a freestanding thought, or is it

1 related to one of these two policies?

2 MR. PYENSON: It's freestanding. I suspect it's
3 related to the 2016 recommendations on things like
4 protected classes. I lumped it in with that kind of a --

5 DR. MILLER: I just wanted to follow the
6 connection.

7 MR. PYENSON: So the bigger-picture question I
8 have is looking at Table 5 in the material, and that's page
9 25. There's a terrific chart. It shows the increase in
10 the percent of gross, as you've defined it, that is DIR and
11 how that's dramatically increased in recent years. What do
12 you think accounts for that change?

13 So, for example, towards the beginning of that
14 period, there was a patent cliff, I think. If you could
15 give your view from a macroeconomic picture or
16 microeconomic picture, this industry.

17 DR. SCHMIDT: Right. So, as you are saying,
18 around 2010, that is generally when people think of it as
19 the largest part of the patent cliff, and at that point in
20 time, brand manufacturers were facing much more
21 competition, and in order to compete at all, they need to
22 start introducing rebates. So you saw some rebates, which

1 is the vast majority of this DIR in this table, be a
2 significant value.

3 But over time, you see faster growth at the end
4 of the years, I would say. So now you are starting to see
5 more specialty drugs that have come out into the market as
6 some competition between some of those, so these are higher
7 priced drugs, much higher, tens of thousands of dollars per
8 year for a patient.

9 But to the degree that there is some competition
10 between those products, then you are starting to see much
11 larger rebates. You also see the price protection rebates
12 starting to be used pretty widely, so the plan sponsors are
13 demanding of the manufacturers: "Any increase in prices
14 midyear above X amount, we want rebated back to us." So
15 all of those factors, I think, have led to this dramatic
16 increase in DIR.

17 MR. PYENSON: But just to follow up on that, of
18 course, there is competition between brands before that
19 period. Why did the patent cliff lead to this change, real
20 fundamental change?

21 MS. SUZUKI: I don't know that we have an answer
22 to say whether one factor led to this kind of pricing

1 dynamic, but what we are seeing is that with a lot of
2 brand-name drugs, not just in Part D, the prices are
3 growing fast.

4 But also for some of the drugs, like Rachel said,
5 with competition, you are seeing that rebates are also
6 growing on those products, and so you end up with a
7 situation where you see a huge gap between gross and net,
8 and DIR is growing.

9 I think it may be the competition in some
10 classes. I think it may be that there were lots of changes
11 made with ACA, and coverage gap discount was added. Lots
12 of things may factor into pricing decision.

13 MR. PYENSON: Thank you.

14 DR. CROSSON: Okay. Pat.

15 MS. WANG: So I apologize for whispering. Can
16 you hear me okay?

17 It is a very complicated benefit, and your answer
18 to Greg's question was helpful to me, but I was wondering
19 if you could talk also about the intersection of the RxHCC
20 with all of these changes. I don't know whether last year
21 in the context of the June recommendation, you talked about
22 that, because obviously pushing more into a risk-based

1 premium puts a very high, high premium on getting risk
2 adjustment correct. How do you even think about that given
3 there are rebates flowing? I mean, does the fact that DIR
4 kind of takes the Medicare share of that neutralize the
5 phenomenon you were talking about with the inaccuracy and
6 some of the HCCs overcompensating because of large rebates?
7 How are you thinking about that?

8 MS. SUZUKI: So I think we are concerned with
9 exactly what you said. I don't think it's the matter of
10 CMS paying too much on average, but it's between the HCCs
11 that some are overcompensated, which naturally means the
12 others are maybe paid less than what it should be.

13 And I think what we are raising in this report is
14 that they may want to consider factoring in the rebates
15 that are associated with certain drugs. If it's very high,
16 then a plan's net cost is much lower than what you see on
17 the pharmacy transaction.

18 DR. MILLER: When you said factor in, what you
19 mean is the CMS recalculating the weights, the relative
20 weights within the HCC after adjustment for the DIR.

21 DR. SCHMIDT: Right. But we recognize that is
22 not a trivial thing, because the rebate information, they

1 are starting to collect it on a drug-by-drug basis. But
2 that is what they negotiate in the past, not necessarily
3 what might be negotiated in the future.

4 MS. WANG: I think that's important because I
5 think rebates change for a lot of different reasons, for
6 example, trying to get a better price on your formulary,
7 and it's the market at work. Has there been any research
8 on the accuracy of the RxHCCs generally? Because I can
9 tell you at least from the Medicaid experience, it totally
10 doesn't work. They don't know how to risk adjust for
11 drugs. So I think this is a very important topic.

12 DR. SCHMIDT: Early in Part D, there was some
13 work that was finding that the compensation for low-income
14 subsidy enrollees was too low, and in fact, we were seeing
15 some market dynamics where some plan sponsors were trying -
16 - it appeared to be they were avoiding LIS enrollees.

17 Subsequent to that, CMS redid its approach to the
18 RxHCCs and has separate regression estimates for different
19 categories, including LIS enrollees. We did speak with a
20 number of actuaries for all the major plans, and of course,
21 a couple of years of research before we came up with the
22 recommendations. And at that point, they were telling us

1 that they thought for the most part that the compensation
2 for LIS enrollees was fair. There were some issues with
3 particular drugs, but it was much better than it had been.

4 And with respect to the recommendations from last
5 year, we recognize that it was very important to
6 recalibrate the RxHCCs if the recommendations were to take
7 place, but we should also point out that the risk corridors
8 are still there. So that is an added level of protection
9 for the plan sponsors.

10 DR. CROSSON: Rita.

11 DR. REDBERG: Thanks for an excellent chapter and
12 a really important topic.

13 I just am a little confused on why there is no --
14 for the reference biologic, the discount does not count
15 towards the out-of-pocket threshold. It just seems
16 inconsistent why the biologic would and the biosimilar
17 would not.

18 DR. SCHMIDT: That's just the way the law was
19 written. It was part of the ACA.

20 DR. REDBERG: Do you think it was an intentional
21 thing or -- someone is nodding behind you -- or was it an
22 oversight?

1 DR. SCHMIDT: And someone is nodding behind you
2 too.

3 DR. REDBERG: Oh, I see. Intentional. Well,
4 there you go.

5 [Laughter.]

6 DR. REDBERG: I will continue this later. Thank
7 you.

8 DR. CROSSON: Warner.

9 MR. THOMAS: Have we quantified the annual and
10 maybe five-year impact of what this change may generate? I
11 might have missed it in the detail reading, but I didn't
12 see the exact number of what we think this may generate for
13 savings.

14 MS. SUZUKI: Which policy?

15 MR. THOMAS: Well, just having the biosimilars
16 kind of count similar to --

17 DR. MILLER: Yeah. I think this is more of a
18 setup conversation, and the question would be, is if we
19 move forward with this, move into the fall, that type of
20 thing, that's where all of that would come out, because I
21 am not aware in any of our internal conversations that
22 anybody has been throwing numbers around.

1 DR. SCHMIDT: And at this point in time, there
2 are just a handful of biosimilars on the market. This is
3 something to kind of prepare for the future. So putting
4 together an estimate is a little bit tricky there. You
5 have to kind of think about when there's going to be entry
6 of these biosimilars.

7 DR. CROSSON: Okay. I'm sorry. Amy?

8 MS. BRICKER: You also mentioned the concept of
9 removing the 50 percent discount from the benes out of
10 pocket, and you equated it to coupons. Can you talk a
11 little bit more about that?

12 I understand what you're saying. I just wonder
13 how we would then -- rebates are higher, to your point.
14 Yes, the gross list price is also inflating, but therefore,
15 the 50 percent discount is inflating as well. And to
16 remove that from the benes kind of benefit, can you talk
17 more about that?

18 MS. SUZUKI: So in the recommendation, the way it
19 would work, beneficiary would still face the same cost
20 sharing as they would under current law, but what it would
21 do is not no longer count that discount that plans are
22 receiving as out-of-pocket spending to figure out when that

1 person reaches the catastrophic threshold.

2 So in 2020, if a beneficiary used a brand-name
3 drug, 75 percent of the cost in the coverage gap would
4 account it towards the catastrophic threshold. Whereas, if
5 someone was using a generic drug, 25 percent, which his
6 their out-of-pocket cost-sharing amount, that would count
7 towards the threshold.

8 DR. SCHMIDT: This was a very controversial point
9 as part of the recommendations because there were more
10 people who would stay in the coverage gap long as a result
11 of this policy, but we tried to balance that by having a
12 hard cap in place. So for people who were actually
13 reaching the highest levels, they would have some relief.
14 And it was a tradeoff. It was a package full of tradeoffs,
15 and no one was completely happy with it, truth be told.

16 But we felt it was important that there was this
17 very distinct, different treatment of branded drugs versus
18 generics, and we were trying to put them on more equal
19 footing.

20 MS. BRICKER: Yeah. I'm following what you're
21 saying, Shinobu. To the extent there is a generic
22 alternative, I think you're right. You should encourage to

1 a greater extent, the utilization of those more cost-
2 effective therapies and allow the plans the ability to put
3 greater restrictions or more tighter management around
4 lower-cost therapeutic-equivalent products. But I -- it's
5 a Round 2, but thank you for the commentary.

6 DR. CROSSON: Warner.

7 MR. THOMAS: In the reading on page 30, Figure 5,
8 I just want to make sure I'm interpreting this right. The
9 below-threshold spending has grown to \$86 billion. Is that
10 right? And is that the Medicare program liability? It has
11 got the cost sharing, the --

12 DR. SCHMIDT: It has got the cost sharing on the
13 top, right. So the bottom part is what the benefit is
14 covering.

15 Am I answering your question?

16 MR. THOMAS: Yes. What I'm trying to get at is
17 what is the exact federal cost for the program. So is it
18 the darker blue bar, which is the bottom piece, which is
19 about, I guess, about \$30 billion? And then how does that
20 relate to the above threshold graph as well? Do you have
21 to add those together? Are they included in each other?

22 MS. SUZUKI: So the federal cost is a little bit

1 hard to get from this chart because what we were calling
2 "plan covered portion" is partly direct subsidy, which his
3 federal cost, but partly premiums paid by beneficiaries.
4 And we don't have the breakout for that in this chart.

5 MR. THOMAS: Is there a better part that just has
6 the total federal spending on the program trended over
7 time?

8 DR. SCHMIDT: We have that in the March report
9 chapter.

10 MR. THOMAS: Okay.

11 DR. SCHMIDT: I'm happy to send that to you.

12 MR. THOMAS: Okay, great.

13 I am just trying to get a handle on kind of the
14 total, the total amount of dollars, the trend on the total
15 amount of dollars that we can understand, and then as we
16 think about contemplating policy, what sort of magnitude is
17 the change? Is it billion? Is it 10 billion? I mean,
18 just try to understand the magnitude of the change, it
19 sounds like it's relatively small, given that there's just
20 not a tremendous amount of biosimilars.

21 DR. SCHMIDT: In the near term, yes, but I think
22 over time, it could be much larger.

1 DR. MILLER: Actually, we can send in the table
2 out of the -- because I think I know the table. That is
3 the one where it shows the reinsurance 20 percent growth
4 rate. Yeah.

5 So you could sort of be looking at this and
6 saying, "Yeah, but the biosimilar thing is a relatively
7 small thing," but as a phenomenon in the drug benefit
8 throughout the entire range of drugs, the federal portion
9 is growing very rapidly, and it's not a small-dollar issue.

10 I think part of what we're up to with the D
11 recommendations in June and our conversation here, kind of
12 building structures that are going to help the program
13 doing forward when the biosimilars start to hit in a big
14 way.

15 MS. BUTO: But, Mark, those federal dollars are
16 being helped not just by biosimilars --

17 DR. MILLER: Absolutely.

18 MS. BUTO: -- but by not counting the 50 percent
19 discount and a number of other things, so delaying the
20 arrival of some of the beneficiaries or, I guess, stopping
21 the arrival of some from getting even through the coverage
22 gap. So there are a number of things going on in terms of

1 what federal dollars will be saved as well as the shift in
2 federal liability above the threshold.

3 DR. MILLER: And Rachel referred to the
4 controversy. It is saying to the beneficiary, "Well, this
5 dollar won't be counted," and so you're going to be delayed
6 at getting to the catastrophic cap, as she mentioned. If
7 they get there, then they're fully protected, which is not
8 the case in current law, but some of the tradeoff. And
9 this is triggered by Amy's questions and other comments.

10 But by giving the discount, you are attaching the
11 beneficiary to the more potentially expensive drug. You're
12 raising the question: Well, is there an alternative? But
13 in the instance where there is, you're attaching that
14 beneficiary to the more expensive drug and saying why don't
15 you just go ahead and stay there because the discount is
16 there, and if there is an alternative, they are being
17 driven off the decision to go find that. And that's why
18 things get pretty hairy in this coverage gap.

19 DR. CROSSON: Okay. So I think we will move on
20 to the discussion here. If we could put up Slide 12 again.

21 So what we have on the table here is a proposal
22 to, in the next term, do more work to supplement the 2016

1 recommendations, as has been described, to change the DIR
2 allocation and then to add the biosimilars to the policy
3 that we have subsequently -- previously described, rather,
4 for the coverage gap.

5 The question on the table is, Is there support
6 for this direction? Would people see a way to enhance
7 this, add to this, subtract? And the intention, if there
8 is support, would be to proceed with this. We will discuss
9 it in the fall, and as noted, it would become part of the
10 March report.

11 So I think, Paul, you -- Paul is going to start
12 off.

13 DR. GINSBURG: Sure.

14 Stepping back, this is really about -- starts
15 with flexibility and benefit design. This Commission has
16 wrestled for a long time with the problems where the
17 legislation that created Parts A and B wrote the benefit
18 design into law, and it is very difficult to change to
19 bring up to date, as many other things have changed.

20 In Part D, it appeared to be that given the
21 structure of plans and plans' ability that there would be
22 more flexibility. But then the relationship between the

1 Medicare program and the plans was written in law
2 precisely, and what we're seeing is two developments that
3 have really made the original relationship problematic.
4 One is the entry of new and very expensive drugs, meaning
5 that more people get into the catastrophic range with the
6 reinsurance, and also the growing gap between gross and net
7 prices driven by both the marketplace and by policies,
8 particularly the coverage cap discount being the policy
9 driver.

10 I, for one, am very interested in moving forward,
11 taking up the biosimilar issue, and working on fundamental
12 change in this relationship between the Medicare program
13 and the plans to, in a sense, reflect the current realities
14 in the market and hopefully maybe even do it in a way so
15 that when the market changes further in the future in a way
16 that we may not be able to envision, it won't be such a
17 restriction down the road as it is today. But that's a
18 tall order.

19 Just a specific comment on biosimilars, I take
20 the substantial investment by the major brand-name
21 manufacturers in biosimilars as an indication that this is
22 going to be very substantial, and it is really worth our

1 while not being dissuaded by the very small number approved
2 now, but just anticipating that this is going to be a large
3 phenomenon unless we inadvertently cut it off through bad
4 Medicare policy.

5 DR. CROSSON: Thank you, Paul.

6 So we will have a discussion. Can I see hands?
7 Okay. We have got a lot over here. Let's start with Craig
8 and come up.

9 DR. SAMITT: So I concur with Paul's views on
10 biosimilars. I think that the policy change that you've
11 recommended for applying coverage gap discount to
12 biosimilars makes complete sense.

