

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
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AGENDA	PAGE
The Medicare prescription drug program (Part D): Status Report	
- Shinobu Suzuki, Rachel Schmidt,.....	3
Opioids and alternatives in hospital settings: Payments, incentives, and Medicare data	
- Jennifer Podulka.....	54
Public Comment.....	93
Assessing payment adequacy and updating payments: Hospital inpatient and outpatient services; and Redesigning Medicare's hospital quality incentive programs	
- Jeff Stensland, Stephanie Cameron, Ledia Tabor.....	100
Assessing payment adequacy and updating payments: Physicians and other health professional services; and Medicare payment policies for advanced practice Registered nurses and physician assistants	
- Brian O'Donnell, Ariel Winter, Kate Bloniarz.....	140
Assessing payment adequacy and updating payments: Ambulatory surgical centers and hospice	
- Zach Gaumer, Dan Zabinski, Kim Neuman.....	151
Assessing payment adequacy and updating payments for post-acute care providers: Skilled nursing facilities; home health agencies; and inpatient rehabilitation facilities	
- Carol Carter, Evan Christman, Craig Lisk.....	159
Assessing payment adequacy and updating payments: Long-term care hospital services	
- Stephanie Cameron.....	171
Assessing payment adequacy and updating payments: Outpatient dialysis services	
- Nancy Ray, Andy Johnson.....	201
Public Comment.....	212

P R O C E E D I N G S

[9:52 a.m.]

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DR. CROSSON: Let me welcome our guests to our January meeting. For those of you who are not familiar with MedPAC, January is the time during which we discuss and vote on recommendations for payment updates. That process will begin this afternoon.

In addition, at this January meeting, however, we're going to take on a set of policy issues, and the first one we're going to talk about is in preparation for a discussion that we're going to have tomorrow on potential approaches to drug cost control. We're going to have a status update on the Part D Medicare prescription drug program. Rachel and Shinobu are here, and it looks like, Rachel, you're going to begin.

DR. SCHMIDT: Good morning. Shinobu and I are bringing you a status report on Part D, Medicare's outpatient drug benefit. Under Part D, private plans deliver drug benefits to enrollees, and in return Medicare pays plan sponsors monthly capitated amounts and other cost-based subsidies. This morning I'll give you some information about the program and tell you about some

1 recent program changes, and then Shinobu will lay out some
2 trends we see and some concerns we have about the program's
3 incentives for cost control.

4 In 2018, among nearly 60 million Medicare
5 beneficiaries, 73 percent were enrolled in Part D plans;
6 2.5 percent got drug benefits through the retiree drug
7 subsidy, in which employers provided primary drug benefits
8 to their retirees in return for Medicare subsidies. The
9 remaining 24 percent was divided fairly equally between
10 beneficiaries who had other sources of drug coverage as
11 generous as Part D and beneficiaries with no drug coverage
12 or less generous coverage. That 24 percent has held stable
13 in recent years.

14 Medicare program spending for Part D was nearly
15 \$80 billion in 2017, predominantly for payments to private
16 plans, but with about \$1 billion for the retiree drug
17 subsidy. Part D makes up about 13 percent of total
18 Medicare spending.

19 In addition, Part D enrollees directly paid \$14
20 billion in premiums for basic benefits, as well as
21 additional amounts for cost sharing and supplemental
22 coverage. More than eight in ten enrollees say they are

1 satisfied with the program and with their plan.

2 Let me describe the plans that enrollees chose in
3 2018 and what's available for 2019.

4 In 2018, 58 percent of Part D enrollees were in
5 stand-alone prescription drug plans and 42 percent of
6 enrollees were in Medicare Advantage drug plans, compared
7 with 70 percent in PDPs and 30 percent in MA-PDs during
8 2007.

9 In 2018, 28 percent of all enrollees received
10 Part D's extra help with premiums and cost sharing called
11 the low-income subsidy. This is compared with 39 percent
12 in 2007. A growing share of LIS enrollees are in Medicare
13 Advantage drug plans. In 2018, this share rose to 39
14 percent. That is much higher than at the start of Part D,
15 but still most LIS enrollees are in fee-for-service
16 Medicare and in stand-alone drug plans.

17 For 2019, there was a very healthy increase in
18 the number of plans offered -- 21 percent more MA-PDs and
19 15 percent more PDPs -- so a very broad choice of plans.
20 Most of the increase in PDPs was for plans that combine
21 basic and supplemental benefits, and that is likely the
22 effect of some recent regulatory changes. The number of

1 PDPs that qualify as premium-free to enrollees with the
2 low-income subsidy remains stable in 2019. One region,
3 Florida, has two qualifying PDPs, but the other regions
4 have three to ten available.

5 Since the start of Part D, enrollment has grown
6 at about 6 percent per year. Enrollment among
7 beneficiaries who do not receive the low-income subsidy has
8 grown faster than among those with LIS. Since 2010, a
9 number of employers have moved their retirees out of the
10 retiree drug subsidy program and into Part D plans that are
11 set up just for them. And today about 16 percent of Part D
12 enrollees are in employer group plans.

13 The average Part D premium has remained steady at
14 around \$30 to \$32 per month between 2010 and 2018.
15 However, that's the average, and there's a lot of variation
16 among Part D plans and their premiums.

17 Over the same period that average enrollee
18 premiums have been flat, there's been much faster growth in
19 Medicare's cost-based reinsurance payments to plans. The
20 Commission has been pointing this out for many years now
21 and in 2016 made recommendations that were designed to
22 address this issue by reducing Medicare's reinsurance and

1 simultaneously increasing capitated payments to plans. So
2 far, though, the recommendations have not been implemented.

3 Part D uses a market-oriented approach in the
4 sense that plan sponsors compete for enrollees through the
5 benefits and services they offer and the attractiveness of
6 their premiums. Part D plan sponsors manage pharmacy
7 benefits using the same general approaches that PBMs use
8 for commercial populations, such as: designing tiered
9 formularies that use differential cost sharing and tools
10 such as prior authorization to encourage the use of certain
11 drugs over others; negotiating rebates with drug
12 manufacturers in drug classes where there are competing
13 therapies; and developing pharmacy networks.

14 There are restrictions Medicare places on these
15 approaches that are tighter than what plans can do for
16 their commercial populations. For example, Part D plans
17 cannot exclude willing pharmacies from their networks.
18 Nevertheless, these sorts of management approaches have
19 been effective at encouraging Part D enrollees to use
20 lower-cost drugs and generics.

21 However, we've got concerns that certain trends
22 and changes in the program may be eroding some of Part D's

1 incentives for cost control. I've already described how a
2 growing share of Medicare's payments to plans take the form
3 of cost-based reinsurance. There are also phases of Part
4 D's benefit in which plan sponsors don't have much
5 financial responsibility for paying for covered benefits,
6 yet plans collect rebates for that spending. The magnitude
7 of rebates has been growing over time, and so this gives us
8 concern about the underlying incentives behind which plans
9 are selected for formularies.

10 Let me describe some recent changes to Part D
11 that have taken place over the past year. Through
12 regulatory actions, CMS has given plan sponsors new
13 flexibilities with their formularies. Sponsors can now
14 make certain changes to their formularies midyear if a
15 generic comes out on the market and it's therapeutically
16 equivalent to a covered brand-name drug. Sponsors can set
17 prior authorization or step therapy criteria differently
18 for the same drug depending on the indication for which the
19 drug is being used. That strategy is hoped to give
20 sponsors more bargaining leverage with manufacturers in
21 certain drug classes. And Medicare Advantage drug plans
22 may now use step therapy for provider-administered Part B

1 drugs. For example, in certain drug classes a plan sponsor
2 could require an enrollee to try a covered Part D drug
3 before the Part B drug, and the idea behind this is to spur
4 more price competition among drug therapies that fall
5 across medical benefits and pharmacy benefits.