13 I have some significant concerns about changing
14 the DIR allocation, and part of it just really stems from
15 not clearly understanding what the impact of that change
16 will have on total drug prices and even on premiums for
17 consumers. I think that plans seek to achieve the best
18 total -- or the lowest total cost as conceivable for drug
19 prices, whether it's direct discounts or whether it's
20 rebates. And what I don't fully understand, especially
21 given the drivers of increasing drug costs, is a simple
22 redirection of the allocation, does that truly suppress the

1 drug costs or does it just reconfigure a broken system in a
2 way that doesn't make sense?

3 The other thing that I just do not fully
4 appreciate is it seems like a pretty fundamental change to
5 especially the pharmaceutical supply chain infrastructure
6 in terms of how this would work, and whether that
7 reallocation of DIR, given that that isn't the way that the
8 industry is applying rebates versus up-front discounts,
9 whether we can actually fundamentally make that
10 infrastructure shift and how that would work. So I think
11 it's very much about uncertainty of the implications of DIR
12 and whether it's operationally feasible.

13 DR. SCHMIDT: Just to help me understand, I'm not
14 fully following how it would change things for the supply
15 chain.

16 DR. SAMITT: Would the recommendation be at sort
17 of applying the rebate effect at the point of sale, or
18 would this be an after-the-fact reallocation between plan
19 sponsors and CMS?

20 DR. SCHMIDT: I think we were thinking the
21 latter, that things would be as they are, that rebate
22 negotiations would take place as they are. They might be

1 affected by knowing that CMS is going to keep a larger
2 share of it. But we were thinking that this is an after-
3 the-fact thing. And I guess the end result we were
4 contemplating is, yes, if there's less rebate revenue that
5 the plan sponsors are holding onto, that might make them
6 kind of submit a higher bid for what would ultimately be
7 the fixed direct subsidy piece, so that they'd submit a
8 higher bid anticipating less rebate revenue that they get
9 to keep. But, in turn, since Medicare is keeping its
10 subsidy the same, there would be higher capitated payments
11 from Medicare.

12 DR. SAMITT: My first issue in terms of the net
13 effect on premiums or whether plans would actually have the
14 ability beyond the ability they have today to control the
15 net cost, whether this fundamental change in DIR improves
16 that circumstance.

17 MS. SUZUKI: So this is not necessarily to change
18 the incentives plans currently face or the way they manage
19 the benefit. But what it would do is simply reallocate the
20 rebates so that all benefit phases are getting the same
21 share offset from the rebates. And in terms of how that
22 affects the premiums, if nothing -- assuming no behavioral

1 change, it is a simple shift in the rebates from -- some of
2 the rebates from plan liability portion to reinsurance
3 portion. And both pieces are feeding into the beneficiary
4 premium, so theoretically, there would be no -- there could
5 be no effect on bene premiums. But if plans do change
6 their behavior, that could, again, change the beneficiary
7 premiums.

8 DR. SAMITT: I think I'd probably want to
9 understand more, and there may be others that have a
10 perspective.

11 DR. MILLER: I have to process this, too, so I've
12 had one more iteration than you. This is -- right? And
13 they patiently try and take me through it. This is my
14 civilian way of thinking about this. This in no way
15 undercuts the need for the 80/20 recommendation. And to
16 your comments, that's what we think changes the incentive
17 structure for the plan. Okay? And, you know, people can
18 disagree and have those arguments, but this doesn't change
19 that. And you're correct -- the need for that. You're
20 correct that this allocation thing doesn't necessarily
21 change the overarching incentives. It's an accounting
22 transaction at the end. I view it very much at the end of

1 the day that says, okay, now that these dollars have come
2 in -- and I'm just using this term because you used it --
3 under the currently continued broken system, how do you
4 allocate that between the plan and the government? But
5 without in any way changing the notion that you really need
6 to fix that 80/20 so you get a better incentive structure
7 overall.

8 So it really is an -- I have always viewed it as
9 just an accounting shift at the end of the day that now
10 here's the block of dollars, how are you going to split it
11 between the plan and the government?

12 DR. SAMITT: And I guess just to counter, the
13 question is, while it's not just an accounting shift --
14 unless I misunderstand this -- it's also a shift of risk.
15 And so while the rebate dollars are shifting to CMS, the
16 risk is now borne on the plan to manage the rising drug
17 costs. And the question is: Can they feasibly manage that
18 risk with the shift in the DIR?

19 DR. HOADLEY: Isn't that more driven by the -- I
20 mean, that's more driven by the 80/20 reallocation. This
21 allocation we're talking about here is not so fundamental,
22 partly because it's still going to be 74.5 percent federal

1 subsidy to the plan, we're just messing around with which
2 of that 74.5 percent comes out of different pots, right?

3 DR. MILLER: Yeah, I would agree with that, and
4 I'm keeping an eye on those two. I would agree with that
5 and would say -- I would have said just directly in
6 response to this comment, no, it's not fundamentally
7 changing the risk. The 80/20 will, just to make sure that,
8 you know, I'm walling that off. That's a separate thing.
9 But this allocation deal, I wouldn't see that as
10 fundamentally restructuring the risk. And so I'm agreeing
11 with you, and I'm getting a nod out of Shinobu. And as
12 usual, Rachel won't give me any response.

13 [Laughter.]

14 DR. CROSSON: Okay. Who is next coming up? It
15 looks like Sue.

16 MS. THOMPSON: Thank you, Rachel and Shinobu, for
17 your continued good work. And I do look forward and
18 support the fact that we continue to work on Part D drugs,
19 and I'm noticing the 2018 March report that we're preparing
20 for.

21 It strikes me, though, that there's a piece of
22 work that I really want to have available around the

1 assumption that drugs are good. I mean, there's an
2 underlying assumption here that because they're available
3 we should be using them, which I think in part is driving
4 this increase in spend and this increase in utilization.
5 And I know we've had some discussion about polypharmacy, so
6 whether it be in the context portion of the chapter in
7 March, I just think in order to more than just shine a
8 light on the formulas and the 80/20 and where the risk
9 moves, it feels a little bit like moving the deck chairs,
10 when really getting to the root cause of what we're doing
11 to our Medicare population by the direct-to-consumer
12 markets that's going on, this point in time where these
13 biosimilars are going to become very available, it just --
14 it strikes me that an important piece of work, as we make
15 these recommendations -- and thank you for your good work
16 and all the analytics that have gone into it -- has to do
17 with the fact that the dollars we're spending on the drugs
18 is but a small piece of the effect it has on our
19 utilization of skilled and long-term care and the falls
20 that are created and the confusion that happens as a result
21 of 75-year-old people using five, six, sometimes 20 drugs.
22 And who's accountable for that? And yet I just think

1 contextually that part of the story is really important as
2 we move forward in our recommendations.

3 DR. CROSSON: Thank you. Pat.

4 MS. WANG: Hi there again. So I think that the
5 product direction on biosimilars is good, and it is a
6 tradeoff for the beneficiary. But to Paul's point about
7 kind of getting in early and establishing a framework that
8 does not stifle in any way or put a thumb on the scale, you
9 know, biologic versus biosimilar, I think is important.

10 I share Craig's hesitation around the
11 recommendation for DIR because rebates are not a static
12 phenomenon. You know, they change based on plan approaches
13 and PBM approaches to really trying to get the best price
14 possible. And so this is kind of a point-in-time
15 depiction. I just don't know enough about how that would
16 change behavior on the part of the plans, how it affects
17 the risk corridors, how it ripples through to the risk
18 portion of the premium, you know, to think that maybe it's
19 quite as straightforward as just CMS getting a larger
20 share. So I would like to know more about it and just
21 understand it better.

22 As far as the 80/20 recommendation which was made

1 last year, I really think whether we're talking about the
2 80/20 or any changes in DIR, I would like to see the
3 Commission do more work around risk adjustment. It's very,
4 very important to get that right. I mean, we can change
5 incentives from 80/20 to 20/80, but, you know -- and I
6 think all plans -- but I think regional plans, smaller
7 plans really need to have correctly adjusted risk-adjusted
8 premium in order to have, you know, a go at that and
9 [inaudible] even though there were risk corridors. If risk
10 adjustment is not correct, you may be underutilizing or
11 utilizing those risk corridors in an arbitrary way. And
12 the ideal, the goal I think would be appropriate use of the
13 risk corridors because the risk-adjusted premium is pretty
14 good to start with.

15 The other thing is just -- this is a separate
16 thing that I can talk to you guys about separately, but on
17 the issue of LIS, I think that there is a phenomenon in the
18 way that the bid [inaudible] is set up in the bidding rules
19 that Carlos would know more about. That makes it very
20 difficult to offer zero premium products to LIS enrollees.
21 That might be worth looking at as a recommended change. A
22 tweak there would be helpful, I think, to encourage use of

1 generics and so forth.

2 DR. CROSSON: You know, I'm starting to like this
3 whispering thing.

4 [Laughter.]

5 DR. CROSSON: I mean, I think we should take into
6 consideration maybe this would be a policy for everybody.

7 I'm not sure. At least in -- well, we could impose --

8 PARTICIPANT: [off microphone] equity.

9 DR. CROSSON: Yeah, right. We could impose
10 whispering at a certain point in the discussion. I'm not
11 sure. I'll work on it. Who's next? Rita.

12 DR. REDBERG: Thanks. Again, I will certainly
13 just say I agree wholeheartedly with Sue's comments about,
14 you know, before we look at prices, which are clearly
15 important, we need to look at what is the value, and the
16 value first means, you know, are our beneficiaries better
17 off for the drugs that we're talking about? And I will
18 just note that the same things we talked about yesterday
19 with, you know, the pressure to get things on the market
20 are certainly also operative for drugs, and a lot of drugs
21 are now getting approved on surrogate markers, which are
22 only useful if they actually correlate to clinical

1 outcomes, and that often has, you know, not been shown. So
2 that is certainly an important point.

3 In terms of the recommendation, obviously, from
4 my Round 1 question, I think it's really important to apply
5 the coverage gap discount to biosimilars. I don't
6 understand why it wouldn't apply to biosimilars.

7 In the pricing in DIR, I have to say I really
8 don't understand the whole idea of having a price but then
9 having a discount and then everyone gets the discount, but
10 Medicare then ends up paying them because of what seems
11 like to me gaming on this coverage gap and then Medicare,
12 you know, pays more reinsurance because people are coming
13 out of the coverage gap. It reminds me of, you know, the
14 rug stores that always say, "Going Out of Business, 40
15 Percent Sale." I mean, every day for years it says that?
16 And after a while, you think, okay, no one ever pays full
17 price for these. You have to be really -- I mean, why
18 don't we just have a price instead of having a gross price
19 and a net price? I don't understand how we got into this
20 system. It doesn't make sense to me. Am I missing
21 something here?

22 [Laughter.]

1 DR. SCHMIDT: I don't know the full history of
2 how we got to where we are, and I imagine Amy might like to
3 jump in and --

4 MS. BRICKER: Sure. We could spend a whole --
5 maybe at our retreat on how we got here. But rebates are
6 the tool that have been used well before Part D to just get
7 formulary decisions, right? And so if -- albeit in the
8 regulated space or in the commercial space, rebate was the
9 tool to get additional discount to ensure formulary
10 placement. To say we should just have a price I think on
11 the surface sounds great, but in reality would never really
12 pan out.

13 It's not often known at the point of sale what
14 the rebate effect will be. So in the regulated space --
15 we've talked about this somewhat, maybe not in this forum,
16 but just put the rebate at point of sale, right? None of
17 this kind of after-the-fact nonsense. The price at the
18 point of sale is the price, and rebate -- it's not known at
19 point of sale what the rebate value is oftentimes because
20 plans might negotiate 100 percent of rebate, not a flat
21 dollar rebate. And so these percentages aren't known at
22 point of sale. So then you have false claims issues, or

1 that's the concern of plans, and so there are lots of
2 things that the government has restricted from a "why can't
3 we just" kind of philosophy that doesn't allow plan
4 sponsors to do some of the things that you might think,
5 well, that makes more sense to the beneficiary or even to
6 the plan sponsor themselves.

7 So I think we have to really unwind this quite a
8 bit, and that's my concern with some of these things that
9 are -- we're just putting our finger on little holes in the
10 bucket and not actually taking a more holistic view of the
11 issues and how we might be able to remedy. But,
12 philosophically, how we got here was just literally the
13 competition in the market and someone saying, "I'll give
14 you another nickel if you prefer my drug over my
15 competitor's." So that's how we got here.

16 DR. CROSSON: I'm trying to keep track of the
17 conversation, and so far, Rachel and Shinobu, I've got two
18 ineffable items for you to work on for next year. One is,
19 How does legislation get written the way it does?

20 [Laughter.]

21 DR. CROSSON: And the other one is, How do
22 markets evolve the way they do? Just take notes.

1 Next, David.

2 DR. NERENZ: Will that run over a hundred pages
3 if it's done?

4 PARTICIPANT: I think it would be 200.

5 DR. CROSSON: Do you want to go?

6 MS. BRICKER: Okay. So just a couple things.
7 Absolutely in support of the biosimilar recommendation. I
8 would want to go a little further with what was recommended
9 back in 2016. You can look at the effect -- and maybe it's
10 my fault for not having thoroughly read or recalling all
11 that was provided in the 2016 report. But on protected
12 classes, the phenomenon that occurs if you take, you know,
13 oncology meds of themselves, you know, anytime you create a
14 system or a structure or regulation, the market will
15 respond and attempt to benefit itself, of course, whoever
16 that is. And so I fear by just putting, again, one
17 recommendation around DIR and not looking at holistically
18 kind of the impact of that, the unintended consequence that
19 might occur, and just maybe Pat's or someone else's point
20 about this being a point in time -- that was your point,
21 Pat -- I agree with that.

22 And to the extent that the plan isn't going to

1 benefit in the same extent it does today by driving deeper
2 rebates, they may take their foot off of the gas. I don't
3 know. But I do think that the market will respond, and
4 it's not going to necessarily continue in the same way.

5 I'm okay with, you know, continuing the
6 conversation around shifting risk to the plan, but you've
7 got to allow the plan to manage the benefit. And we have
8 so many restrictions around, you know, what they can and
9 cannot do, and we know there are plenty of studies that
10 you've provided around the number of choices that
11 beneficiaries have, and, you know, 700 plans or something
12 that exist today, and many people have 20 or more choices.
13 I think to just say there are plenty of options for folks
14 and to be able to manage the benefit in a way that makes
15 sense if you're going to shift the risk to the plan I think
16 is absolutely crucial.

17 So I'm not as enthusiastic about the DIR option
18 that was presented because, again, I think we need to look
19 at it in total versus just one aspect of the benefit. But
20 I understand why, to your point, you're not going to --
21 it's not going to require legislation, and maybe it's
22 something we could do quickly. But I just think there's

1 more risk to the overall plan by just moving one piece of
2 it around.

3 Thank you, though.

4 DR. CROSSON: Jack.

5 DR. HOADLEY: So on the specific issues of the
6 things you raised on the slide here, I think on the
7 coverage gap discount to biosimilar, I think that's
8 absolutely something we should do, and I'm actually sorry
9 we can't be putting it in this year's report because it
10 just seems like a simple fix that it sounds like there's
11 pretty much agreement on.

12 ON the DIR allocation, again, my instinct is that
13 this is a good change. One question that occurs to me now
14 as we've been talking about this, you talked about a fix
15 along these lines the last time you presented on this
16 issue, but this is a different approach than -- I'm trying
17 to remember what was in that previous conversation.

18 DR. SCHMIDT: We didn't get to the point of
19 proposing any alternative, just raised the issue that the
20 current plan allocation may not be -- may be overly
21 generous.

22 DR. HOADLEY: And I guess after some of the

1 discussion, I'd just like to think it through and hear
2 through more of the details because to me it still seems
3 like it's a fairly straightforward mechanical fix to sort
4 of the way the allocation is working and some of the sort
5 of odd disincentives that the current method has. So I
6 think it would help when we bring this back to make sure we
7 understand for everybody's benefit sort of whether -- how
8 to think through whether there are broader implications or
9 not. But I definitely would like to see us continue to
10 talk about that.

11 What I think this DIR issue to me raised is just
12 this broader -- and a couple people brought this up,
13 especially in some of the Round 1 questions -- is the
14 broader issue of how this relates to the out-of-pocket cost
15 for the beneficiary in those cases where coinsurance is
16 used. Not only is this an issue for any individual
17 purchase of a drug -- so I'm getting a particular drug.
18 Whether it's a bio -- biological or biosimilar on a
19 specialty tier or whether it's just a brand on a tier with
20 coinsurance in the sort of regular part of the benefit, I'm
21 paying a coinsurance of 25 percent or whatever the amount
22 is based on the retail price, without getting the advantage

1 of that rebate.

2 I get some benefit from that rebate, presumably,
3 eventually in my premium calculation. It's saving cost for
4 the plans. It's bringing the premium down. But there is
5 an allocation issue of where the -- all beneficiaries in
6 the system benefit from the premium, but the individuals
7 who particularly end up using these more expensive and
8 brand-name drugs that are in the coinsurance tiers don't
9 get the benefit of that. So there is sort of a
10 reallocation issues among beneficiaries that's implicated
11 in this.

12 And then, similarly, because the overall design
13 of Part D was actuarial equivalence to 25 percent
14 coinsurance, again, that 25 percent is coming out based on
15 the pre-rebate gross price or whatever term we think is
16 right. The invoice price, I guess, would be another way to
17 talk about it. So it has implications of how much people
18 overall are spending in that initial coverage phase and
19 eventually in the gap phase, putting aside the issues of
20 the manufacturer discount.

21 So I really would like to see us think about how
22 to provide some relief for the beneficiary in these

1 situations, and while like Rita, part of my instinct says
2 sort of do it and just completely transparent prices, I do
3 hear some of the arguments about we will get better
4 discounts through the system.

5 I would like to hear more about the economics of
6 that and whether there is good evidence of that. I know
7 there has been some discussion of those points here and in
8 some other settings, and so if there is a different way to
9 provide the beneficiary who is using these brand drugs,
10 some cost sharing relief, that is something we could look
11 at, maybe. I have some ideas about that too.

12 The other thing that I am kind of struck by in
13 this whole issue of the price increase protection that
14 plans are increasingly negotiating on their thing is we
15 kind of don't have that same price increase protection for
16 a beneficiary, and an issue that I have talked a lot about
17 in another setting is this notion that when a beneficiary
18 shops for their plan during open season, they are seeing a
19 set of prices.

20 But when they go to buy the drug -- so that's in
21 November. When they go to buy the drug in February or even
22 more so in June or September of the following year, they're

1 seeing different prices. So they feel like, "I shopped for
2 this. This is what the plan told me it would cost," and of
3 course, the premium is locked in. Your copays are locked
4 in, if they're flat copays, but your coinsurance isn't, or
5 the cost of the drugs that you're getting in a deductible.

6 While I think that's probably not fixable, I
7 think what some of these issues might go to try to think
8 about, is there a way to provide something more like price
9 inflation protection for the beneficiary during the year?
10 If we can't get all the way to that, how can some kind of
11 policy options, particularly for those paying coinsurance
12 or for prices faced during deductibles and other places
13 could be addressed better?

14 The last point I'll make is just to remind us
15 all, similar to yesterday's conversation about Part B
16 drugs, is there's a lot of things affecting this that are
17 outside of the narrow bounds of Medicare policy, and so the
18 interchangeability issues for the biosimilars from the FDA,
19 the state laws on substitution -- you know, we have gotten
20 a lot of the generic -- the advantage of generics because
21 pharmacists can make the substitution automatically without
22 the doctor having to understand that there is a new

1 generic.

2 State laws have been changing to mean that can't
3 necessarily happen for biosimilars, particularly those that
4 don't have the interchangeability designation. While we
5 can't make a recommendation to state legislatures to do
6 something different, we can at least point out some of
7 these kinds of factors. I think broader acceptance of what
8 it means to be a biosimilar that is really substitutable in
9 the eyes of many physicians, the naming conventions that
10 FDA uses, the backlog of getting the biosimilars approved
11 and on to the market. And as somebody mentioned, the
12 direct-to-consumer advertising could become an even bigger
13 issue and already is, yesterday, a lot of advertising on
14 some of the biologicals.

15 Obviously, one issues is whether they're
16 necessary drugs at all, to the point that Sue raised and
17 Rita has raised, but some of those are ads, trying to make
18 sure you're attached to the original biological. At a
19 point when they're soon to be competition of biosimilars,
20 will we see advertising from the biosimilars? I don't
21 know.

22 So there is just really a laundry list, and I

1 could probably come up with another dozen of external
2 factors that we need to keep in mind and maybe figure out
3 whether there's any angle to work on any of those from
4 inside our jurisdiction.

5 MS. BRICKER: Can I --

6 DR. CROSSON: Yeah.

7 MS. BRICKER: I would like for us to continue
8 that particular, Jack, the discussion you had around
9 inflation protection for the bene.

10 So the conversation has heated up as of late
11 because of the increase in prevalence of percentage copays.
12 Back when we were all paying 10 bucks or 20 bucks for a
13 script, lots of things were happening behind the scenes,
14 but the patient at the counter was none the wiser because
15 their copay was flat.

16 With ACA and lots of things that have driven
17 percentage copays, now you have the outrage of the mom at
18 the counter with the EpiPen script for \$600.

19 So it's philosophical. Do you move away from
20 that percent copay to then not have the patient actually
21 have line of sight into the actual price of the drug? I
22 think pharma would love that because then they can

1 discontinue doing whatever behind the scenes, but the flip
2 of that is if you continue with the percentage copay and
3 you don't have these protections both for the plan and for
4 the bene, then that also is quite unfortunate.

5 So I would love for us at some time to have more
6 of -- if we could control for either scenario or what are
7 the ramifications of going back to something that takes
8 away the true experience of the drug increase at the point
9 of sale, at the counter, what then happens to pricing in
10 the country, and what levers could we pull so that we're
11 holding pharmaceutical manufacturers accountable for the
12 decisions that they are making with respect to price?

13 So it's a much, much broader conversation, but I
14 think it would be a value to have that.

15 DR. HOADLEY: Yeah, I definitely agree. That's a
16 good conversation.

17 One of the Medicare policy levers that's
18 potentially implicated in this is that 25 percent base, so
19 that's one of the levers that says -- apart from these
20 factors that you're raising, a plan in making its design,
21 when they're looking at expensive drugs, they are going to
22 have to raise the flat copays a lot over time to maintain

1 that 25 percent.

2 So in that broader conversation, we should think
3 about whether that's getting in the way of some kind of
4 policy that might work better for everybody. I mean, this
5 is definitely a broader conversation on this topic.

6 DR. CROSSON: Okay. Bruce and then Kathy and
7 Brian.

8 MR. PYENSON: I've got a couple of points and
9 suggestions.

10 First, in response to Craig on the incentive and
11 the risk, I wanted to give an example and maybe get some
12 response to it.

13 Suppose a patient comes in with a \$100,000 script
14 and you are not quite sure if the script is indicated, if
15 it's the right one for the patient. Normally, if that were
16 in a health insurance company, of course, prior
17 authorization and that sort of thing. If you're getting a
18 50 percent rebate on the \$100,000 script and you have to
19 give 30 percent of that to the feds, but the feds are also
20 picking up 50 percent of the cost, you don't have an
21 incentive to even check whether it's an appropriate script
22 or not. The incentive is to write the script. You make

1 more money. Because of the 50 percent rebate, you only
2 give 30 percent of that.

3 So changing the rebate from the 30 percent
4 federal share to approximately 50 percent would actually
5 change some of the incentives in the plans, provided the
6 manufacturers didn't also increase the rebate, and some
7 rebates are north of 50 percent already.

8 So I agree it's not a fundamental shift, but I
9 think in the short term, it would change some of the risk
10 management incentives currently for plans.

11 But I agree that it's a short-term issue and
12 probably has implications elsewhere for the member premium
13 and things like that. So, ultimately, the shifting from
14 15/80 to 80/20 is the solution to that because that would
15 fundamentally change the nature of risk unless -- except
16 for products where there is more than 80 percent rebate or
17 something like that, and there's probably a few of those
18 but not many.

19 I think an important issue here to recognize what
20 we're dealing with -- because the industry probably has one
21 price that they apply to both Medicare, one gross price or
22 WAC price or AWP that they apply across the industry to

1 both Medicare and commercial, what we have seen with the
2 price inflation fueled by Part D has affected commercial
3 plans. And likewise, fixing this will be important and
4 helpful to commercial plans, I believe, so I think it's
5 really an important task that we're taking for beyond
6 Medicare. So I agree with moving ahead.

7 On the biosimilars and biologics, there's an
8 enormous amount of confusion over terms across the
9 industry. You can't find a -- there's no universal list of
10 what specialty pharmacy or which biologics. There's
11 insulin and there's vaccines, and there's huge confusion
12 around that. I think MedPAC has been successful in
13 introducing new concepts or clearer definitions for a
14 number of things, Healthy Days at Home, the MedPAC regions.
15 And I'd ask that as part of the biosimilar issue that we
16 actually come up with -- see if we have a better way or a
17 clear way of defining what that is and to use it.

18 In particular, there is a shorthand large
19 molecular, small molecule. I think given the advances in
20 protein synthesis and things like that, perhaps that's not
21 the most useful definition. There is going to be --
22 there's other considerations there. So I think developing

1 -- seeing if we can develop something that's clear, maybe
2 it's tied to regulatory, maybe it's tied to molecule size,
3 maybe it's tied to something else.

4 Thank you.

5 DR. CROSSON: Okay. Thank you.

6 Kathy.

7 MS. BUTO: Let me just -- I think the work is
8 terrific here and adds a lot to the -- at least suggests
9 continued momentum in this area.

10 I started thinking about the biosimilars
11 recommendation, and I agree with adding the coverage gap
12 discount for biosimilars.

13 I began to think about whether that might cause a
14 biosimilars manufacturer to raise prices for biosimilars
15 that are aimed at the Medicare beneficiary population, and
16 I guess that would depend on whether they are mostly
17 delivered under Part D or Part B and how those two policies
18 interact. So I think we just ought to keep that in mind.
19 I don't think it's just a neutral policy, but --
20 particularly since many of these haven't even been launched
21 yet, we ought not to be aware that that could have impact.
22 We already know the discount off of the original biologic

1 is going to be smaller than generic. So I think we just
2 ought to be aware of that.

3 By the way, we don't apply a coverage gap
4 discount to generics. Right? Is that correct? And is
5 that because we think, at the moment, anyway, that those
6 are a lot more affordable and that is not necessary? But I
7 think we have seen, in some cases, generic prices have
8 really jumped. So it is something we ought to keep on our
9 radar screen as long as we are trying to be equitable here.

10 On the DIR allocation, I was listening carefully
11 to Craig and Jack and others who have raised the issue of
12 it's a good short-term approach until the 80/20 change is
13 done through statute. I just don't know -- so our major
14 benefit is the Federal Government gets more of the benefit
15 of those DIR payments. I don't know if that's a lot of
16 money. I assume it must be significant to go from 30 to 50
17 percent. Do we have an idea of what that --

18 MS. SUZUKI: So, in 2015, the total DIR was \$25
19 billion, and the example we're showing, about \$7.6 billion
20 going to Medicare reinsurance. And under the policy, it
21 would be not nearly double, but --

22 MS. BUTO: Go up to about 15 or so, yeah.

1 MS. SUZUKI: 12.6 billion.

2 DR. SCHMIDT: Remember that the capitated
3 payments for Medicare would go up as well. So I think the
4 net effect is more on kind of incentives to the plans for
5 considering which drug to put on their formulary and that
6 sort of thing.

7 MS. BUTO: Okay, okay. So it has two benefits.

8 Sort of my major issue in this set of
9 recommendations is I'm not sure about DIR allocation and
10 whether it's really going to have any impact on beneficiary
11 premiums. We seem to think maybe a little bit.

12 What I'm struck by is that the beneficiary is
13 really not particularly benefitting from these changes.
14 There may be a slight increase in premiums. They don't get
15 any benefit of DIR, and as I kind of mentioned -- and both
16 Amy and Jack have elaborated on at greater length -- I
17 think it would be good if we could think about if there is
18 a beneficiary piece of this DIR that we can -- whether it's
19 through some coinsurance relief or -- I don't know that we
20 -- I don't know that I would support turning coinsurance
21 back to copays, but is there some way to hold the
22 beneficiary harmless to a price increase at least or

1 something like that?

2 So if you could think about that for the next go-
3 round, so that it isn't all benefit to the Federal
4 Government and -- really, it's the Federal Government in
5 both cases, I think these recommendations would benefit.

6 The other thing is, of course, that the
7 biosimilars recommendation would also create -- well, it
8 wouldn't change at all the speed at which the beneficiary
9 reaches the coverage gap, the threshold or the catastrophic
10 threshold, as I understand, because now they are not
11 getting a coverage gap for a discount for that, for
12 biosimilars. So it is only brand-name drugs right now that
13 there is a delayed access to catastrophic care.

14 What I am struggling with here is that these
15 sound like the right direction to go, but if there's some
16 consideration we could give to how the beneficiary might
17 benefit from some of these changes, I think that would be a
18 good thing.

19 DR. CROSSON: Brian.

20 DR. DeBUSK: Thank you for an excellent report.

21 I do support the proposed treatment of
22 biosimilars, and I also appreciate the fact that in this

1 report and in other reports, we keep a mindful eye on their
2 development and ensuring that they would get off the ground
3 cleanly.

4 On the DIR, I do agree with Amy. I think it's
5 sort of an unfortunate reality that we are going to have to
6 deal with these direct and indirect rebates. I personally
7 would be more interested in understanding the sources, how
8 much of it is price protection, how much of it is an up-
9 front rebate, and understanding -- because to me, it's
10 almost like these DIRs are its own technology that evolve
11 over time. They will develop a new type of DIR.

12 If we could at least keep an eye on and in a
13 framework going forward to understand so that we can watch
14 this technology evolve, again, so that we can see, to
15 Kathy's point, is it affecting beneficiaries, because you
16 are doing, say, a midway price increase that the plan is
17 shielded from, but because due to coinsurance that the
18 beneficiary isn't, I just understanding the DIR technology
19 as it evolves, I think, would be very helpful to me. And
20 you may have it. It may just not be in the report.

21 DR. SCHMIDT: Actually, no we don't.

22 DR. DeBUSK: Okay.

1 DR. SCHMIDT: Because it's considered so
2 proprietary --

3 DR. DeBUSK: Okay.

4 DR. SCHMIDT: -- we don't have access to that.

5 DR. DeBUSK: I think being able to back into some
6 of that -- I realize that's no small feat, but I think once
7 we recognize the DIR is a -- again, I am going to keep
8 using the word. It's a "technology" in and of itself.
9 It's a price maneuvering technology, in my opinion. I
10 would like to understand and follow that more.