6 There are also some changes to Part D that were
7 enacted in law. Last year, the Balanced Budget Act called
8 for closing the coverage gap for brand-name drugs one year
9 earlier than scheduled. Remember, there has been a benefit
10 phase that has higher cost sharing called the "coverage
11 gap," which I'll show you in a minute. The change in law
12 means enrollees pay consistent cost sharing for brand-name
13 drugs instead of higher cost sharing in the coverage gap.
14 The law made this change by increasing the discount that
15 brand manufacturers must pay in the coverage gap from 50
16 percent to 70 percent, leaving plan sponsors with just 5
17 percent plan liability in that benefit phase.

18 I'll show you the change I just mentioned as we
19 go over the structure of the defined standard benefit for
20 2019. This is what it looks like for a person who does not
21 have the low-income subsidy.

22 On the left, starting from the bottom to the top,

1 you can see there's a \$415 deductible, and then the
2 enrollee pays 25 percent of covered benefits and the plan
3 pays 75 percent until the enrollee reaches the initial
4 coverage limit. After that, there's the coverage gap
5 phase. And then if an enrollee has even higher drug
6 spending and reaches the out-of-pocket threshold, he or she
7 pays 5 percent, the plan pays 15 percent, and Medicare pays
8 80 percent through reinsurance. In practice, nearly all
9 Part D plans use benefit designs that look different from
10 this but that meet certain requirements around actuarial
11 equivalence.

12 Now let's talk more about the coverage gap. The
13 right-hand side graphs show you brands and biologics on the
14 top and generic drugs at the bottom. So starting at the
15 top this time, in 2019, an enrollee taking a brand-name
16 drug will pay 25 percent cost sharing in the coverage gap,
17 so he or she pays the same 25 percent from just after the
18 deductible through the initial coverage phase, and then
19 through the gap all the way to the out-of-pocket -- until
20 you reach the out-of-pocket threshold.

21 In the coverage gap, brand manufacturers are
22 paying a 70 percent discount, up from 50 percent in 2018.

1 And the plan pays just 5 percent in the gap. Also,
2 remember that the manufacturer discount gets counted as if
3 it were the enrollee's out-of-pocket spending. So with a
4 higher manufacturer discount, enrollees move toward the
5 out-of-pocket threshold more quickly than before. And
6 Medicare covers 80 percent after that point.

7 On the bottom right, in 2019, if a beneficiary
8 fills a generic prescription in the coverage gap, he or she
9 pays 37 percent cost sharing and then the plan covers 63
10 percent. Cost sharing for generics will fall to 25 percent
11 in 2020.

12 This table compares Part D spending at the first
13 full year of the program, 2007, with 2016 and 2017.

14 The direct subsidy is the monthly capitated
15 payment, adjusted for risk, that Medicare pays plans for
16 each enrollee. Reinsurance is a cost-based payment because
17 Medicare reimburses plans 80 percent of the actual
18 prescription cost in the catastrophic phase of the benefit,
19 and those two subsidies combined are designed to cover
20 about 75 percent of the cost. The low-income subsidy is
21 Medicare's payment to plans to cover the extra assistance
22 that LIS enrollees receive for cost sharing and premiums.

1 You can see that total Medicare program spending for Part D
2 was basically flat between 2016 and 2017. That seems like
3 good news after big increases that we saw related to
4 spending for hepatitis C drugs a few years earlier.

5 Nevertheless, we're not so sanguine about program
6 spending because Medicare's payments for reinsurance
7 continue to grow rapidly. In 2017, reinsurance grew to
8 \$37.4 billion, up from \$35.5 billion in 2016. Over those
9 same two years, the direct subsidy declined. Between 2007
10 and 2017, reinsurance grew by an annual average of nearly
11 17 percent, compared with a 2 percent decrease for the
12 direct subsidy. Remember that Medicare's reinsurance is
13 cost-based while the direct subsidy is risk-based, and it's
14 risk-based payments that generally provide sponsors with
15 stronger incentives to manage spending.

16 MS. SUZUKI: Increase in price is one of the main
17 factors driving Medicare's reinsurance spending.

18 Overall prices, including generics, moderated,
19 decreasing slightly in 2016 and increasing by 1.6 percent
20 in 2017.

21 These are in contrast to the uptick we observed
22 after the launch of the new hepatitis C treatment at the

1 end of 2014.

2 In 2017, prices of brand-name drugs continued to
3 grow but not as fast as in previous years. However, it
4 remained strong in some classes, such as insulin.

5 Notably, drugs in some specialty drug classes,
6 such as anti-inflammatories for rheumatoid arthritis and
7 therapies to treat multiple sclerosis, grew more slowly
8 during 2017. But even in these classes, manufacturers'
9 price increases over the previous decade had already
10 increased the prices of those therapies to three or more
11 times what they were in 2007.

12 Media and drug trend reports suggest that prices
13 of brand-name drugs generally continued to grow at a modest
14 rate for 2018, which may have been affected by the
15 uncertainty around potential policy changes to address high
16 drug prices. However, recent announcements by some
17 manufacturers about increasing prices may indicate a return
18 to the higher growth rates.

19 In 2016, 3.6 million or about 8 percent of Part D
20 enrollees had spending high enough to reach the
21 catastrophic phase of the benefit. Among the high-cost
22 enrollees, the number of non-LIS enrollees have grown more

1 rapidly than LIS enrollees.

2 Part D's spending is increasingly driven by high-
3 cost enrollees. A larger share of the spending is
4 accounted for by those high-cost enrollees. That share has
5 grown from 40 percent in 2010 to nearly 60 percent by 2016.

6 Rapid growth in the price of prescriptions filled
7 by high-cost enrollees explains most of the growth in their
8 spending. Between 2010 and 2016, average prices of drugs
9 used by high-cost enrollees grew 10 percent annually
10 compared with an annual decrease of 3 percent for other
11 enrollees.

12 Patterns of drug spending differ between LIS and
13 non-LIS enrollees with high costs, and that difference
14 explains why we're seeing faster growth in the number of
15 non-LIS enrollees who reach the catastrophic phase.

16 Overall, one in ten high-cost enrollees filled at
17 least one prescription in which a single claim would have
18 been sufficient to reach the catastrophic phase of the
19 benefit. The use of such a prescription is significantly
20 higher among non-LIS enrollees, with 18 percent having
21 filled such a prescription compared with about 6 percent
22 among LIS enrollees in 2016.

1 Between 2007 and 2016, average spending for high-
2 cost non-LIS enrollees has grown faster, increasing by 190
3 percent compared with 100 percent for LIS enrollees. As a
4 result, by 2016 high-cost non-LIS enrollees had spending
5 that averaged about \$30,000 per year compared with just
6 under \$21,000 for LIS enrollees.

7 The cost difference between high-cost enrollees
8 with and without LIS are largely attributable to the drug
9 classes used by these two groups. One study found that
10 high-cost non-LIS enrollees were more likely to use drugs
11 and biologics in classes dominated by high-priced specialty
12 drugs, such as therapies to treat cancer, multiple
13 sclerosis, and pulmonary hypertension. LIS enrollees, on
14 the other hand, were more likely to use medications for
15 diabetes, mental health, and pain -- classes which are
16 mostly non-specialty drugs. Our own analysis of the 2016
17 data corroborates these patterns.

18 Going forward, the pharmaceutical pipeline will
19 continue to shift its focus on biologics and specialty
20 drugs that command high prices. Use of these new therapies
21 will further increase the burden on Medicare's reinsurance.

22 Already, the effects of this shift towards

1 higher-cost products are affecting Part D spending.
2 Specialty tier drugs, which, by definition, have high
3 prices, accounted for less than 1 percent of all Part D
4 claims in 2017, but 25 percent of all Part D spending, up
5 from 6 percent in 2007.