11 The final thing, I'd like to agree. Susan and
12 Rita made the point about poly-pharmacy. I do hope at some
13 point, whether it's in this policy or in another -- I'd
14 love to look at poly-pharmacy and then the other end of the
15 bookend of medication adherence, because what would be
16 great is to take fewer drugs, but take them the proper way.
17 And I don't know if that's part of this work or if that's
18 an entirely separate chapter, but it is nice to at least
19 look at that in the context of how we are going to finance
20 these drugs because it seems like they go hand in hand.

21 And, again, thank you.

22 DR. CROSSON: Okay. Let me see if I can

1 summarize here. I think I heard pretty much general
2 support for applying the coverage gap discount to
3 biosimilars, assuming, as Bruce said, we know what
4 biosimilars are, but I think that's something we can
5 handle.

6 With respect to changing the DIR allocation, I
7 think we have mixed support and not a lot better than that,
8 but I think there's a sense here that it's worthwhile
9 continuing to look at that, particularly -- and this may be
10 stuff that's easy or not so easy to do. If we can
11 understand the context a little bit more about what we're
12 really dealing with here, I think Brian's point, the
13 dynamics of that, the interrelationship between making this
14 change, a Craig brought up, and the 2016 recommendations,
15 so maybe reprising those recommendations and the dynamics
16 that we might anticipate would be helpful.

17 I think I also heard -- and I think this is not
18 entirely tangential, but it is a little bit -- a thought
19 about the position of the beneficiaries in this collection
20 of changes, including this one, and whether or not there's
21 some thought to thinking about a different allocation
22 process, which would in some way include the beneficiaries

1 more directly than they currently are benefitted. I think
2 that's a point that Kathy made.

3 And then the last piece, which I think is both
4 important and not necessarily relevant to your thinking
5 about what you might be doing in September or October, is
6 this question about to what degree we can take and how we
7 should do that in developing and consistently reiterating
8 our holistic philosophy towards drug use and drug cost, and
9 I heard a number of pieces of that from people.

10 Now, almost everything I've heard here has been
11 something that we've done in part over the last number of
12 years, at least that I've been here. But there may be some
13 thought to not letting some of those pieces drop, and
14 perhaps we can consider some way of bringing that all
15 together and doing it in a more unified way, so that the
16 important pieces of work that have been done before don't
17 sort of get dropped and they're included in sort of an
18 ongoing way of thinking about our position.

19 So those are just a couple of things, I think, to
20 think about, but we'll be pleased to see what you come up
21 with in September or October or some other time like that.

22 So thank you very much, Rachel and Shinobu, for

1 your usual clear, concise, and valuable work.

2 So we'll move on to the next presentation and
3 discussion.

4 [Pause.]

5 DR. STENSLAND: Good morning. Today we're going
6 to discuss consolidation in the health care industry. This
7 is a follow-up on two earlier discussions you had in the
8 fall.

9 As you may remember, in November Kate presented a
10 paper on physician consolidation, and I presented a paper
11 on other types of consolidation. Today we're going to
12 combine those two papers into a possible June chapter.

13 We will start this presentation by showing how
14 physicians and hospitals have been consolidating into
15 larger organizations, and this consolidation we will show
16 you can lead to higher Medicare and private insurer costs.
17 Medicare costs increase when hospitals acquire physician
18 practices due to Medicare paying facility fees. Private
19 costs increase due to providers negotiating higher prices
20 after consolidating into larger organizations. And then
21 after we present data on the magnitude of the
22 consolidations, we'll discuss two policy responses: a

1 site-neutral response, meaning leveling prices across
2 settings; and we'll also discuss the importance of
3 restraining Medicare prices rather than following
4 commercial prices.

5 And then we'll really shift gears, and in the
6 second half of this presentation, we'll discuss
7 consolidation of provider functions with insurance risk,
8 and this can happen in ACOs or in MA plans. ACOs allow
9 providers to take on insurance risk. And in the case of MA
10 plans, some MA plans own provider groups and in other cases
11 MA plans are formed or purchased by provider groups.

12 We'll discuss findings in the literature on
13 whether these provider/insurer consolidations improve cost
14 or quality, and that will be a key discussion topic for
15 today of whether we want to favor these integrated entities
16 when setting payment policy.

17 So now we'll get into consolidation. Let's start
18 by categorizing four types of integration or consolidation.

19 The first type of consolidation is horizontal
20 hospital consolidation where hospitals join into systems.

21 The second is where physicians consolidate into
22 larger groups.

1 The third is where hospitals purchase physician
2 practices, and this is vertical consolidation.

3 The fourth is the merger of providers into an
4 organization that accepts insurance risk. As I said, this
5 can occur when provider groups take on insurance risk
6 through ACOs. It can also happen when insurers purchase
7 physician practices.

8 So let's start with the first of these, which is
9 the horizontal hospital consolidation. As we discussed in
10 your paper, hospitals have significant market power in many
11 markets. In about a third of markets, a single system has
12 more than 50 percent of all discharges. Many small metro
13 areas only have one hospital system, and there is no
14 expectation that the FTC will materially unwind
15 consolidated hospital systems. Therefore, hospital market
16 power is expected to be retained and possibly grow into the
17 future. In other words, market power is now part of the
18 health care environment that Medicare works in and is
19 expected to work in in the future.

20 The literature cited in your mailing materials
21 presents some strong evidence that market power leads to
22 higher commercial hospital prices. There is much less

1 evidence that consolidation results in greater efficiencies
2 or improved quality. In fact, some have argued that
3 greater competition leads to greater quality.

4 In addition to looking at average hospital
5 prices, we have looked at variation in hospital prices, and
6 we have found that prices commercial insurers pay hospitals
7 vary wildly from market to market and hospital to hospital.
8 As we showed you in your mailing materials, a high-cost
9 hospital may have a negotiated head CT rate that is five
10 times the rate negotiated at a low-cost hospital for
11 exactly the same service. This suggests that markets are
12 not bringing prices down to a consistent level.

13 On average, we find hospitals' commercial prices
14 are about 50 percent above cost and well above Medicare,
15 with some of the highest rates obtained by hospitals with
16 strong market power.

17 There has also been some horizontal consolidation
18 of physician practices. For example, the share of
19 physicians in practices with over 50 doctors increased from
20 16 percent in 2009 to 22 percent in 2014.

21 Practices are merging into larger groups that can
22 jointly negotiate contracts. However, we find that

1 physical location of the practice often does not change
2 when they join that bigger system of practices.

3 It is also interesting to note that about 20
4 percent of Medicare billings continue to be from solo
5 practitioners. This suggests that the pace of physician
6 consolidation has been slower than the pace of hospital
7 consolidation.

8 In addition to horizontal integration, we have
9 vertical integration where hospitals purchase physician
10 practices.

11 After a hospital buys a practice, it often starts
12 billing for the services as a hospital outpatient service.
13 This means that the program and the beneficiary will
14 receive two bills. Instead of just getting a physician
15 bill, they get a physician bill and a second bill for the
16 hospital facility fee. The result is Medicare program
17 spending and beneficiary spending both go up.

18 For commercial insurers, we see less evidence
19 that they are paying facility fees for E&M visits.
20 However, two recent studies suggest that physician-hospital
21 mergers lead to higher negotiated prices with commercial
22 health plans.

1 One hope is that vertical integration could
2 generate efficiencies. But the way the Medicare and
3 commercial payment worlds are set up, there is an incentive
4 to merge even when there are no efficiencies gained. In
5 fact, even if some inefficiencies are created by converting
6 physician practices to hospital outpatient departments,
7 hospitals may still acquire practices in order to secure
8 referrals and then partially fund the cost of those
9 acquisitions with new Medicare facility fees and
10 negotiating higher commercial prices for physician office
11 visits.

12 So let's discuss an example of how Medicare
13 facility fees affect program costs and beneficiary costs.

14 As I said, when a practice is bought by a
15 hospital, that hospital often declares that physician
16 office an outpatient department and starts to bill for
17 facility fees for office visits and other services at the
18 clinic. These fees increase Medicare costs.

19 For example, in 2015, Medicare paid an additional
20 \$1.5 billion for hospital-based evaluation and management
21 services, and this reflects the hospital facility fees.
22 Similarly, beneficiaries paid an additional \$400 million in

1 cost sharing due to facility fees on office visits.

2 Now let's turn to the effect of horizontal and
3 vertical consolidation on commercial prices for office
4 visits.

5 This slide examines the association between
6 horizontal consolidation of physician practices and the
7 prices paid for E&M visits by three large private insurers.
8 Market share in the first column refers to the group
9 practice or health system's share of E&M visits in our
10 data. The first three rows of this slide are for physician
11 practices that are not owned by a hospital.

12 So let's start by looking at that first column of
13 numbers you see -- first row you see for small independent
14 practices. These are practices with less than 10 percent
15 of the E&M claims in their market. These are the numbers
16 in green. We see that for a small independent practice
17 with a 10 percent share, they have an average price equal
18 to 100 percent of the national Medicare price. In other
19 words, if a physician practice does not have market power,
20 commercial insurers will often pay them a rate close to
21 Medicare rates. In contrast, as the market share
22 increases, prices increase far above Medicare rates.

1 So if you go down to the third row in yellow,
2 you'll see that practices with over 30 percent of claims
3 have an average price equal to 141 percent of Medicare.

4 Now we're going to go down below to the next
5 three rows. Now we're shifting from independent physician
6 practices to hospital-owned practices. And you'll see when
7 the hospital practice is owned, even for those with small
8 market share, they tend to receive higher rates than the
9 Medicare rates. And these findings of higher prices for
10 larger practices and higher prices for practices that are
11 hospital-owned are both consistent with the literature.

12 Now next we wanted to look within markets to see
13 if the dominant practice within a metro area received
14 higher prices than its competitors, and this is the column
15 on the right. And if we look at the green number in that
16 right-hand column, it shows that a small practice in a
17 market tends to receive 93 percent of the average fee paid
18 in that market as compared to the larger practices in that
19 same market tend to receive 106 percent of the average
20 price received by practices in that market for an E&M
21 service. What this tells us is that there isn't a single
22 commercial market price, even within a single city. Prices

1 will depend on market power.

2 In your mailing materials, we also provided some
3 multivariate analyses. These other analyses are consistent
4 with this descriptive story. Market power definitely has a
5 statistically significant effect on the price.

6 Now, we just explained how Medicare has been able
7 to restrain prices paid to physicians and hospitals to
8 rates that are below commercial rates obtained by providers
9 with market power. So a related question to ask is: How
10 does this restraint of prices translate into lower costs
11 for the Medicare program and beneficiaries relative to the
12 costs of private insurance?

13 In this chart we look at growth in the cost of
14 private insurance and fee-for-service Medicare over the
15 past nine years. We find that the cost of employer-
16 sponsored HMO and PPO insurance has risen by about 50
17 percent. Those are the orange and yellow lines on this
18 slide.

19 In contrast, Medicare costs grew by about 23
20 percent. This is the green dotted line. Others have
21 compared commercial and Medicare cost growth over a longer
22 time frame with different data sets and have come up with

1 similar conclusions. Medicare costs have been growing
2 slower than commercial costs since the late 1980s. In
3 recent years, Medicare's cost advantage over commercial
4 insurance has been getting larger as that price
5 differential paid by the two is getting larger.

6 So we have seen the effect of horizontal and
7 vertical integration on Medicare costs and on commercial
8 insurer costs. How should Medicare policy respond?

9 MedPAC's first traditional response has been to
10 not follow commercial prices upward. There was general
11 support for that position in your discussions last fall.
12 In fact, update recommendations in the past have been
13 constrained in part to keep pressure on hospitals to
14 constrain costs. However, in the long run, if private
15 insurers do not limit price increases, the gap between
16 Medicare and commercial prices will increase, and
17 eventually this could create access concerns.

18 With respect to vertical consolidation, the
19 Commission recommended site-neutral pricing for E&M visits
20 as well as certain other services. Site neutral means a
21 level playing field. Therefore, vertical integration that
22 generate efficiencies should still happen with site-neutral

1 pricing, but integration that is driven purely to capture
2 larger Medicare facility fees would not happen.

3 Now we shift gears to talk about the fourth type
4 of consolidation, and this is the merger of providers with
5 organizations taking on insurance risk.

6 There have been managed care plans in Medicare
7 for 40 years, and for about 20 percent of MA plans, the
8 managed care plan is aligned with or owns a physician
9 practice. The single entity then has responsibility for
10 insurance risk and for the provision of care.

11 As we discuss in your mailing materials, we see
12 some providers acquiring insurers and some insurers
13 acquiring providers. While some integrated systems have
14 been longstanding successes, it is not clear that this
15 model has a large enough advantage to always win in the
16 marketplace. In some cases, providers have divested their
17 insurance arms in recent years. In other cases, insurers
18 have divested their physician practices.

19 Another option is the ACO. There is an
20 increasing interest among providers in being rewarded for
21 managing population health. Providers can take
22 responsibility for the health of their patients, and in

1 models with two-sided risk, they also take full
2 responsibility for the annual cost of care. That is the
3 long-term expectation where ACOs are going.

4 Now we look to see how the integration of
5 insurance risk and provision of care in MA plans and ACOs
6 has affected patient outcomes and the costs.

7 The literature suggests that MA plans have had a
8 mixed level of success relative to fee-for-service, and
9 within that MA plan universe, provider-affiliated plans
10 have a mixed level of success relative to other MA plans.

11 First, MA plans tend to do better than fee-for-
12 service on process measures such as mammogram rates. But
13 they are about equal to fee-for-service on patient
14 satisfaction.

15 MA plans have also been shown to reduce service
16 use below fee-for-service on average, but even with service
17 use below fee-for-service, they tend to cost the taxpayer
18 more due to administrative costs and the cost of
19 supplemental benefits.

20 In 2017, Medicare pays MA plans about 4 percent
21 more on a risk-adjusted basis than fee-for-service on
22 average. The 4 percent reflects the MA bids, the cost of

1 extra benefits, and the coding differences between MA and
2 fee-for-service.

3 Looking at different types of MA plans, it
4 appears that integrated plans that are affiliated with
5 their physicians have slightly better quality metrics on
6 average, and we have seen this in two recent studies of
7 higher quality in these integrated MA plans.

8 But one study found that they also charged higher
9 premiums on average. A recent study suggests that while
10 the number of integrated plans is growing, the market share
11 held by integrated plans is shrinking. And it could be
12 that even among integrated plans there are some that are
13 better than others. And, eventually, the best integrated
14 plans should rise to the top and gain market share.

15 With respect to ACOs, in general, there is
16 evidence that ACOs have been improving their quality
17 metrics; and from a cost standpoint they are about a
18 breakeven point for the taxpayer.

19 I should say that ACOs and MA plans that I've
20 talked about on average are about breakeven, but there are
21 some markets where MA plans and ACOs do definitely save the
22 taxpayer money, and these are often high-use markets. And

1 in these markets, you see MA plans bidding well below fee-
2 for-service, and you also see ACOs generating some
3 substantial savings. And I think Craig talked about our
4 ACOs generating some reduction in the regional variation we
5 see, and I think that is true, because when you look at the
6 ACOs that are generating the biggest savings, they tend to
7 be in the high-use markets, the predominant predictor of
8 whether you're going to generate shared savings.