6 Average cost of a single claim for drugs placed
7 on a specialty tier grew 14 percent annually from about
8 \$1,100 in 2007 to nearly \$4,500 by 2017.

9 The growth in prices of specialty tier drugs have
10 led to a rapid increase in the use of drugs in which a
11 single claim would be sufficient to reach the catastrophic
12 phase. In 2010, just 33,000 beneficiaries filled such a
13 claim. By 2016, that number rose more than tenfold to
14 about 360,000.

15 Many changes are taking place in the environment
16 that is going to affect the Part D program. Specialty
17 drugs and biologics will continue to drive the growth in
18 drug spending -- not just in Part D but for the entire U.S.
19 health care system.

20 The market structure of plan sponsors has changed
21 dramatically and continues to do so, with some sponsors
22 merging with insurers, and thereby becoming more vertically

1 integrated.

2 To manage benefit costs, more insurers and PBMs
3 are using high deductibles and/or percentage coinsurance
4 for higher-priced drugs and biologics, resulting in sticker
5 shock for patients at the pharmacy.

6 There are also changes that are specific to Part
7 D, such as regulatory changes to allow Part D plans to use
8 some of the tools they use to manage pharmacy benefits for
9 their commercial populations.

10 Increase in manufacturers' coverage-gap discount
11 that Rachel described reduces plans' insurance risk,
12 raising concerns about financial incentives sponsors face.

13 Medicare's payments to plans are increasingly
14 retrospective and based on cost, and many of the changes
15 happening in the environment will likely contribute to this
16 trend.

17 So there is an urgent need to better align plans'
18 financial incentives with that of the beneficiaries and
19 taxpayers while at the same time giving formulary tools to
20 encourage benefits management.

21 In April, we plan to bring to you potential
22 policy approaches to address two issues we highlighted

1 today. One relates to coverage gap discount, and the other
2 relates to beneficiary's out-of-pocket costs for high-cost
3 drugs.

4 And with that, we'd be happy to take any
5 questions.

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

7 We'll take clarifying questions. I see Brian,
8 Amy, Jon. Jonathan, did I see your hand? Brian, Amy, Jon,
9 David, Pat, Warner.

10 DR. DeBUSK: First of all, thank you for a great
11 chapter. In the reading materials, on pages 34 and 35, you
12 start to talk about the growing divergence in point-of-sale
13 prices and net prices. And in the text -- and I think it
14 as sometime last year, we talked a little bit about the
15 allocation of DIR and how it's disproportionately
16 allocated, I think, to the plan and away from the
17 reinsurance program. You mentioned that in this chapter
18 when it said, "Medicare reinsurance payments that reduce
19 plan liability for a benefit may create a situation in
20 which there is a financial advantage to plan sponsors when
21 they select high-cost, high-rebate drugs over lower-cost
22 alternatives."

1 Could you refresh me on that just a little bit?
2 I went back and looked at some of that material, but I
3 noticed we seemed to stop short in the chapter of
4 describing it again.

5 DR. SCHMIDT: I think there's two pieces to that.
6 I mean, Bruce has raised in the past the general notion
7 that the odd structure of Part D's benefit and the facts
8 that plan sponsors don't have consistent financial
9 liability for the benefit spending can create a situation
10 where the rebates -- there may be an un-incentive in some
11 cases to put high-rebate, high-cost drugs on the formulary
12 relative to lower cost alternatives. That's a general
13 thing.

14 But I think the DIR case -- I'll let you know who
15 to speak to -- that's something a little bit different.

16 MS. SUZUKI: So the DIR, currently CMS uses gross
17 spending, so the prices at the pharmacy, to figure out what
18 share of Medicare keeps versus what share plans keep, and
19 the share that plans keep for the most part are weighted
20 heavily because they use gross spending below the
21 catastrophic threshold. And that includes the coverage gap
22 phase where plans have very little liability, particularly

1 for brand-name drugs.

2 So relative to the benefit cost, using the gross
3 drug spending, weighs -- gives plans more, larger share of
4 the DIR than had they used the actual benefit liability to
5 calculate how much plans keep versus Medicare keeps.

6 DR. DeBUSK: So it's a two-tier mechanism is what
7 you're saying, then, because there's sort of the overt
8 incentive to have the high-price, high-rebate drug, but
9 then when it's time allocate the DIR, there's a compounding
10 of that effect because it gets disproportionately
11 allocated.

12 [Staff nods head in the affirmative.]

13 DR. DeBUSK: Okay. Thank you.

14 DR. CROSSON: Amy.

15 MS. BRICKER: Great job on the chapter.

16 So a couple questions around price increases.
17 You make a couple of different observations, and I just
18 thought it would be helpful to maybe connect the dots for
19 the room.

20 At one point, we talk about how overall spending
21 has moderated, and then there are other places throughout
22 the document that we talk about price; prices are actually

1 increasing at double-digit rates.

2 To what extent are we factoring in rebate? And
3 so just to -- period. To what extent are we factoring in
4 rebate when we talk about the overall cost implications to
5 the program?

6 MS. SUZUKI: So the price index that we talk
7 about -- and we mention that even the pharmacy prices have
8 moderated in recent years -- that is a pharmacy price. So
9 it doesn't include the post-sale rebates and discounts from
10 manufacturers.

11 And we talk about how for some classes, such as
12 insulin, that may not be the accurate picture; but for
13 other classes like cancer therapies, there may not be as
14 much rebate. And the price index that we show in the
15 chapter or the mailing material may be more of an accurate
16 prediction of how the prices have grown over time.

17 In terms of spending, we do use data that
18 incorporates the retrospective rebates and discounts. So
19 those growth rates do reflect the amount -- the rebates
20 from manufacturers.

21 MS. BRICKER: So which number is that exactly,
22 then, in the material you just presented that would be

1 reflected of rebate?

2 MS. SUZUKI: The spending.

3 DR. SCHMIDT: The \$80 billion and spending for
4 2017, for example. That's inclusive.

5 MS. BRICKER: But it's flat from '16.

6 DR. SCHMIDT: Right. That's net of rebates.

7 MS. BRICKER: I think that's important. I think
8 that's important because it's easy to look to one data
9 point, like list price, and say in Part D, we have a
10 problem. We could debate that, but overall spending, if I
11 have it right, is flat, '16 to '17. Is that accurate?

12 DR. SCHMIDT: That's accurate.

13 MS. BRICKER: Thank you.

14 DR. CROSSON: David.

15 DR. GRABOWSKI: Thank you for this great work.

16 I wanted to come back to the first bullet you had
17 on Slide 5: private plans compete for enrollees. I'm not
18 disagreeing with that, but I want to reconcile that with an
19 observation from the literature. There's a lot of academic
20 work suggesting enrollees often end up in a plan, whether
21 they choose it, that doesn't best meet their drug needs,
22 and so there's a lot of suboptimal decision-making that's

1 out there. That's not something that's dealt with a lot in
2 the chapter.

3 How much does that interact with some of the
4 trends you presented in the material and in the chapter and
5 the presentation today, and is that something we've thought
6 about as a Commission?

7 MS. SUZUKI: So we have in the past looked at
8 switching behavior by Medicare beneficiaries, particularly
9 those without low-income subsidies. So they're voluntarily
10 switching.

11 We found somewhere between 12 and 14 percent
12 voluntarily switch from year to year during the annual
13 enrollment period.

14 It's hard to say whether that's sufficient or
15 not, but in the focus groups with beneficiaries, some of
16 them have indicated that they do check Plan Finder annually
17 to see whether their drugs are covered at more favorable
18 rates with other plans. So it seems like they are looking
19 to lower their out-of-pocket cost, not just the premiums.

20 We have found when people switch, they tend to
21 minimize their total out-of-pocket cost in terms of cost
22 sharing, despite maybe using even a little more drug than

1 in the previous year.

2 DR. GRABOWSKI: We did a chapter recently on
3 post-acute care decision-making, and my sense is some of
4 what we recommended there could filter over to here in
5 terms of helping beneficiaries with choice here in this
6 sector.

7 You raised the Plan Finder tool. I think that
8 that tool is really poor. I'll say that. I don't think it
9 provides a clear indication to enrollees about the lowest-
10 cost plan necessarily, and so I've wondered if we've done
11 any previously about that and whether we might think about
12 sort of some revisions there and also building on some
13 choice architecture here around thinking about placing
14 beneficiaries into a default plan and making better use of
15 some of the big behavioral economics literature.

16 DR. SCHMIDT: Last year, we were considering
17 doing some work on Plan Finder, but there were some other
18 organizations that are already taking that under and did
19 some pretty thorough looks at it and had some suggestions
20 for how to improve that. So we decided with our limited
21 resources, you have to kind of pick and choose where to put
22 your emphasis.

1 In the past, we have kind of looked at things
2 like intelligent assignment ideas around the low-income
3 subsidy population, but the Commission that was gathered at
4 that time chose not to go ahead with those ideas. It was
5 looking as though there was a tradeoff so that there was
6 higher government spending associated with picking optimal
7 plans, and there was some concern around selection, so are
8 you going to perhaps get plans into a spiral by picking
9 what's optimal for each enrollee based on their past drug
10 use.

11 DR. CROSSON: Okay. I've got Pat -- Warner, did
12 you have your hand up? -- Warner and then Dana.

13 MS. WANG: Thank you.

14 DR. CROSSON: Did I miss somebody? Oh, Jon.
15 Sorry.

16 DR. CHRISTIANSON: Am I next?

17 DR. CROSSON: You're next. Sorry. I didn't see
18 your hand go up.

19 DR. CHRISTIANSON: This is really quick.

20 DR. CROSSON: You're too close.

21 DR. CHRISTIANSON: Yeah.

22 This is really, really quick. So on the slide, I

1 didn't see this, and I didn't see it in the chapter. So
2 maybe we don't have this number, but do we know what
3 percentage of Medicare beneficiaries have no drug coverage?

4 DR. SCHMIDT: Not exactly. We know that it's
5 about half of the 24 percent have coverage that's either
6 less generous than the -- or no, and we think -- we're not
7 sure exactly what that is.

8 DR. CHRISTIANSON: Yeah, I saw that, but we can't
9 break that down and say 5 percent have no drug coverage at
10 all.

11 DR. SCHMIDT: No, we can't.

12 And I think it used to be a question we could
13 sort of get to on the Medicare Current Beneficiary Survey,
14 but it's no longer there.

15 DR. CHRISTIANSON: It's odd because that seems
16 like sort of a basic piece of information we'd like to
17 know.

18 DR. CROSSON: Pat.

19 MS. WANG: Going back to Slide 10, 11-ish, were
20 you -- and you've mentioned this before. Is the growth in
21 spending for non-low-income beneficiaries going to the
22 reinsurance later, and that they have surpassed the low-

1 income subsidy beneficiaries in terms of the high-drug
2 expenditures?

3 I wondered whether you have more information
4 about sort of the characteristics, I guess, of spending
5 between the non-low-income and the LIS population.

6 In other words, you mentioned the difference in
7 the drug utilization, but in terms of -- I don't know if
8 this is the right word -- "preference," I guess, of the
9 non-low income, is it a fewer number of people who have
10 extraordinary drug cost as opposed to the LIS, which is
11 maybe more people have similar drug expenditures?

12 The reason I ask is -- and maybe this is the
13 implications for what are the policy questions to be
14 answered as well as implications. As you know, I'm very
15 interested in refining risk adjustment for the Part D
16 premium that exists. I just was curious if you knew
17 anything about that or whether that was a --

18 MS. SUZUKI: So we did look at non-LIS versus LIS
19 among the high-cost beneficiaries, and you're probably
20 talking about this piece. That, for example, cancer
21 treatments accounted for a much higher share of non-LIS
22 high-cost enrollee spending compared to LIS enrollees who

1 reach the catastrophic phase.

2 And we were also finding that among the low-
3 income subsidy population, a lot of the spending weren't
4 because individual prescriptions were extremely high cost.
5 It was that they were using more medications, and some of
6 them were in common classes like antihyperlipidemics.

7 And one that showed up in one of the lists that I
8 looked at is Nexium. That sort of thing tends to add up to
9 get a lot of those enrollees to the catastrophic phase.

10 MS. WANG: So is it kind of the right direction,
11 then, to be saying that for the non-low income, the focus
12 on the cost of the specialty drug is probably the thing to
13 focus on, but for the low-income population, a generic
14 substitution is a fruitful avenue?

15 MS. SUZUKI: And I think that was one of the
16 recommendations we made.

17 MS. WANG: Yeah. Apparently different avenues.
18 Okay.

19 DR. CROSSON: Warner.

20 MR. THOMAS: So in Slide 7, the construct here
21 with the initial coverage and the out-of-pocket threshold,
22 are those indexed, or do those numbers change over time?

1 DR. SCHMIDT: Yes, they do. They're indexed to
2 the average per capita spend for Part D.

3 But there's been some difference in each of these
4 different parameters and their treatment over time.

5 In 2010, the Affordable Care Act, one of the
6 goals was to close the coverage gap.

7 MR. THOMAS: Right.

8 DR. SCHMIDT: And so they indexed the out-of-
9 pocket threshold more slowly. So it actually will increase
10 in 2020, as you heard about in the mailing materials, by
11 over 20 percent because that was scheduled in the
12 Affordable Care Act. That it would bounce back up to what
13 it otherwise would have been.

14 MR. THOMAS: And on Slide 8, just looking, it
15 looks like in the mailing materials that the premium
16 increase is relatively nominal, yet the total cost of the
17 program is escalating. So can you comment on your thoughts
18 around that or the rationale behind that?

19 DR. SCHMIDT: Right. So let's be clear. In 2016
20 to 2017, it's been flat, but we have seen fairly rapid
21 growth in spending before that, certainly.

22 The flatness of premiums, we think speaks to this

1 reinsurance increase I spoke about on this particular
2 slide. That a lot of the cost growth has been in the
3 catastrophic range of the benefit spending, where the
4 Medicare program is picking up 80 percent of the costs in
5 that benefic phase. So the portion of benefits that go
6 into the premiums remained relatively flat.

7 MR. THOMAS: But if you look at this slide -- and
8 I just want to make sure I understand this slide. So the
9 Medicare program total, that's the total cost of Part D,
10 kind of all in, or that's the government portion to be paid
11 at the program?

12 DR. SCHMIDT: Those are essentially the
13 government payments to the plans, and in addition, there's
14 another \$14 billion that the enrollees have been paying to
15 plans for basic benefits. And there are other costs for
16 cost sharing and for supplemental premiums.

17 MR. THOMAS: Okay.

18 So kind of looking at this, the makeup of this,
19 is there transparency or clarity around the profit in the
20 Part D programs or the Part D insurers, or is that kind of
21 aggregated in all of their profits?

22 MS. SUZUKI: So we have looked at plan payment

1 data through 2015, and we found that the majority of the
2 plan sponsors do make profit in the risk corridor and risk
3 corridors of part of the cost-based portion of the payment,
4 and there's a risk corridor around it. And plans are
5 allowed to keep -- the risk-based portion. Sorry. The
6 plans are allowed to keep, plus or minus, 5 percent of the
7 profit or the loss. That's on them.

8 The next piece of it is 50-50 from 5 percent to
9 10 percent on both sides, that sort of thing.

10 And we found that plans on average were making
11 profits above those that were included in their bids. A
12 lot of the plans got to keep the extra 5 percent plus
13 whatever else they got to keep in the second tier and third
14 tier.