9 Now, in 2015 we examined regional variation in
10 the relative costs of different models by looking at
11 relative costs of MA plans, ACOs, and traditional fee-for-
12 service, and we looked at 78 markets where all three of the
13 models competed with each other. We found that traditional
14 fee-for-service was the low-cost option in 28 of the
15 markets, and ACOs were just a little bit lower cost in 31
16 of the markets. MA plans were the low-cost option in 19 of
17 the markets, and MA plans tended to do the best in high-use
18 markets such as Miami.

19 The point of this slide is to show that different
20 delivery structures may have different levels of success in
21 different markets.

22 Now we shift to the potential policy responses to

1 this type of consolidation.

2 With respect to insurer-provider consolidation,
3 one approach is to level the playing field between fee-for-
4 service and MA and let the models compete with each other.
5 Fee-for-service can compete with integrated MA plans that
6 have salaried physicians, and fee-for-service can compete
7 with MA plans that contract with providers. Whichever
8 model can convince beneficiaries that they have the most
9 value, they will win market share. For example, if HMOs
10 with employed providers are able to provide higher-quality
11 care at a lower cost, they should win market share under a
12 level playing field.

13 The second alternative is to favor one model.
14 For example, in some markets CMS now favors MA plans by
15 setting benchmarks above fee-for-service costs. We could
16 also go a step further and favor specific types of MA
17 plans. However, this has several risks.

18 First, we would need to accurately identify the
19 characteristics that have led to success in the past, but
20 that could lead to gaming. If we paid more for a specific
21 corporate structure or organizational structure, MA plans
22 may adopt that structure just to receive higher payments.

1 More importantly, it could also stifle
2 innovation. Once payments are tied to a legal or
3 organizational structure, it would act as a disincentive to
4 innovate into more efficient models in the future.

5 In contrast, financial neutrality would create
6 incentives for providers to continually innovate into the
7 most efficient delivery model.

8 Now we'll shift to discussion. There are four
9 types of organizations we have talked about today:
10 traditional fee-for-service, ACOs within the fee-for-
11 service model, MA plans that are integrated with providers,
12 and MA plans that only contract with providers. And the
13 question is: What should the Medicare program's policy or
14 payment policy be with respect to these four types of
15 organizations?

16 One option is financial neutrality. This means
17 providers would only get higher rates if the patient has
18 greater needs or the organization has better outcomes.

19 The other option is to favor one model over the
20 other. This implies higher payments for certain legal or
21 organizational structures.

22 I'll open it up for discussion.

1 DR. CHRISTIANSON: So, as usual, clarification
2 questions for Jeff. David.

3 DR. NERENZ: Thanks. Very nice work as always.
4 I appreciate it.

5 A clarification question. Can you put Slide 3
6 up, please, and this is also on 11 but 3 is good. The term
7 "insurance risk," in these kind of discussions I'm
8 comfortable with a distinction between insurance risk, on
9 the one hand, and utilization risk on the other, and I'm
10 looking at Bruce because there is a 2015 Society of
11 Actuaries report that clearly makes that distinction.

12 In this context, I would argue, and I would have
13 said before we started this, that ACOs, for example, are
14 intentionally buffered from insurance risk, or protected to
15 the point that they carry essentially none. It's the
16 clinical risk adjustment feature that does that.

17 So in Round 1 I'm just clarifying, when you use
18 the term "insurance risk," are you using it in that narrow,
19 technical sense, or are you using it in a broader sense,
20 essentially just meaning financial risk, in general?

21 DR. STENSLAND: I'm using it in the broader
22 sense, because I don't think that we can really distinguish

1 between the insurance risk and the utilization risk, in
2 terms of what they are able to accomplish.

3 DR. NERENZ: Okay. Well, in Round 2 I will
4 assert we can --

5 DR. STENSLAND: Okay.

6 DR. NERENZ: -- but I just, for now, I just
7 wanted --

8 DR. STENSLAND: Okay.

9 DR. NERENZ: -- no, I just wanted to know what
10 the word means for now.

11 DR. STENSLAND: All right.

12 DR. CHRISTIANSON: Let's go up this --

13 DR. GINSBURG: Yeah, just sometimes I've heard
14 the distinction between insurance risk and performance
15 risk, performance risk meaning, you know, delivering more
16 efficient services, and insurance risk, as David says, is
17 presumably just differences in beneficiaries, perhaps you
18 could say not accounted for by the risk adjustment system.

19 DR. CHRISTIANSON: Bill.

20 MR. GRADISON: There certainly were some who felt
21 that ACOs were sort of a training ground for moving on to
22 MA status. I have the impression if that is the case not

1 much has happened in that direction as yet, but I just
2 wonder what is actually going on, if anything, in terms of
3 that two-step possibility.

4 DR. STENSLAND: I don't have data but we
5 certainly do see people that have ACOs that are interested
6 in setting up MA plans and have gotten involved, and you
7 see both things happening at the same time, expansion of MA
8 enrollment and expansion of ACO enrollment.

9 DR. GINSBURG: Actually, if I could add, I've
10 heard some anecdotes where just provider organizations
11 really thinking through, is ACO or MA more attractive to
12 me, and some of them going to MA.

13 DR. CHRISTIANSON: Warner, Craig, any -- Warner.

14 MR. THOMAS: How do you think about other types
15 of consolidation kind of outside the provider world? So do
16 you contemplate insurance consolidation, and, you know,
17 that there is, you know, markets where the Blues have, you
18 know, 60, 70, 80, 90 percent market share, the commercial
19 market. I mean, have you thought about that? Do you think
20 that plays a role here? You're just really focused, at
21 this point, on the provider side of consolidation.

22 I think it also plays into GPOs and Pharma, and -

1 - I mean, just how do you think about consolidation overall
2 in the industry, not just in the provider world?

3 DR. STENSLAND: The only thing we talk about in
4 the paper is how some people have argued -- I think, the
5 insurers might argue that when they have bigger market
6 power they can offset the provider's market power, but I
7 don't think we see any evidence in the literature that that
8 is actually necessarily filtering down to lower premiums
9 for the beneficiary.

10 In terms of the other things, I think the general
11 concepts that we're talking about here of market power, of,
12 say, being a sole hospital in a market is very similar to
13 being a pharmaceutical company with the sole provider of a
14 drug.

15 DR. CHRISTIANSON: And my recollection is that
16 there's a paper by Glenn Melnick that addresses this topic
17 and that, in fact, it does filter down to lower premiums.

18 MR. THOMAS: Yeah. I'm just wondering if you've
19 looked specifically at states where you see a pretty
20 dominant role of a payer, and if you have any data specific
21 around that. I mean, there's -- I mean, look at the state
22 of Alabama, for example. I think Blue Cross of Alabama has

1 about a 90 percent market share on the commercial.

2 DR. STENSLAND: We do. We just talked about that
3 at one point. We do see lower prices in those markets
4 where the provider has dominant shares. So you see lower
5 commercial prices and then you also tend to see lower
6 costs. So like Alabama you're going to see some of the
7 best Medicare margins of any hospitals in the country, in
8 part because Blue Cross has a dominant market share. They
9 keep the commercial costs low because the commercial costs
10 are low. They have to keep their costs low. Because their
11 costs are low they have better Medicare margins.

12 MR. THOMAS: And just one last question. How do
13 you think Medicare rates themselves play into kind of
14 setting the rate structure in any given market? You know,
15 I mean, obviously there's different -- taking utilization
16 aside, just looking at the rate. Obviously there's a wide
17 range of Medicare rates in the country, just based upon,
18 you know, how the rates are configured. And how do you
19 think that plays out, or doesn't play out in the commercial
20 pricing as well?

21 DR. STENSLAND: So how do Medicare rates affect
22 the commercial rates?

1 MR. THOMAS: Yeah, just on a -- you know, because
2 what you're doing is a comparator. You're saying -- you're
3 comparing everything to the Medicare rate, but my point is
4 that the Medicare rate is significantly different in
5 different geographic parts of the country, versus looking
6 at it as a true dollar amount. You know, understanding
7 that you have the wage index and there's different kinds of
8 costs of living in different parts of the country, and I
9 understand that's why the rate is configured that way. But
10 also understanding that that probably plays into just how
11 it drives the overall cost structure in all of those areas.
12 Any thoughts around that?

13 DR. STENSLAND: Well, the Medicare rate doesn't
14 vary nearly as much as the commercial rate. It's a much
15 tighter band because it's really only based on the input
16 cost differences. And the traditional provider argument is
17 that if Medicare lowers their rates then we have to raise
18 our rates, and that's why we raise our rates.

19 But I think the literature, in general, there's
20 more -- especially recently, the literature sort of goes
21 the other way around, that the commercial, and if anything,
22 kind of follows Medicare, to a degree. So, for example, if

1 Medicare increases its rates for physician services, the
2 commercial rates tend to go up, at least in the short run,
3 because they may have -- we're paying X percent of Medicare
4 in their contract.

5 DR. CROSSON: [Presiding.] Craig.

6 DR. SAMITT: So can we go all the way back to
7 Slide 3? The thing that I'm struggling with is this slide,
8 for me, is like which of these things is not like the
9 other, and the fourth one, for me, is just a whole other
10 different dimension than the first three. And you spent
11 most of the deck talking about sort of what's happening
12 with outcomes and pricing in horizontal and vertical
13 consolidation, and I think that the general answer was it
14 goes up.

15 But the fourth one, I didn't get that sense from
16 you, and I just -- I wanted to understand why we put these
17 two buckets together, because I started to get lost in the
18 problem we're trying to solve. I guess the question in the
19 fourth is have you seen that provider insurance
20 consolidation is also driving up cost, or is the message
21 more that we haven't seen the impact of the results that we
22 would hope to see, because from my point of view that's a

1 whole other different issue than whether consolidation is
2 driving up cost.

3 DR. STENSLAND: These are kind of like two
4 batches, and I tried to say we're really shifting gears in
5 the midpoint. And I think you're right. On the first
6 three it's all pretty clear and the effects can be pretty
7 big.

8 In the last part, I think that's not so much a
9 choice of -- if you look at the general feeling out there
10 in the market, it's going to be we're trying to lean
11 against these first three types of consolidation because we
12 really think it's going to increase costs. In the third
13 one, the question is more, how much should we be leaning
14 into this type of consolidation of the providers and the
15 insurers. So it's very different and I think the whole
16 questions are very different, and the outcomes that we
17 talked about, I think, are very different.

18 When you talk about the magnitude of the effect
19 on prices you can have through consolidation, it can be
20 really big. When you look at the effect that ACOs and MA
21 plans have had on Medicare costs, they're smaller
22 difference, and even in the quality, which are generally

1 benefits of this consolidation, better quality for the MA
2 plans, better quality for the ACOs, those, I think, are
3 still also moderate in magnitude.

4 But I think that is more where we're thinking --
5 more of your discussion is going to be, because, to me,
6 that's more of the difficult topic.

7 DR. SAMITT: So not to put words in your mouth
8 but I think what we're asking, from a policy perspective is
9 what policies can we put in place that dissuade the first
10 three, and then which policies can we put in place that
11 either encourage or further evaluate the fourth?

12 DR. GINSBURG: [Off microphone] -- yeah, at least
13 to have -- allow things to happen in the fourth, because we
14 don't have a strong opinion.

15 DR. DeBUSK: May I ask, on the first three, too,
16 not dissuading seems almost overly ambitious. I would
17 settle for us just not accidentally pouring fuel on the
18 fire and forcing the consolidation, unintentionally.

19 DR. CROSSON: Okay. Brian. Is that your
20 comment, Brian? Paul.

21 DR. GINSBURG: Two things. One is that it's
22 really unfortunate that our field has labeled hospital

1 acquisition of physician practices as vertical
2 consolidation, because it really isn't. And the thing I
3 want to point out is that all of these transactions have
4 very important elements of horizontal consolidation, that
5 the -- you know, the acquired physician practice is going
6 to be joined with physicians already employed by the
7 hospital. It's going to affect -- you know, basically, a
8 lot of physicians are competitors to the hospital. They
9 may compete with hospital-employed physicians, or they
10 might compete in their providing services in their offices,
11 or ASCs, with the hospital outpatient departments. I think
12 this is one of the reasons that hospital acquisition of
13 physician practice is such a problematic phenomenon.

14 Oh, and the second point is that you had looked
15 at commercial prices versus Medicare prices, and you did it
16 for E&M services. I suspect if you did it for procedures
17 you would get a different answer. It probably would be a
18 larger difference. Kate?

19 MS. BLONJARZ: I just wanted to kind of pivot off
20 that and answer something else Warner asked. One thing we
21 do see with Medicare kind of influencing private rates is,
22 you know, I don't know how much I would say that there's a

1 geographic effect, but the bigger one is the use of the
2 Medicare RVUs for payment, you know, is very common
3 throughout the private market, and in other work, you know,
4 some other researchers have shown that, you know, the
5 relative weights kind of persist in the private market but,
6 you know, for a specific provider group or a specific type
7 of service that's very consolidated, it may be multiples of
8 those RVUs that kind of, you know, are the prices on the
9 private side.

10 DR. GINSBURG: If I could add, I think it was
11 initially after the Medicare fee schedule was implemented,
12 the fact that commercial insurers used the Medicare
13 relative value scale, of course, with their own conversion
14 factor, to me was very gratifying. But recently -- but,
15 you know, it diverges from that in two ways, that, you
16 know, of course, as you've shown, that practices with a
17 larger market share get higher rates, they tend to be
18 single-specialty practices.

19 The other thing is in a discussion -- I haven't
20 seen any data on this, but in a discussion I had with
21 insurance executives recently, they did mention that
22 sometimes, maybe all the time, they will actually negotiate

1 a lower rate as a percentage of Medicare for E&M services
2 than they will for procedures. So this is something where
3 the long-standing market forces are kind of pushing against
4 the structure that Medicare has set up.

5 DR. CROSSON: Kathy.

6 MS. BUTO: So, you know, as I went through the
7 paper and then as you did the presentation, Jeff, I found
8 myself asking the question of what problem we were trying
9 to solve, because I thought a lot of good issues or
10 challenges were raised. The issue of provider
11 consolidation, and you mentioned things like site-neutral
12 policy and so on, to address that, the issue of the
13 disparity between commercial and Medicare, and the
14 possibility that access issues could arise in the future.
15 But then when we get to the policy solutions, we are really
16 talking more about the forms of Medicare payment to either
17 fee-for-service or managed Medicare, or ACOs, which are
18 kind of managed Medicare.

19 So I didn't connect the dots, really, among
20 those, and so I wondered if you could, either one of you or
21 both of you, tell us a little bit more about how that
22 journey connects the dots between, or among, provider

1 consolidation, commercial versus Medicare, and then to the
2 policy approaches that you are kind of asking us to look
3 at.

4 DR. STENSLAND: Okay. So the easiest one
5 probably goes back to Brian's comment of don't throw fuel
6 on the fire, and this would be the site-neutral policy of
7 if we tell an organization well, if you buy this physician
8 practice, and now if they brought it on to the hospital
9 campus, they would still get higher payments for those same
10 visits that the doctors are doing now, and therefore we
11 are, in essence, encouraging this, and as Brian would maybe
12 say, putting fuel on the fire here.

13 MS. BUTO: But that's a policy solution that
14 we've already addressed --

15 DR. STENSLAND: Right.

16 MS. BUTO: -- and it really doesn't -- it's not
17 where you leave us at the end of the paper. You're sort of
18 asking us, should a certain structure be favored over
19 another? Should we use payment policy to do that? And I'm
20 just trying to --

21 DR. STENSLAND: Yes.

22 MS. BUTO: -- understand how those connect.

1 DR. STENSLAND: So I think that's in the --
2 that's kind of on the first three types of organization,
3 and then the other type is, okay, we see -- every year when
4 we go through our margins or our rates we're tending to see
5 this discrepancy growing between Medicare and fee-for-
6 service, and there's the question of do we raise our rates
7 or do we hold firm? And so far we've held firm, and we see
8 that that has helped keep the overall cost of Medicare low.
9 So that's kind of the other question, of what do we do in
10 our fee-for-services rates?