15 DR. SCHMIDT: There isn't as much visibility into
16 it as you might want. The information that goes into bids,
17 for the MA side of the house --

18 MR. THOMAS: Right.

19 DR. SCHMIDT: -- you can go back and look at
20 historical data and see the profits in there to see what
21 the profit rates have been.

22 On the drug side, it's less easy to do because

1 the data that are submitted in bids are not reconciled
2 data.

3 MR. THOMAS: Okay. Thank you.

4 DR. DeBUSK: On that --

5 DR. CROSSON: On that point?

6 DR. DeBUSK: On Warner's specific questions
7 because I think in the reading material, you alluded to
8 this. Could you explain a little further? There seems to
9 be a dominant strategy for how to proceed with a Part D
10 bid, sort of a can't-miss strategy. And you sort of spoke
11 to that, but could you sort of clarify it?

12 MS. SUZUKI: So related to Warner's question
13 about why premiums have been flat is that plan sponsors on
14 average have been underestimating the reinsurance portion
15 of the benefit. What that does is -- because reinsurance
16 is the cost base that's reconciled after the end of the
17 benefit year, the part that's in the premium is the
18 expected piece, expected amount of reinsurance.

19 At the end of the year, Medicare, on average,
20 have been paying plans additional amounts for reinsurance.
21 So whatever the extra payment that Medicare made to plans
22 were not included in the premium the beneficiary paid.

1 DR. CROSSON: Okay. I have Dana and Marge and
2 Jaewon.

3 Dana.

4 DR. SAFRAN: Thank you.

5 Can you go back to Slide 7? I'm just trying to
6 make sure I understand. I have to say I find this topic
7 confusing every time we talk about it. So I think this is
8 my moment where I may be having a breakthrough in some of
9 my understanding, but I just want to check a couple things.

10 So on the left side, I'm trying to make sure I
11 understand the coverage gap and what happens in there, and
12 one of the things that I think you're showing us here is
13 that the coverage gap is not really entirely a gap for the
14 beneficiary. In fact, they're paying 25 percent in their
15 initial coverage, and they're still paying 25 percent in
16 the coverage gap if they're using a brand and in fact, as
17 of next year, even for a generic.

18 So is that right?

19 DR. SCHMIDT: You got it.

20 DR. SAFRAN: Am I reading this right?

21 DR. SCHMIDT: Yeah, right. But that's a new
22 thing. It's been kind of phasing in that direction since

1 2010.

2 It used to be, before 2010, 100 percent on the
3 bene cost sharing during the coverage gap phase. After
4 2010, there was immediately a 50 percent discount provided
5 by brand-name manufacturers. That also counted towards the
6 out-of-pocket threshold, but the bene was paying the other
7 50 percent. And over time, it's been phasing down, down,
8 the cost sharing for the beneficiaries, and as of 2019,
9 it's 25 percent on brands in the coverage gap.

10 DR. SAFRAN: Okay. Thank you.

11 And then the other thing I want to understand is
12 beyond that. So above the out-of-pocket threshold, I'm
13 assuming that when you refer to catastrophic levels, you're
14 referring to that point.

15 And so later in the presentation, you made the
16 point that it's about 8 percent of beneficiaries that reach
17 that level, and this sort of shocked me that one in ten of
18 those get there with one claim.

19 So I just wonder what can you tell us about those
20 folks? What are those medicines, and is it actually just a
21 one-time claim? Or is this a medicine that costs a
22 boatload of money, and they're having to take it all the

1 time -- it's for cancer treatment; it's for chronic illness
2 -- that specialty drug? Can you just tell us a little bit
3 more about that?

4 MS. SUZUKI: So 1 in 10 beneficiaries have at
5 least one claim for which, just that one claim would have
6 gotten them to the catastrophic phase. That doesn't mean
7 it was the only claim.

8 So a lot of the drugs that are used by non-LIS
9 enrollees were cancer drugs, which had an annual spending
10 of \$30,000, leukemia drugs, Copaxone for multiple
11 sclerosis, which was also in the \$20,000 range for annual
12 costs. So they tend to use a lot of those very expensive
13 drugs.

14 To get to the threshold, you only need, you know,
15 \$7,000 or \$8,000, and these are drugs that annual cost
16 average is in the tens of thousands of dollars.

17 DR. CROSSON: Dana.

18 DR. SAFRAN: What I hear you saying is these are
19 drugs that they are taking over the course of the year, not
20 one time. So even though that one claim could have put
21 them over that threshold, they're continuing to take a
22 medicine that, over time, costs \$20,000, \$30,000 in the

1 year.

2 MS. SUZUKI: And that's shown by the average cost
3 for non-LIS enrollees that's reached \$30,000, on average.

4 DR. SAFRAN: Thank you.

5 DR. CROSSON: I mean, you could have some
6 patients like hepatitis C where it's one time.

7 Okay, Marge.

8 MS. MARJORIE GINSBURG: In the report itself,
9 talking about the low-income subsidy folks, there's a quote
10 I pulled up that says "plan sponsors cannot encourage use
11 of lower-cost in the same way as non-LIS." I'm curious as
12 to why that was written. Obviously, some categories of
13 LIS, a few, have no copayments, but most of them, they're
14 small, do have copayments that differentiate between
15 generic and brand name.

16 So I was just curious what the basis for this
17 statement was.

18 DR. SCHMIDT: I think our point is that just the
19 magnitude of the difference in the copays is fairly small
20 and not necessarily large enough to make a change in
21 behavior. You look at the cost-sharing applied to non-LIS,
22 and the differentials that are quite substantially larger.

1 MS. MARJORIE GINSBURG: We know historically,
2 then, that LIS participants, you know, it's like \$8 versus
3 \$3, that that's not big enough to influence their choice,
4 or are physicians not encouraging the lower cost? I mean,
5 I guess I -- these are low-income folks --

6 DR. SCHMIDT: Right.

7 MS. MARJORIE GINSBURG: -- and even that \$5 may
8 be meaningful. And I just wanted to make sure there was
9 some evidence behind this that said it's really hard to
10 move them to lower cost.

11 DR. SCHMIDT: I think we're basing that on seeing
12 it. Even though generic dispensing rates for low-income
13 subsidies, overall, average -- they're lower than non-LIS,
14 not substantially lower but a few percentage points lower -
15 - but some LIS folks, particularly the ones who are
16 reaching what we're calling the catastrophic phase, are
17 using the Nexiums and things where there are generic
18 options available, and they haven't quite switched.

19 DR. CROSSON: Okay. Jaewon.

20 DR. RYU: Yeah, I also had questions about Slide
21 10 and the high-cost enrollees and the impact of the LIS
22 versus the non. I'm just trying to tease apart, I guess,

1 the impact of -- because a lot of different variables here.
2 There's a volume dynamic, there's unit cost dynamic,
3 there's a brand preference and maybe behavioral dynamic,
4 which I think is kind of where Marge is going, depending on
5 your copays, versus a disease prevalence and what happens
6 to hit the LIS folks versus the non-LIS folks.

7 Do we know, or has there been studies around
8 within a certain drug class or disease class, within that
9 high-cost enrollee population, whether there's a difference
10 in trend between the LIS population and the non-LIS
11 population, in terms of, you know -- it would have to be a
12 drug class, I guess, that would have alternatives. But is
13 there a behavioral difference there, or do we just chalk it
14 up to, you know, it's just because different disease states
15 hit those two populations differently?

16 DR. SCHMIDT: I don't know that we've seen any
17 studies that would get to that specifically. I guess -- I
18 don't know, do you have a thought?

19 MS. SUZUKI: So I'm trying to figure out -- so
20 what we looked at a couple of years back, in making the
21 recommendation about generic, increasing generic drug use
22 for LIS population, is that even for classes such as

1 antihyperlipidemics or antihypertensives, those most
2 commonly used therapeutic categories, we found higher brand
3 use among LIS population compared to the other people who
4 did not reach the catastrophic phase of the benefit. And
5 it may not be that they're not using the direct generic
6 substitute. A lot of them do, are automatically
7 substituted to generics.

8 I think what we're seeing between LIS and non-LIS
9 population is that non-LIS beneficiaries may be more likely
10 to ask for a therapeutic generic substitution compared to
11 LIS beneficiaries. And I know some of the categories of
12 low-income population pay \$8, potentially, for a brand-name
13 drug. Not all of them do. Some of them don't have any
14 cost sharing. Some of them pay lower copay amounts. And
15 so we thought that if the Secretary thought that some
16 classes could use some therapeutic generic substitution,
17 that's when these copay differences could really move LIS
18 populations to use lower-cost generics. And we also
19 recommended that in those class maybe Secretary could make
20 the generics free to those beneficiaries.

21 DR. CROSSON: Okay. We're going to move on. Put
22 the last side up, if you would. We're going to move on to

1 further comments. This is a status report, and I make two
2 notes.

3 Number one, as you see on the slide we are
4 planning, this spring, to take on two Part D issues,
5 restructuring the coverage gap discount and reducing out-
6 of-pocket costs for high-cost drugs. In addition, as I
7 mentioned in the beginning, tomorrow morning we're going to
8 have a broader discussion here at the Commission on a wider
9 range of approaches to reducing the cost of prescription
10 drugs, as a jumping-off point for future work in the next
11 session or two.

12 Actually, Amy is going to start.

13 DR. BRICKER: Thanks. Thanks again for a chapter
14 that I think has a lot of people leaning in to better
15 understand and to really begin to grapple with what this
16 Commission, and, more broadly, the industry needs to do to
17 take on a very sensitive issue.

18 I made the point earlier around spend being flat,
19 only to highlight that there are winners and losers in this
20 program and in this sort of phenomenon. I think it does
21 bear consideration that we have to think about the
22 beneficiary at the point of sale. The structure, if Bruce

1 is the one that highlighted it, I agree. The structure is
2 unique and it's hard to draw parallels because there isn't
3 anything else like it in the commercial market.

4 I think the unfortunate scenarios are those that
5 beneficiaries are faced at the counter not being able to
6 afford, you know, deductibles, not being able to afford co-
7 insurance, and again, because of the way this is
8 structured, bear a lot of that burden.

9 And so absolutely in favor of taking a look at
10 how we can ensure that beneficiaries are getting the value
11 of rebates, and whether or not it's a wholesale application
12 and rebate at point of sale, I'm not there yet. But for
13 those specialty products that are high cost, having a cost
14 cap for those beneficiaries and, in effect, using rebate
15 dollars to hold down the out-of-pocket for beneficiaries I
16 think is something to consider and one that we should
17 further review.

18 There are many things that this program can still
19 do within the traditional space, and you've highlighted
20 many of them in your paper. You mentioned briefly any
21 willing pharmacy. There have been a number of studies that
22 demonstrate that any willing pharmacy actually raises

1 costs, not just improves access. So the extent that,
2 again, looking at any willing pharmacy allowance, so long
3 as certain access requirements were met, doing away with
4 that.

5 There have been a number of conversations around
6 DIR, whether or not DIR should be factored into the
7 patient's out-of-pocket if it could be reasonably known,
8 and there's another sort of round of this now with CMS
9 putting out some additional observations on this point. So
10 I think we should also address that in the work that we
11 have in the future and our perspective.

12 I'm encouraged by B-versus-D management. I think
13 this is the right direction. It came out very late last
14 year so we're likely not going to see much of that in '19,
15 and so we won't be able to see the impacts of that change
16 likely until '21. So I think that is something that will
17 play out over time.

18 And for manufacturers, I think that today,
19 through B, have not feared exclusion, not feared having to
20 be competitive. This now is a different dynamic and so I'm
21 encouraged by that.

22 I think it should be noted, though, the

1 manufacturer requirement from 50 to 70 percent likely will
2 have an unintended consequence, and while the political
3 environment isn't comfortable for manufacturers and raising
4 list prices have moderated to some degree, you would expect
5 that this additional obligation on the part of the
6 manufacturer will result in list price increases and,
7 therefore, the commercial market will bear a lot of that --
8 because of this change will bear that impact.

9 Lastly, value-based programs. I encourage us to
10 look at what has been done successfully in the commercial
11 market, these high-cost drugs that you can set measurable
12 and objective, you know, goalposts around what does success
13 look like. And if the program is going to cover a drug,
14 refunding of putting incentives in place that if the drug
15 doesn't work, if the patient isn't compliant, if there is
16 lack of outcome that the program would seek a refund for
17 that drug. So there are many things to consider if that
18 were to be allowed, but again, it's worth taking on.

19 And lastly, while pharmacy payment at the point
20 of sale is real-time, meaning you know if a drug is
21 covered, you know the co-insurance, you know if it's on
22 formulary, the pharmacy, at the counter, knows this, we

1 still are lacking data to provide the pharmacist at the
2 point of sale the most information about how to guide the
3 patient. So if it's not the physician, the pharmacist,
4 there has to be some investment in information-sharing so
5 that we do seek the best outcomes for the beneficiaries.

6 There's so much work here to do. I am, though, I
7 am encouraged by what feels like an opportunity for us to
8 take advantage of some of the momentum in the market to
9 begin to move the needle on this very issue.

10 So thanks.

11 DR. CROSSON: Thank you, Amy. I saw Brian.

12 DR. DeBUSK: Thank you again for a really great
13 report.

14 In terms of topics for spring, and I saw that on
15 the slide there, I would love to add us digging deeper into
16 this whole idea around formulary construction, DIR
17 allocation, and then this whole issue of bidding on the --
18 the way these bids are constructed.

19 The thing that fascinates me is since this
20 program's inception, it doesn't look like it's ever reached
21 its statutory 25.5 percent premium collection through
22 beneficiaries. And I know actuaries are terrible at what

1 they do and do terrible jobs, but we're going on like --
2 Bruce -- we're going on to 11 years of missing the market.
3 And I remember, when I read the 2016 report, I remember
4 what really jumped off the page was that over half the
5 plans were hitting their upper risk corridor, so they were
6 giving money back. And I get that. I mean, I understand
7 risk corridors are very important. But when over half the
8 plans are hitting the risk corridor, it makes me think
9 there's something systemic here. And, sure enough, on page
10 43 of the mailing materials, this year, again, more than
11 half the plans returned that.

12 So I do hope this spring -- I want to understand
13 more about the formularies, how the rebates are handled,
14 how they're going to the plans, just sort of build that
15 from the ground up, because it does feel like something's
16 off when over 50 percent of the plans hit the upper
17 corridor.

18 Thanks.

19 DR. SCHMIDT: Can I respond briefly, just to say
20 we're happy to talk about some of this but also please look
21 at our 2015 chapter from June. It goes into this in some
22 detail.

1 DR. CROSSON: I'm seeing some quick, jumpy -- I
2 think I saw Bruce first and then Paul and then Jaewon.

3 MR. PYENSON: It's hard to follow up on Brian,
4 but this is actually perhaps a Round 1 item. I'm wondering
5 if it would be possible to illustrate, with actual
6 formularies, situations where higher-priced drugs are on
7 the formulary and lower-priced equivalents are not.
8 Shinobu, you had mentioned Nexium, which, of course, has,
9 as an example, with a brand generic, but I think there are
10 also examples with brands. So I think for sure the 2019
11 formularies are out, and I'm wondering if would be
12 appropriate to give those as examples.

13 DR. SCHMIDT: I think the tricky thing is that we
14 don't see rebates, so we're not going to know that side of
15 things.