11 Now there's also the question that something is
12 going to have to happen with the growth rate of commercial
13 prices, but that's kind of out of our bailiwick, so we
14 don't have any sort of policy that we've stated there.

15 MS. BUTO: It seems to me there -- correct me if
16 I'm wrong, but there we tend to look at it from an access
17 perspective, and we evaluate that, right --

18 DR. STENSLAND: Right.

19 MS. BUTO: -- to see whether we're seeing any
20 harm from that discrepancy.

21 What I'm just really trying to get at is are we -
22 - is this short of premium support, trying to level the

1 playing field, or is it something else? Is it an interim
2 step to look at ways --

3 DR. MILLER: Can I try this?

4 MS. BUTO: -- to improve -- yeah.

5 DR. MILLER: And maybe organizing the top three
6 bullets with the fourth bullet turned out to be a mistake,
7 which we'll just put that on Jeff.

8 [Laughter.]

9 DR. MILLER: But I think what Jeff -- and it's
10 not, because I was very much, you know, involved in these
11 discussions, so if this comes across as confused, I have
12 the responsibility here.

13 What we were trying to say is that you could
14 think of different forms of consolidation occurring in the
15 market. Whatever the actual vocabulary ends up being on
16 the risk or performance, I think, you know, that to the
17 side. We're looking at consolidation, and we wanted to run
18 through and kind of pull together, in one place, the
19 evidence that's out there, because people still argue over
20 those top three things, and whether their phenomenon have
21 one effect or another. So we wanted to put that down, and
22 we also wanted to put down -- and you're obviously picking

1 up on it -- where we've been in the past. And so you're
2 correct in saying, "Why are you telling me about, you know,
3 restraining rates or site-neutral, because I've already
4 talked about that and I kind of know where we are?" And
5 you're right. You're picking up on what's going on in the
6 paper, no matter how much we accidentally confused you.

7 And then we come to -- what are you doing here,
8 Jeff?

9 [Laughter.]

10 MS. BUTO: He's going to the end, because that's
11 where I don't -- the disconnect occurs for me at the end,
12 Slides 14 and 15.

13 DR. MILLER: So it's really kind of this -- you
14 know, now, as a commission, we have this other phenomenon
15 happening, where, you know, providers are taking risk,
16 however we end up defining it, performance risk or
17 otherwise, and as a commission, what policy posture do we
18 want to begin to take there? It's not strictly a premium
19 support thing. It's more whether we start to say we're
20 going to tilt our payment to favor one kind of, you know,
21 model or another, or whether we're going to try and
22 maintain this. No, we're neutral. May the best man win,

1 type of phenomenon.

2 I think that is really what we want, from a
3 policy perspective, to think about going forward. And we
4 packaged it all together and perhaps confused people in the
5 process of what we were trying to get them to focus on.

6 MS. BLONJARZ: Can I just answer your access
7 point? I think one other thing, you know, yeah, the
8 framework that the Commission generally uses on payment
9 adequacy pivots off access on the physician side. That's
10 what we measure most directly.

11 You know, you could see a situation where the
12 Commission has to face, you know, relatively declining
13 access for physician services because physicians make such
14 -- you know, have so much higher revenue on the private
15 side. And we will just have to face that, and I think
16 we're trying to just kind of put that out there -- not that
17 it's here, but you may want to think about it.

18 MS. BUTO: Right, and I think if you're going to
19 do that, if we want us to look at that, then one of the
20 payment policies we have to look at is the adequacy of the
21 physician fee schedule. But that's not the way -- this is
22 more like structures of care. Do you know what I mean?

1 So I'm just saying -- and we can get back to this
2 in Round 2. I think more connectivity among these ideas
3 would be a good thing.

4 DR. CROSSON: Okay. We're still on questions.
5 Bruce.

6 MR. PYENSON: Actually, the confusing nature of
7 this has led me to some other thoughts that I'd like to ask
8 about, which is we're focused on payment rates, but there's
9 a bunch of other policy kinds of issues that could be tied
10 in with this that could be important for the markets and
11 success, I think. And I'm wondering if you've explored
12 some of those.

13 For example, if a hospital wants to participate
14 in Medicare, its affiliated physicians must, or, you know,
15 things that tend to force integration and remove some of
16 the risk of nonparticipation is an example.

17 DR. STENSLAND: We have not gotten into that.

18 MR. THOMAS: Just as a follow-up, do you see that
19 there's -- where physicians and hospitals are integrated,
20 that physicians are not participating in Medicare? Because
21 I think that probably is not a phenomenon.

22 MS. BLONIARZ: No, generally not. And there's

1 actually --

2 MR. THOMAS: Probably actually then being
3 involved with a hospital keeps them in Medicare, frankly.

4 DR. COOMBS: That's right [off microphone].

5 MR. THOMAS: I think you'd see more physicians
6 dropping out of Medicare if they were not involved with
7 hospitals.

8 DR. HOADLEY: So in the paper, you had some
9 findings on the facility fees and, you know, the notion
10 that they were not so much paid in the commercial sector
11 and, when they were, they were small. I just wanted to
12 hear slightly more about that and, you know, the
13 implication being that this is, I guess, reinforcement for
14 the direction we've been going on the site-neutral
15 policies.

16 DR. STENSLAND: Yes, so what we found -- and the
17 same thing was found by Cory Capps in one his studies that
18 looked at a different data set --was that it looks like
19 while the commercial insurers generally are paying some
20 multiple of Medicare and it looks like they are following
21 the RVU schedule, so, you know, if your Level 4 visit is
22 whatever multiple of a Level 2 visit, but when it comes to

1 are they going to follow Medicare and also then pay the
2 hospital a facility fee for the E&M visit, they seem to not
3 follow Medicare for that part of the game, and they say,
4 "No, we're not going to do that."

5 And, anecdotally, over the past seven, eight
6 years, we've heard hospitals -- or, I mean, insurers
7 saying, "We are going to stop doing that." So in some
8 places they used to do it, and then they said, "Okay, now
9 we're not going to do it anymore." And I think, you know,
10 part of it may have been some of the discussions we've had
11 here and also certainly some of the stuff in the press
12 where patients always did not appreciate getting two bills.

13 DR. HOADLEY: It seems like an important finding
14 that is worth not getting lost in the midst of our sort of
15 shifting over to these other topics. I wanted to make sure
16 we highlighted that.

17 MS. THOMPSON: Just one quick question. Jeff, do
18 we have any information in terms of from a standpoint of
19 measuring effectiveness and care coordination, maybe
20 specifically readmissions rates, in organizations where
21 hospitals and physicians are integrated versus low
22 integration rates?

1 DR. STENSLAND: We don't have anything that's
2 really up-to-date. The one thing we did is at one point we
3 showed a description of the integrated organizations and
4 the nonintegrated organizations on hospitals and what was
5 their 30-day episode cost, and you didn't see a whole lot
6 of correlation there.

7 MS. THOMPSON: How old is that data?

8 DR. STENSLAND: Maybe three years or so.

9 DR. CROSSON: Yes, Alice, go ahead.

10 DR. COOMBS: Sue, so there's actually -- I just
11 wanted to respond to your question. In Health Affairs in
12 2014, there's a comparative study that looks at small
13 groups, onesie, twosie practitioners, compared to groups of
14 nine to ten, by Castellino, and what they looked at was
15 readmission rate, and the readmissions rate was 33 percent
16 less with the small groups.

17 MS. THOMPSON: And that was '14?

18 DR. COOMBS: 2014, in Health Affairs.

19 DR. CROSSON: Okay. Thank you for the questions.

20 I'm going to -- have we got Slide 15? I'm going
21 to turn to you in a second, David. First I'm going to tell
22 you what to say. No, just kidding.

1 [Laughter.]

2 DR. CROSSON: I think people have said, okay, but
3 we have a set of problems that have been posed. We've got
4 a bunch of solutions, you know, previous recommendations
5 that address some parts of that. But I think what's being
6 asked here is a little bit more global question that's on
7 the bottom of this slide, which is, you know, how should we
8 be thinking about organizing our thoughts around payment
9 policy? You know, we want to be completely neutral --
10 talking Medicare payment policy, we want to be completely
11 neutral. We would like to develop ideas over time to
12 change Medicare payment policy such that it favors certain
13 legal or organizational structures. And then I would add,
14 if this is acceptable, I would add a third bullet point to
15 that. Do we want to favor changes in Medicare payment
16 policies that are likely to lead to higher quality and
17 lower cost and then we'd have the incidental effect of
18 changing organizational structures? Because I think that's
19 a third alternative, which is consonant with some of our
20 other recommendations over time.

21 DR. NERENZ: All right. Thanks, Jay. I'll try
22 to be quick and not to repetitive of things other people

1 have said.

2 Jay, just the way you led into this, I'll make my
3 last point first. I would myself be a strong no on this
4 last point here. I would not favor paying differentially
5 on the basis of model. I don't see a conceptual argument
6 for it. I don't see a data argument for it. It seems to
7 run against some other things we said. I would just say
8 no. But we'll see.

9 Just a few other points. This was an interesting
10 chapter to me because of its complexity. Often we have
11 issues in front of us, and I think this kind of plays off
12 Kathy's comment. We say, "Here's a good thing. How do we
13 get more of it?" Or we say, "Here's a bad thing. How do
14 we get less of it?"

15 Now, here we've got a mix, and the goods and bads
16 almost inevitably run together. But when we use terms like
17 "integration," that has a good connotation. We tend to
18 like that. Clinical integration is good, integrated care
19 is good. Okay, that's all good.

20 Consolidation, at least this morning, is bad.
21 You know, it drives up costs, it does bad things. But it's
22 really hard to separate that. But I think that's an

1 interesting challenge to take up. Is there any way in the
2 context of Medicare payment policy that you can actually
3 get more good and get less bad? Given how tightly bound
4 they are, I think that's tough.

5 Warner, Craig, Paul, and others pointed out how
6 Medicare policy doesn't live in isolation here. A lot of
7 these factors are driven by forces in the commercial
8 insurance world, and those might be bigger and more
9 powerful. I hear providers talking about getting together
10 as a counter -- essentially a defensive posture against
11 insurance consolidation. So a lot of these things may
12 happen regardless of what we do.

13 And, as usual, I'm picky on the semantics. I
14 already have been once today. In the chapter, not so much
15 on the slides, you talked about pay for outcome as maybe
16 one of the directions. Again, I'm not sure that's quite
17 literally what you mean. I'm one of the folks that grew up
18 in the Donabedian era, and "outcome" has a precise meaning.
19 And as I saw it used in the chapter, I think that's --
20 again, you're using it in a broader sense. I was reading
21 pay for value, pay for quality, not literally pay for
22 outcome. But, actually, I think it would be fun to take up

1 literally that, but maybe this isn't the chapter to do it
2 in. So, again, I just want to make that observation. I'm
3 always a splitter and a literalist on words, and it doesn't
4 always fit. But we ought to clarify that.

5 In the chapter, there are three policy options.
6 They're framed a little differently than what we have on
7 the slides, and without referring back and repeating them.
8 I just thought we ought to add a fourth. I like them all.
9 I thought they were all good.

10 The fourth one I would add was reduce
11 administrative burden on small practices. We've talked
12 about that in the context of MIPS. I think we could turn
13 to meaningful use in EHR as another example. You know,
14 those territories also have some mix of up-down benefit,
15 but often I look at these and I say, "Well, there's the end
16 of private practice" or "There's the end of small private
17 practice." They can't do these things.

18 So it seems to me every time we have a discussion
19 on one of these other points, we should be thinking about
20 if it appears to us that this is something that big
21 organizations can do more easily than small, are we then
22 now unintentionally giving fuel to the fire, I think was

1 added.

2 Back to the insurance risk, I really think those
3 can be separated. I really think that the separation is
4 quite clear, actually in the ACO program, that the risk
5 adjustment, particularly the way it's applied in a current-
6 year basis, really protects ACOs almost entirely from
7 insurance risk. What's left is performance risk or
8 utilization risk.

9 Now, in my own taste, I think that's good and I
10 think it's okay, which then is sort of my closing point. I
11 think that there's a valid and good distinction between
12 insurance entities and provider entities, and the kind of
13 risk that insurance entities take on, and then a different
14 kind of risk that provider entities should take on.

15 You know, insurance entities are governed by
16 license and their governed by state insurance regulations,
17 and they have the feature of financial reserve
18 requirements. Okay. ACOs typically do not have that.
19 Medical group practices do not have that. Hospitals may
20 accidentally have it, but they're not in that same
21 business.

22 And, you know, a couple times in the chapter

1 we've talked about sort of in a desirable sense taking on
2 full capitation risk. I think that's a bad, bad idea. I
3 think we learned 20 years ago that's a bad idea. So I just
4 don't like -- I don't like the idea of provider groups
5 taking on insurance risk in general, but certainly not full
6 cap risk.

7 DR. STENSLAND: If you could explain a little bit
8 more, you said these things are clearly distinguishable?

9 DR. NERENZ: Yes [off microphone].

10 DR. STENSLAND: In my mind, if you have an ACO
11 and it's taking two-sided risk and you see that your
12 utilization went down by 5 percent or up by 5 percent, how
13 do we know that that utilization going down by 5 or up by 5
14 was due to good behavior on your part or -- you know, it
15 went down by 5 because you had stellar management or it
16 went down by 5 because you got lucky and your people just
17 didn't get sick that year?

18 DR. NERENZ: It's the risk adjustment,
19 particularly the way in the MSSP it's applied in the
20 concurrent year. Now, others can correct me if I'm wrong,
21 but I think the way it works is if you get a bunch of
22 people either the incoming new people are healthy or the

1 people continuing -- well, it's easier to describe the
2 other way. You know, if there's an outbreak of infectious
3 disease or something, that is accounted for in the risk
4 adjustment, and the financial target is adjusted on that
5 basis. I think that really takes away the insurance risk.
6 If your people are healthier, you have got a lower
7 expenditure target because of that. If they're sicker,
8 you've got a higher expenditure target. And then your risk
9 is based on that adjusted target.

10 Am I misperceiving MSSP?

11 DR. GINSBURG: Yeah, I think there are a couple
12 of things you're missing. First of all, you're assuming
13 the risk adjustment mechanism is perfect.

14 DR. NERENZ: I wouldn't say -- well, I probably
15 got close to saying there's no risk, but I think it's
16 really small.

17 DR. GINSBURG: Yeah, but the other point I want
18 to make is that there's a lot of other risk that's not
19 classic insurance risk, which is just from pooling people.
20 That's classic insurance risk. There are other risks that
21 insurers take on, like the appearance of Sovaldi in the
22 delivery system. You know, that meant a lot of insurers

1 paid out more in claims than they were projecting for that
2 year.

3 MS. BUTO: New technology.

4 DR. GINSBURG: So a new technology. Having a bad
5 flu season is another risk. So in a sense, it's a third
6 category of --

7 DR. NERENZ: But just as a point, because this is
8 a factual question. If there's a bad flu season, is that
9 not adjusted for in the clinical risk adjustment in MSSP?