16 MR. PYENSON: Right, but you would have list
17 price, and there are some differences that, you know, a 5
18 percent rebate or a 10 percent rebate is more than the list
19 of the competitor product. So I think there might be some
20 examples like that.

21 DR. CROSSON: On that?

22 DR. BRICKER: So you might want to look at --

1 there are a couple of manufacturers that just introduced
2 alternate NDC, so Repatha did this. So you could look at
3 where it's the same drug, they just introduced a lower NDC
4 with presumably little to no rebate. So there are some
5 examples, without knowing the rebate, just the behaviors of
6 plans. That would then get to your question.

7 DR. CROSSON: Paul.

8 DR. PAUL GINSBURG: This was a terrific chapter
9 and I agree on your singling out reinsurance and the way we
10 handle coverage cap discounts is really important.

11 I was really struck by the differences in types
12 of drugs used by the low-income people versus the other,
13 and, you know, when you're working with prescription drug
14 claims data you gain much more insight into what people's
15 medical issues are, than when you're dealing with other
16 types of data that we work with.

17 And just something that we should really always
18 keep in mind when we're not seeing these differences is
19 clearly when we're talking about hospital care and
20 physician services, the fact that the differences are big.
21 And I don't want to jump ahead to our next session but, you
22 know, I'm really glad the way our HVIP handles the

1 difference between the low-income and higher-income
2 beneficiaries.

3 DR. CROSSON: Thank you, Paul. Jaewon.

4 DR. RYU: Yeah. I was just going to add that the
5 dynamic between the catastrophic and the capitated, and it
6 may be just dusting off the prior recommendations or work
7 from 2015. I think you alluded to that.

8 The other element, I just want to get back to the
9 human behavior side and the price sensitivity around copays
10 and cost shares. I think there's something there that
11 would be good to get a little more fine-tuned around.
12 Obviously I don't think we're trying to be prescriptive to
13 the plans around how they structure those things but having
14 a better understanding of the impact that that has on some
15 of the decisions, where alternatives are possible. I mean,
16 some of these you don't have alternatives and it's a unit
17 cost issue. You know, that's a separate dynamic. But
18 where there are alternatives it seems like, you know, what
19 are the levers and how much can you shape human behavior.

20 DR. CROSSON: Okay. Dana.

21 DR. SAFRAN: I'm back on thinking about the
22 coverage gaps issue and the point that reducing, over time,

1 the amount of cost-sharing for the enrollee like to have on
2 the manufacturer pricing, which, you know, Amy brought up.
3 And so that leads me to wonder, you know, are we, in the
4 name of helping ease the out-of-pocket cost burden and
5 thereby reducing cost-related non-adherence to necessary
6 medicines, maybe creating a different kind of harm, which
7 is raising costs across the board?

8 And so that just leads me to wonder whether
9 there's a way that we could approach that analytically. Do
10 we have data on cost-related non-adherence to
11 prescriptions? It's something that years ago, before my
12 time at Blue Cross, it was at the heart of what my research
13 was about. I don't know that the Medicare beneficiary
14 survey has that information, but if it did would there be a
15 way to kind of do an analysis of the tradeoffs that we're
16 making. While maybe we're reducing cost-related non-
17 adherence, what are the other harms that we may be creating
18 potentially by driving costs up across the board, or some
19 of the other effects here. Just a thought.

20 DR. SCHMIDT: We can certainly brainstorm on it.
21 The chapter includes a bunch of citations to previous
22 literature that's kind of trying to measure adherence

1 between the LIS and non-LIS population because they have a
2 difference in cost sharing. So there are some estimates
3 for some particular classes.

4 DR. SAFRAN: And changes over time, not just --

5 DR. SCHMIDT: Less so.

6 DR. SAFRAN: Because it seems like that's what
7 we'd need, like how much has reducing the out-of-pocket
8 cost sharing, the coverage gap, helped improve cost-related
9 non-adherence but at what expense? I think that is the
10 question I'm asking.

11 DR. CROSSON: So, Dana, now that you understand
12 the donut hole, as you look around in depth with your
13 flashlight, you're going to find all kinds of things, I can
14 guarantee it. Jon.

15 DR. CHRISTIANSON: On that same question, I
16 guess, I was a little bit confused on the process of how
17 this would work, Amy, so I probably didn't understand it.
18 But it seems to imply that the drug manufacturers have some
19 unexploited ability to raise prices that they would then
20 take advantage of, which seems so unlike the perception of
21 how drug manufacturers price their product. Can you say
22 something more about that? It seems like if they could

1 have raised their price, they would have, irrespective of
2 what happens to the rebates.

3 MS. BRICKER: They do.

4 DR. CHRISTIANSON: Okay. So I don't get why --
5 this seems like a similar argument we make around hospital
6 pricing.

7 MS. BRICKER: No; they do raise their price, and
8 it can -- and there's nothing that prevents it from, you
9 know, being thousands of a percent. I mean, you see this
10 across the spectrum. It's moderated in the last year just
11 because of the political pressure, I think no other reason.
12 And then we're starting to see it again, not to the same
13 historical extent, but we're starting to see price
14 increases again.

15 My point was just if you -- you can actually look
16 at when there was an obligation for the manufacturer to
17 contribute 50 percent discount, what happened to their
18 prices at that point in time. I fear now with a 70 percent
19 obligation we're just fueling this sort of indirect
20 consequence of our action -- it's a direct consequence,
21 actually.

22 DR. CHRISTIANSON: Yeah, so I don't understand

1 the argument here. I don't understand why they're not a
2 profit-maximizing company and they've already set their
3 price at approximately -- at the rate that they could get.
4 But we could talk later about this.

5 MS. BRICKER: They raise them every year, again,
6 for shareholder return, for a number of reasons, but they
7 will raise their prices every year, unfettered.

8 DR. CROSSON: It also provides justification in
9 the minds of some.

10 DR. PAUL GINSBURG: Actually, I think I heard
11 from Amy something that you -- what would make sense to
12 you, is that, you know, they're setting prices in different
13 markets, and so in a sense, if they're constrained in one
14 market, how the array of prices should look could be
15 different.

16 DR. CROSSON: Warner.

17 MR. THOMAS: As we get to the recommendations,
18 when we come back for the spring discussion, I guess one of
19 the things I would ask the team to think about is, you
20 know, in essentially the reinsurance area, which, you know,
21 flips to 80 percent coverage from Medicare, should there be
22 some additional rebate or discount provided by the

1 manufacturer to the extent that drugs get into the
2 reinsurance pool, you know, so that there's kind of a --
3 that they're contributing to -- and, you know, maybe it
4 takes some of the incentive away from, you know, getting
5 into the reinsurance pool, but even if there is an
6 incentive, once they get in there, they have to put some of
7 those dollars back. Also, I just think that we need to
8 make sure that the plan has incentive across all the pools,
9 including the donut hole and in the reinsurance pool, to
10 control costs. I mean, it seems like in the readings and
11 in the article that was provided that was recently in the
12 Wall Street Journal that there's just -- you know, maybe
13 there's not as much incentive on the plan side once you get
14 into the reinsurance area. And so I think, you know, some
15 recommendations around how that could be modified and how
16 the manufacturer could play in the reinsurance pool may
17 provide more cost controls of this.

18 DR. CROSSON: Okay. Good discussion. Thank you
19 very much. We'll look forward to hearing from you again
20 tomorrow morning.

21 We'll move on now to the second presentation,
22 final presentation for this morning's session.

1 [Pause.]

2 DR. CROSSON: Okay. We're going to proceed now
3 with a discussion of an important public health issue, and
4 that has to do with opioid use. And the question that was
5 asked of the Commission was to undertake an analysis to see
6 whether or not, in hospital settings at any rate, there
7 were incentives for hospitals to use opioids as opposed to
8 other methodologies to control pain. And Jennifer is going
9 to present us with that analysis.