10 DR. GINSBURG: No.

11 DR. NERENZ: Then why -- well, okay. We may get
12 off -- I'm sorry if I'm wrong, but I --

13 DR. MILLER: I think your point, David -- and you
14 were getting close to saying it -- it's all taken care of.

15 I think what he was saying -- and you're sitting
16 right here, so you can check it -- is because the
17 benchmarks in, say, the MSSP world built off of history,
18 that was -- you were saying in a sense you've captured the
19 inherent risk in that population. I think that was your
20 point, because it's not like an MSSP. There's a risk
21 adjuster that gets applied to that. I took your comments
22 as saying but it's the -- you know, you're building it off

1 of the history of my population; therefore, the risk is in
2 there.

3 DR. NERENZ: Well, I clearly -- apparently I'm
4 wrong on this, but I'll just say it and then you make sure
5 that I know I'm wrong. When MSSP first came out, it seemed
6 like one of its design features was that if a -- because of
7 the retrospective view of it, you do not control
8 enrollment, it's not -- but you had to protect the entities
9 from an influx of sick people, and that in order to do
10 that, the risk adjustment was not applied just based on
11 history, but it was applied on the diagnostic mix in that
12 year.

13 Now, if that's wrong, it's wrong. But that's
14 what I thought was going on.

15 DR. GINSBURG: It is, but given the fact that
16 there is churn in the attributed beneficiaries, you know,
17 the ones that you had historically are going to be
18 different from the ones that you retrospectively turned out
19 to have in your ACO year means that you still are dependent
20 on the risk adjustment mechanism to get that right.

21 DR. NERENZ: And all risk adjustment is
22 imperfect. We certainly don't disagree. But I -- well,

1 okay.

2 DR. CROSSON: Okay. You know, I think, again,
3 what we're trying to do here is we're looking for some
4 direction, if I understand it properly, which is as a
5 consequence of changes in the market, particularly those
6 first three bullet points, how does that change our payment
7 policy going forward at kind of a high level, not, you
8 know, a specific one? We have a lot of specific ones we've
9 gone, and they're listed. They're right as far as I'm
10 concerned. But going forward, how should we be thinking
11 about this? Should we be saying, you know, well, we're
12 just going to continue, as the bullet point says, we're
13 going to be, you know, neutral to this impact, we're going
14 to be just paying based on our perception of patient needs and
15 outcomes.

16 On the other hand, we're going to potentially
17 favor one model or the other or disfavor one structural
18 model in terms of how we think about payment going forward.
19 And then I said -- I'll say it again -- another option
20 here, I think, is to say do we want to favor Medicare
21 payment models going forward for the purpose of driving
22 lower costs and higher quality, and so examples that have

1 been brought up already are going back and looking at the
2 physician fee schedule? Is this the right way of paying in
3 today's world, particularly, for example, with the
4 evolution of single specialty groups, as Paul pointed out,
5 which is driving a lot of the cost, or do we want to
6 consider moving provider payment more towards some sort of
7 global payment which takes into consideration both cost and
8 quality factors? And how do people feel about the -- and,
9 David, you've already said that the notion of paying for
10 certain structures is not -- I would agree with you on
11 that. I don't see any justification for that, but others
12 might feel differently.

13 So unless I'm off base here -- and, Jeff and
14 Kate, tell me if this is going to be helpful to you or not
15 -- could we focus on that sort of question? And I realize
16 it's difficult because we're kind of dealing in a
17 conceptual level, and sometimes it's easy to deal on, you
18 know, a very specific policy level. But let's try that,
19 and if it doesn't work, we'll do something else. Let's
20 start with Brian.

21 DR. DeBUSK: I do also agree that we should not
22 pay for any particular corporate structure. But to answer

1 Jay's question directly, you know, what should we pay for?
2 There's already about a 4 percent bias in MA, and ideally,
3 someday we would work that bias out of the system. But,
4 you know, I don't see that as a front-and-center priority.

5 The question would be: Would you want to put a
6 similar bias into ACOs? I mean, is there a way that you
7 could give, say, participants some latitude in deriving
8 their benchmark, maybe partially from my history, partially
9 from a national benchmark, partially from a region? And I
10 realize that's all changing already. I mean, I think all
11 those rules have been written.

12 My question is: If you were to come up with a
13 method where they had a little bit of flexibility in
14 choosing those component parts -- not absolute choice,
15 obviously, you know, because then you could get tremendous
16 adjustments. But if you gave them a little bit of latitude
17 where you could say, well, I want 25 percent from the
18 national benchmark, I want 50 percent from my own history.
19 If you gave them a little bit of latitude, and let's say it
20 did result in a 4 percent bias similar to what MA has, I
21 don't think that's necessarily a bad outcome.

22 Putting your thumb on the scale a little bit --

1 and, again, I'm not advocating for someone saying, "I want
2 to be 100 percent of my history because I'm a spending
3 disaster," because I think then you're going to get a much
4 bigger than 4 percent result. But I think if you bracket
5 the components of how that benchmark is derived, I think
6 you'd give them the opportunity to get that 4 percent bias,
7 because I would like to see ACOs get a push start.

8 DR. MILLER: This is precisely the conversation
9 that we want to have. Okay? As confusing as all this was,
10 this is why we wanted to set up this second -- or this
11 bottom conversation, because comments like that, in some
12 cases, of our sessions have been "No, no. We should be
13 neutral." We should be neutral, that type of thing, and
14 then comments are, "No. We should put our thumb on the
15 scale."

16 So the thing I would like either you or other
17 people to talk about over time is if you do that -- and I
18 am taking your comment, Brian, and you tell me if this is
19 wrong. You're sort of saying, "I know this might not be
20 the efficient place to be for now, but I'm going to put my
21 thumb on the scale." When does the thumb come off, and
22 how? And how does someone -- and since you're asking,

1 posing it, you know, you -- how does somebody say, "Well,
2 I'm not going to let a financial disaster set their own
3 benchmark, but I am going to let somebody else do that,"
4 that, I think, is the exact question that we're struggling
5 with and we hear sometimes in this group and sometimes not.

6 DR. DeBUSK: And I think this is where we -- and
7 by "we," I mean the royal "we." I mean you guys. Thanks.
8 Thanks in advance. -- could actually model some brackets
9 for us.

10 When we looked at those, I see a performance
11 result several cycles ago. It was obvious there was a lot
12 of selection bias in there. I mean, this was the group of
13 the willing.

14 What would be nice is to have some general
15 brackets where you could say, "Well, you know, don't let
16 anyone do more than 40 percent of their history, but maybe
17 let them choose 25 to 40." I know this is a big ask. Like
18 I said, I don't mean to make minimal of that request
19 earlier. But if you could help us just with a framework
20 of, say, what are those three brackets -- regional,
21 national, and historical -- maybe that's a good place to
22 start just to see how broad those brackets could be,

1 because I think the broader they are, the more appeal they
2 have, but the more financial exposure you have to selection
3 risk as well.

4 DR. STENSLAND: I want to say I think this kind
5 of gets exactly to the points we were trying to get at, and
6 even in this example of the ACOs, I think it still does, in
7 a way, fall into the legal or organizational structure
8 because you could say, "What is my expected payment for
9 Medicare if I do nothing other than have my lawyer put
10 together an ACO and we just continue on as we have and
11 we'll have some random variation in what's going to happen?
12 Do I have an expected positive return on investment for my
13 legal fees, even if I don't change my behavior at all?"
14 That's the kind of question.

15 DR. CROSSON: Okay. Paul.

16 DR. GINSBURG: In response to your question, Jay,
17 about moving into models that get away from fragmented fee-
18 for-service, I think that's very separate from the issues
19 that this presentation brought forward about the fact of
20 consolidation and this issue about the increase in gap
21 between what Medicare is paying and what commercial payers
22 are paying.

1 I think that Medicare has or should have a strong
2 interest in addressing some of these issues that have
3 ramifications in the commercial market because it will
4 ultimately risk putting pressure on its spending. So some
5 of them are Medicare policies, like site-neutral payments.
6 Some of them are not, which gets into Medicare or CMS
7 advocating to the antitrust agencies and even the states to
8 be more vigilant about these threats from consolidation.

9 I have some other comments. I don't know if we
10 should give them now.

11 DR. CROSSON: Go ahead.

12 DR. GINSBURG: One thought on the financial
13 neutrality, I think we've really seen in MA how Congress
14 put their thumb on the scale in favor of MA. It generated
15 substantial growth, but then, of course, it's been very,
16 very difficult to take that back. I guess that growth has
17 continued after some of it was taken back, but it shows.

18 And I think a really good comment from Jeff about
19 it's so much more dangerous with ACOs because it's easier
20 to stay qualified to be that kind of an organization.

21 The notion of higher quality receiving higher
22 payments, this is something that the Medicare Stars

1 experience has made me very cautious about because I
2 believe that Medicare is overpaying for quality based on
3 star bonuses, and I think it's great that we have the
4 stars. The beneficiaries in some cases pay attention to
5 them, but in a sense, market share should be the reward for
6 higher quality. And maybe there's some argument for higher
7 payment, but the problem is that it's easy to become overly
8 generous just because quality -- everyone agrees that
9 quality is good, and why should we limit how much we pay
10 more for higher quality?

11 I also agree that we shouldn't pay more for some
12 structures or processes, but I do see as far as provider
13 and insurer consolidation, my perspective at this point is
14 neutral because we just don't know enough and suspect that
15 the difference is the gains or losses from that might be
16 subtle, and that we're nowhere near ready to actually
17 encourage or discourage that.

18 DR. MILLER: And if I could just say one thing --
19 and I know Paul knows this -- the other part of the story
20 on MA was would you put the thumb on the scale. I think
21 that's what we're saying, and then it did grow the
22 enrollment. And then the Congress had to come in and take

1 it back and still, in some ways, are working on that.

2 The other thing that was happening in the midst
3 of all that is that we were creating really inefficient
4 managed care markets. The fastest-growing product at that,
5 you know, when finally action started to be taken was a
6 private fee-for-service plan, which didn't manage anything,
7 paid fee-for-service rates and took a 10 percent fee. And
8 so that's what I think is the concern is, is if you set up
9 a payment system and somebody legally sets up something
10 that says, "Oh, yeah. It fits this structure, but it isn't
11 doing at all what you think it might be doing" -- sorry,
12 Paul. I know you know that we've had this.

13 DR. CROSSON: Right. And I just would make one
14 other point, Paul. In the decision that was made around
15 Medicare Stars to make it non-budget-neutral feeds into
16 what you're saying. In other words, if it had been budget-
17 neutral, first of all, I think the amount of payment --
18 industry would have pushed for a lower differential amount
19 of payment, and secondly, it wouldn't have added to cost.

20 DR. GINSBURG: I agree with that.

21 DR. CROSSON: Kathy.

22 MS. BUTO: So let me start off by saying I hope

1 we never get in a situation where we're paying -- using
2 payment policy to try to incent the development of some
3 structure because I'm convinced we'll get it wrong. We
4 don't know enough, and the structures are going to evolve,
5 so why would we ever do that? I was appalled, actually, to
6 think about using payment policy in that way.

7 I just want to go back to a couple things, one
8 that Kate mentioned about the fee schedule, and in the
9 report itself, as Dave said, on page 32, one of the
10 principles we talk about is restraining Medicare prices
11 rather than following commercial, which I think we would
12 all agree with. But I think she raised another point,
13 which we need to pick up, which is we need to worry about
14 the adequacy or the availability of services and the
15 adequacy of payment to assure access. So I would just make
16 sure we covered that.

17 In terms of -- I'm still struggling with what is
18 it we're trying to actually do here. In terms of ACOs, in
19 my mind, anyway, MACRA at least attempts to put their thumb
20 on the scale, if you will, by providing that 5 percent
21 bonus for alternative payment models, so I wouldn't add
22 another 4 percent to that. I don't think we even know if

1 that's going to work, and maybe that's how much you meant,
2 Brian.

3 DR. DeBUSK: I would include MACRA as one of
4 those pouring-fuel-on-the-fire sources.

5 MS. BUTO: Well, okay. So let's redesign MACRA,
6 but I don't think we then add another set of layered
7 incentives on top of that.

8 I'm just weary about using payment policy as the
9 grand hand of government to try to tip the scales one way
10 or the other. I think you got it right, Jay, that whatever
11 we need to do to assure access, quality, good outcomes,
12 that's what we ought to be focusing on, and the paper does
13 touch on a lot of the things like site-neutral, where the
14 Commission has really taken some leadership in that regard.
15 And we ought to keep our eye on that ball.

16 Beyond that, I don't know what I'd do with MA
17 payment policy or fee-for-service payment policy. I think
18 we're doing a lot of it already. I don't know what else we
19 are being asked to look at here beyond that, other than the
20 structure issue, and I just think let's not do that. I
21 would definitely be really opposed to the Federal
22 Government getting into deciding through payment policy

1 what structures we want to incent.

2 If we don't like ACOs and the way that they're
3 loosely configured, then let's focus on that and making
4 comments on a better structure. That's more beneficial,
5 rather than using payment to drive a certain result.

6 DR. CROSSON: Okay. Bruce and then Bill.

7 MR. PYENSON: I want to compliment Jeff and Kate
8 on not using the term "cost shifting" anyplace in the
9 report. I assume that that means that the issue has been
10 solved forever, and that's really great news.

11 But I am with Paul on his comment on that it is
12 of -- it should be of concern or investigation, the
13 question what is going on, on the commercial side. That is
14 critically important for Medicare potentially, but I don't
15 know enough about it. For example, the comment that Warner
16 made, the integration with hospitals and physicians is a
17 way to, in effect, protect participation, I think those are
18 things that we need to understand, because the chart on
19 Slide 9 appears alarming. But I think we need to
20 understand more what sort of breaking points. Let's get a
21 picture ahead on what could happen and what, if anything,
22 are the drivers of changing that.

1 I recall in the distant past, Medicare did tie in
2 Medicare Advantage with commercial. I think on a policy
3 basis, a long, long time ago, there was a requirement that
4 you had to have a certain amount of commercial business
5 before you could get into Medicare, the Medicare Advantage.
6 So I raise that as a suggestion that maybe Medicare does
7 have authority or policy to influence in some ways what
8 commercial carriers do, and that might be a useful avenue
9 that's not quite payment method but more policy performance
10 based.

11 And I think, likewise, ACOs, the payment policy
12 is not necessarily the most important issue with ACOs or
13 ACO success. I don't think the financial reporting that
14 we've gotten from ACOs really paints the picture of whether
15 they're successful or not. For example, an ACO that shifts
16 the leakage of its population from 50 percent to 20 percent
17 may not actually show a financial gain, and it may not show
18 savings for Medicare but could be a phenomenal success for
19 the organization itself. And we'd never know, based on the
20 kind of issues we have. So there's other ways, if we think
21 ACOs are a good thing, other kinds of policies that we
22 could think about that would, if you will, put the thumb on

1 the scale.

2 But I do agree really with what Kathy said. I
3 would change the term from "organizational structure" to
4 "bureaucratic structure," but I don't think we should alter
5 payment based on those.

6 DR. CROSSON: Okay. I'm going to point out that
7 we're 20 minutes over, so I'm going to plead for
8 conciseness at this point.

9 Bill.

10 DR. HALL: I will try to be concise.

11 We are looking at a very good report concisely
12 put together by Jeff and Kate that describes the apparent
13 intended and unintended results of a lot of changes that
14 we've instituted under the rubric of provider
15 consolidation.

16 When I look at this, I say why are we doing that.
17 Well, I guess it's because we think it's -- these aren't
18 the results that we really wanted to see from all of this,
19 and it's a little bit like the organizations, that all
20 organizations are perfectly designed to get the results
21 that they're getting.

22 And let's take that just for a second. One would

1 say from that we'd have to challenge why we're doing what
2 we are doing. So I look at this, and I am going to quickly
3 come down to the only world that I know reasonably well,
4 and that's the clinical world that I live in.

5 In my community, virtually examples of this are
6 everywhere, but the advantage I have is I kind of know the
7 people. I know some of their faults and my own faults, and
8 it flavors what I'm doing. So if I look at the
9 consolidation I see in my own community, there's not one
10 cause for that. In fact, the causes are diverse and
11 sometimes going in opposite directions, but they're all
12 getting the results they want to have.

13 Let me just give you a couple of examples. I
14 think we have people who are sincerely interested and
15 motivated along the lines of quality, and they're
16 breathtaking in what we can do, and I think we can take
17 that to -- in any part of the country. I don't know how
18 they do it, but they are getting the results that they
19 intend to.

20 I see a lot of changes in consolidation that are
21 based on enlightened self-interest. Sometimes this is
22 purely market share. Sometimes it has to do with

1 competition between groups, and I see this particularly in
2 the ACO world or between individuals who are very powerful
3 in the organization. But they are getting the results that
4 they want. This is what they want to do in terms of using
5 the mechanisms under the rubric of provider consolidation.

6 Everybody wants more revenue. Why are good
7 ambulatory groups -- why are they anxious to get affiliated
8 with hospitals? Well, so they can gain the hospital share
9 in terms of enhancing their revenue. That's good for them,
10 and they're getting the results that they want.

11 Academic health centers have a great desire to
12 protect status quo Medicare for a couple of reasons. The
13 obvious one is that they benefit from the system now that
14 in a somewhat irrational way pays for medical education,
15 both directly and indirectly. Why would they want to
16 change that system to get results that would make it harder
17 to take care of their academic mission?

18 So I think that we have to understand that part
19 of it and then ask ourselves: Are there other things that
20 we could do that would get through this, people getting the
21 results that they deserve? And as has been mentioned by
22 several people here, I think quality is really where the

1 action is. Unless we can motivate people for higher
2 quality, we might just be kind of moving the deck chairs on
3 the Titanic.

4 So I would make a real plea, and I will have
5 nothing to do with this after the next hour is over.

6 [Laughter.]

7 DR. HALL: I think we always have to ask
8 ourselves. We are getting the results that we have asked
9 people, in many ways, to do, and it isn't kind of working
10 out because a lot of these things can't be done all in one.
11 I think everything we do ought to have a great emphasis on
12 quality and let a lot of other things flow from that.
13 Otherwise, I don't know what we're doing.

14 Thanks.

15 DR. CROSSON: Thank you. Alice.

16 DR. COOMBS: So I wanted to talk a little bit
17 about Slide 3 and the consolidation. So we are faced with
18 some prevailing issues from this chapter, and thank you
19 very much. It was excellent. One is the consolidation
20 being problematic in the sense that we know that the E&M
21 coding and the facilities fee drives up cost, and then the
22 other part is the disparity between the payment and

1 reimbursement on the commercial side versus Medicare, and
2 what impact that has overall on Medicare long-term
3 sustainability, in terms of competitive forces.

4 So this dwindling population of primary care
5 doctors, I'm wondering, even with the recommendations, if
6 we could actually hone in on the -- I guess it would be a
7 physician in transition or a physician forum for us right
8 before they become consolidated, because of the reasons why
9 people are joining groups and what have you. If we could
10 actually focus on, maybe in our interview for the fall,
11 looking at physicians, reasons why they're consolidating,
12 and to see what Medicare could best do to address some of
13 their needs.

14 For instance, the majority of medical students
15 graduating are not looking for a solo practice. They're
16 looking for the minimal barriers to practicing medicine,
17 and that, in and of itself, leads them to an employment
18 type of profession, and right away they are centered in a
19 medical center, which actually would change the paradigm
20 going forward.

21 I don't think there's a lot we can do about those
22 horizontal-horizontal kind of consolidation. I think the

1 last one, in terms of insurers and providers and provider-
2 insurer relationship might be something that we could focus
3 on and hone in on that piece, because the other -- the
4 train has left the station on the other ones and there's
5 not much we can do. And to be honest with you, if I was a
6 solo practitioner, I would be tempted to get on with the
7 bells and whistles and have everything laid out for me.
8 That's just your harsh reality, and I think that we should
9 focus on the ones that are in transition or thinking about
10 -- small groups that are thinking about becoming
11 consolidated.

12 DR. CROSSON: Jack.

13 DR. HOADLEY: So I will be brief but I wanted to
14 reinforce two points that some other folks have been
15 making. You know, one really started from Kate's comment
16 about, you know, what we may look at down the road if
17 consolidation means that commercial plans are raising
18 physician payment rates, and we see an effect on Medicare
19 access. I really want to see that we are prepared for that
20 with what could our policy responses be beyond simply
21 saying raise Medicare rates because it's the only thing we
22 can do to not lose physicians to practice only on the

1 commercial side.

2 So we have a chance now to think about that and
3 think about whether there are other things, and I don't
4 have the answer, but I wanted us to really work on that.

5 And the other one is this sort of thumb-on-the-
6 scale argument, and I think that the Medicare Advantage
7 history, and a couple of folks have said this, is very
8 sobering. You know, we started in the '70s with the notion
9 that Medicare Advantage, or whatever it was called then,
10 should come in at 95 percent of AAPCC, and you know, they
11 would only come in the system if they could save money.
12 And then, by the '90s, we were saying, well, let's figure
13 out ways to pay more, to make sure they come into those
14 areas that don't have them.

15 And we've been sort of dealing with the
16 consequence of that for the last 20 years, and it feels
17 like some of the options out there, that have come up,
18 could get us back into that same game -- we'll pay more but
19 then we'll be stuck with that, and it will be simply the
20 private fee-for-service, I think is a perfect example of
21 this -- we'll be struck with responses that aren't what we
22 had in mind, just basically robbing the federal treasury.

1 DR. CROSSON: Okay. Coming down this way. I see
2 Pat.

3 MS. WANG: I am very worried about the growing
4 disparity between Medicare payments and commercial
5 payments, and I think it's already happening that many
6 organizations view Medicare as like the charity care payer
7 -- I'm not kidding -- and I think it's dangerous. I don't
8 know what to do about it. I think it impedes the
9 negotiation or the setting of value-based payments in a
10 managed care situation because those organizations with
11 leverage will want 100, double-digit, X percent of the
12 published Medicare rate, which, you know, means that if
13 you're an MA plan that is capitated based on a percentage
14 of the benchmark, that means you have to pay somebody else
15 quite a bit less, it just -- that is not a fertile ground
16 for anything that is value-based.

17 So I don't know what to do about the growing
18 disparity, but I do think that one of the values that
19 Commission has expressed is to try to put more pedal to the
20 medal on the shift from volume to value. So I would -- you
21 know, to that point, I think, you know, we should look at
22 payment policy, not paying for structure. I agree with

1 that. That is intentional, and to be intentional to
2 achieve that goal. And I had started a conversation with
3 Jay and Mark that I can't actually complete right now.

4 But on the flip side of what Bill mentioned, part
5 of intentional payment policy is to look for payment policy
6 that actually creates disincentives for people to move to
7 value suggests the way that special payments, GME, on
8 compensated care, are tied to inpatient statistics, I mean,
9 they require organizations that could have the capability
10 to innovate tremendously to reduce admission and
11 readmission rates, who have entire finance departments who
12 are saying "I have to maintain my inpatient statistics in
13 order to get my full share of IME, GME, and compensated
14 care." So I'm not talking about the derivation of the
15 amounts that people get, but I think that that is one area,
16 perhaps, that we could look at along the theme of
17 intentional payment policy includes changing the way that
18 some payments get to organizations to remove the shackles
19 from really moving forward off to value.

20 DR. CROSSON: Sue.

21 MS. THOMPSON: I will be brief, but I'm going to
22 circle back to Brian's comments, in support of putting

1 thumb-on-the-scale for the ACO, because I think while we
2 continue to hear we just haven't seen the results that
3 we've hoped for, these ACOs are in their infancy, and the
4 organizations that have taken on that work have invested,
5 and continued to invest in the capability that is required
6 to improve the status of the health of the population.

7 And I think this is a wonderful chapter to end
8 this discussion, because we've talked about the need to not
9 only improve status of this Medicare population but also
10 look at the opportunities to build on the accountability
11 within the accountable care organization, if we take on
12 utilization of drugs, utilization of devices, and the whole
13 low-value/no-value care, where I think there actually was a
14 reference to ACOs have reduced the use of low-value care.

15 So I think it's a wonderful chapter and it's a
16 wonderful concept to support the work of accountable
17 providers in accountable structures, where you do have
18 physicians, hospitals, and pieces of the full-care
19 continuum on the same -- invest in -- huge investments in
20 electronic health records. Let's not throw the baby out
21 with the bath water here.

22 So I'm quite supportive of putting the thumb on

1 the scale here.

2 DR. CROSSON: Craig.

3 DR. SAMITT: I am as well. I am worried that our
4 policy recommendations, especially the financial neutrality
5 policy, will have unintended consequences. I think what
6 we're trying to accomplish here is we're trying to drive
7 delivery system reform and provider accountability, and I'm
8 worried that our -- good, you know, to the point of good --
9 and that our policies aren't driving that. They're driving
10 provider consolidation, with no better accountability --
11 bad.

12 And so my question is, what policies do we want
13 to put in place that drive to value and drive
14 accountability and not have the unintended consequences of
15 driving to consolidation? And so I agree with maintaining
16 the thumb on the scale, especially for MA, and while I know
17 that we want to have competition between MA, ACO, and fee-
18 for-service, I'm not so sure I agree with the notion of
19 financial neutrality.

20 So what we're saying, essentially, to MA
21 organizations is, you're going to attract a sicker
22 population, you're going to take on risk in a substantive

1 way, you're going to deliver higher-quality results, and
2 you're going to get the same as fee-for-service.

3 And so the perspective that I have is we keep
4 reattaching MA to the fee-for-service chassis, when I think
5 what we want to try to encourage is more -- now, granted,
6 we can't paint all MA with a single brush, but we want to
7 encourage the more innovative, true value-based MA
8 organizations. And so I worry about the organizations like
9 Care More and Health Care Partners and ChenMed, those that
10 are actually out there, truly driving change, and that if
11 we create these financial neutrality vehicles and policies
12 that dissuade MA, and strengthen fee-for-service, that
13 we're going backwards.

14 MS. BUTO: Jay, I think we need a longer
15 discussion, not today, about what thumb on the scale means.
16 I really don't get -- I'm having trouble with this, because
17 the thumb's already on the scale. But -- so if we could do
18 that next year, or retreat, or whatever, I think that would
19 be helpful.

20 DR. CROSSON: Well, okay, so maybe what you're
21 saying, Kathy, and I'm not sure about this, is it appears,
22 on the face of it, that we really have some sharp

1 disagreements here on the Commission. Assuming that we're
2 all saying the same thing when we're talking about favoring
3 or putting thumbs on the scale, or all the rest of that,
4 and depending upon what that means and further explication
5 might be helpful, we might find that we are in more
6 agreement, or we're not. So, I mean, I think that's
7 valuable.

8 But it seems to me to go back to one of the first
9 questions that was asked here, which was, like, what
10 problem are we trying to solve? You know, I do think that,
11 you know, that Jack and Pat -- I don't know if I've got it
12 right -- helped me a little bit, because I think the
13 problem we're trying to solve, or the problem we're trying
14 to prevent is, over time, getting into a situation where
15 the disparity between commercial rates and what Medicare
16 pays, particularly to physicians, becomes so high that the
17 little bit of creeping of access that we've seen in the
18 last few years becomes a flood. Right? And then we've
19 really got a problem, I think. You know, and one response
20 would be to raise rates, but then, of course, we're kind of
21 running counter to everything that we're trying to do here.

22 So is it possible that one way to organize this

1 for future work is to identify that, you know, as the
2 problem we're trying to solve, and then align, you know,
3 some of these other questions, and other solutions -- and
4 again, I think, you know, some issues about how physicians
5 are paid in general, the fee schedule, whether we're
6 appropriately moving towards global payments through ACOs
7 or other things, or are there other ways we could do that.
8 Those are just my own ideas.

9 But the analytical principle would be which of
10 these potential solutions, thumbs on the scale or not, or
11 different payment things, we could project would make that
12 potential problem better or worse, going forward? And to
13 the extent that, you know, we can -- and it's easy for me
14 to say because I don't have to do it -- but to the extent
15 that we could think about some of these questions where we
16 have disagreements, from that perspective, then we might
17 find ourselves coming closer to agreement. That's the best
18 I can do.

19 DR. MILLER: Yeah, and this is just a couple of
20 sentences. I know we're way over time.

21 Taking Kathy's point -- and we fully anticipated
22 this was not one conversation, so, yes, this is going to

1 come up again and you will see it again. But it would be
2 kind of the notion like this. If you meant thumb on the
3 scale meant you get paid more if you have lower costs and
4 higher quality, then we may all be saying the same thing.
5 But if you're saying, no, this ACO model gets, you know, a
6 boost --

7 DR. CROSSON: Irrespective.

8 DR. MILLER: Yeah, right. I'm sorry. I should
9 have said that -- then I think there is more division in
10 the group. And so we will structure this along the lines
11 that Jay said. This was not a one-shot conversation. You
12 could see the level of complexity and however the
13 organization occurred, we were trying to trigger this
14 conversation.

15 MS. BUTO: But, Mark, it's really both the
16 question as you phrased it and it's the question as Jay
17 phrased it, which is, those are really two different
18 things, the access and adequacy, and what are the problems
19 with physicians, vis-à-vis commercial rates, and what kind
20 of reward system does Medicare have to incent the right
21 kind of care integration and quality? Those are related
22 but not the same thing.

1 DR. MILLER: I didn't mean to dismiss that. I
2 just was trying to go very directly at your particular --

3 DR. SAMITT: I would also argue, I wonder, when
4 we continue the conversations, whether we split them,
5 because we didn't even spend a lot of time talking about
6 policy to dissuade or take the fuel off the fire for
7 provider consolidation, because that still is a problem,
8 and I don't know if we had policy discussions about what to
9 do about that.

10 So it may make sense to separate them and have
11 supplemental conversations about each.

12 DR. CROSSON: Okay. Very interesting discussion.
13 Let me put it that way. That was an interesting evening.

14 Before we conclude here and go to the public
15 session, I would ask Bill Gradison and Bill Hall to stand
16 please. Together. Together. Come on. You can do this.
17 And this is just simply to --

18 MR. GRADISON: Is this --

19 DR. CROSSON: No, no. This is just simply to
20 thank you in public -- we've done this in private -- but to
21 thank you in public for your six years of excellent
22 contribution to this commission and its work for the

1 benefit of the Medicare program and its beneficiaries.

2 [Applause.]

3 DR. CROSSON: We will miss you both greatly and
4 hope we will be able to see you again.

5 So we have time for a public comment period. If
6 there are any members of our guests here to wish to make a
7 comment, now is the time to come up to the microphone.

8 [Pause.]

9 DR. CROSSON: Seeing none, we are adjourned from
10 our public meetings until next September. Safe travels,
11 everybody. Have a wonderful summer.

12 [Whereupon, at 11:40 a.m., the meeting was
13 adjourned.]

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