10 MS. PODULKA: Thank you, Jay. Today's
11 presentation will be an update to the discussion we had in
12 October.

13 So the SUPPORT for Patients and Communities Act
14 calls on MedPAC to report to the Congress by March 15,
15 2019, on three items:

16 First, a description of how the Medicare program
17 pays for pain management treatments (both opioid and non-
18 opioid alternatives) in the inpatient and outpatient
19 hospital settings;

20 Two, the identification of incentives and adverse
21 incentives under the hospital inpatient and outpatient
22 prospective payment systems for prescribing opioids and

1 non-opioid treatments, and recommendations as the
2 Commission deems appropriate for addressing these;

3 And the third item is a description of how opioid
4 use is tracked and monitored through Medicare claims data
5 and other mechanisms and the identification of any areas in
6 which further data and methods are needed for improving
7 understanding of opioid use.

8 On the first item, Medicare uses bundled payments
9 to pay for pain management drugs and services in both the
10 inpatient and outpatient settings. They are applied
11 somewhat differently in each. The inpatient prospective
12 payment system, or IPPS, assigns stays to categories
13 depending on patients' conditions and sets payment bundles
14 that reflect the average costs of providing all goods and
15 services, including any drugs, supplied during the stay.
16 In contrast, the OPPS groups services into categories on
17 the basis of clinical and cost similarity and sets payment
18 bundles to cover the costs of providing the primary service
19 plus goods and services that are integral to the primary
20 service. Any additional goods and services are either paid
21 separately or not paid by the OPPS.

22 You may remember that in prior reports and

1 presentations we've described situations where outpatient
2 drugs are usually self-administered, separately payable, or
3 paid on pass-through, but these rules don't apply to pain
4 drugs in the outpatient hospital setting.

5 So the inpatient prospective payment system is
6 fairly straightforward, but the outpatient payment system
7 is not, so we'll dig into it.

8 Pain drugs in outpatient settings may be paid
9 under Part B or Part D or not paid by Medicare at all.

10 First, when the drug is for pain, the next
11 question to ask is: Is the drug directly related and
12 integral to a procedure or treatment?

13 Drugs that are used for postsurgical pain
14 management are, so these are paid under Part B as part of
15 the OPPI bundled payment.

16 But pain drugs can be used in outpatient settings
17 for other reasons. Rather than being directly related to a
18 procedure or treatment, pain drugs can be the sole
19 treatment -- for example, when a patient goes to the
20 emergency department with migraine pain. In these cases,
21 Part B doesn't pay for the drug, and the hospital usually
22 charges the patient. If the beneficiary has a Part D drug

1 plan, the plan might pay for the drug if it is included in
2 the plan's formulary and the hospital's pharmacy
3 participates with the plan, but many don't.

4 And one last note before moving on. CMS'
5 guidance about determining how drugs are paid for in the
6 outpatient setting is directed to the MACs, or Medicare
7 Administrative Contractors. This means that implementation
8 of these rules is up to the discretion of the individual
9 MACs, so there may be variation across geographic regions.

10 The mandate's second question directs us to
11 identify the extent to which there are incentives and
12 adverse incentives introduced by the hospital inpatient and
13 outpatient prospective payment systems for prescribing
14 opioids versus non-opioids. Our study focuses on evidence
15 that these financial incentives could have an effect on
16 hospitals' decisions about which drugs to include on their
17 formularies and possibly promote for use by their
18 physicians. But we recognize that actual prescribing
19 happens on a case-by-case basis when a clinician or team
20 selects the drugs to treat an individual patient, so in
21 addition to any potential financial consideration, there
22 are patient-specific and clinical factors that guide

1 prescribers' pain drug choices

2 In other words, the inpatient and outpatient
3 prospective payment systems are designed to give hospitals
4 a financial incentive to select the lowest-cost goods and
5 services possible.

6 This incentive is balanced by Medicare's quality
7 measurement and reporting programs along with providers'
8 clinical expertise and professionalism.

9 Thus, these balanced incentives ideally result in
10 high-quality outcomes for patients at the best prices for
11 beneficiaries and other taxpayers.

12 To better understand the extent of any systematic
13 financial incentives that would lead clinicians in hospital
14 settings to prescribe opioids over non-opioid alternatives,
15 we analyzed the differences in prices between opioid and
16 non-opioid drugs commonly used in the inpatient and
17 outpatient hospital settings.

18 To begin, we consulted with clinicians to
19 determine which pain drugs to include in our study based on
20 those that are commonly used in hospital settings, which
21 means that this list does not include all pain drug
22 options.

1 Also, this analysis has a key caveat: We do not
2 know the actual prices that hospitals paid for these drugs
3 as hospitals do not report their drug acquisition costs.
4 And let me pause here to note just how little information
5 that we and others have to go on. Hospitals don't report
6 the prices paid for individual drugs or which drugs they
7 pick for patients or anything about dosing, so we don't
8 know the volume of pain drugs used in our study.

9 We considered as a substitute average sales
10 prices, or ASP, which are a weighted average of
11 manufacturers' sales prices for a drug for all purchasers
12 net of price adjustments, but these are not available for
13 many of the drugs in our study.

14 In lieu of either of these, we examined two
15 publicly available list prices: wholesale acquisition
16 cost, or WAC, and average wholesale price, or AWP. We
17 found similar price patterns for these, so we present WAC
18 alone for brevity.

19 We acknowledge that WAC represents an upper
20 bound. Actual prices paid by hospitals are likely lower,
21 as WAC is the manufacturer's list price and does not
22 incorporate prompt-pay or other negotiated discounts.

1 But WAC is still useful as it provides the
2 relative prices of opioids versus non-opioid drugs, which
3 are informative for our study.

4 I'd also like to note that when clinicians
5 prescribe pain drugs in the hospital setting, they have
6 multiple options, including the drug's route of
7 administration -- for example, oral or intravenous -- and
8 the dosage form -- for example, tablet, capsule, and
9 solution.

10 Prescribers can also opt to use multiple drugs in
11 combinations -- that are sometimes called "cocktails" --
12 which give flexibility in the choice of drug agents to
13 treat pain and related symptoms and can mitigate the
14 drawbacks of individual drugs in the cocktail without
15 unduly sacrificing drug efficacy. For example, a lower
16 dose of an opioid can be used along with a non-opioid to
17 reduce risk while still achieving sufficient analgesic
18 effect. This flexibility is important in the hospital
19 setting as opioids are more often indicated for acute,
20 severe pain than many non-opioid alternatives. And while
21 there are some recent studies that suggest similar
22 analgesic effect of opioid and non-opioid drugs even for

1 some cases of moderate to severe pain, it is not clear that
2 non-opioid alternatives can or should replace opioids for
3 all cases of acute, severe pain.

4 Because of these options, our study's non-opioid
5 drug category includes multiple groups, such as the more
6 direct alternative of NSAIDs and other non-opioid pain
7 relievers, as well as other drugs that can be used to
8 partially or fully substitute for opioids when used in
9 combination, such as general and local anesthetics,
10 sedatives, and neurologic agents for nerve pain.

11 We found that the ranges of WAC list prices for
12 opioids and their alternatives overlap. The available
13 choices for opioids and non-opioids that are commonly used
14 in hospital settings both include options that list at less
15 than \$1 per dose.

16 Specifically, for opioids there are ten commonly
17 used options that list at less than \$1 per dose. These
18 represent 31 percent of the commonly used opioids where WAC
19 is available in our study. The lowest list price is five
20 cents per dose.

21 For NSAIDs and other non-opioid pain relievers,
22 there are 27 commonly used options that list at less than

1 \$1 per dose, representing 47 percent of options in this
2 group. And the lowest list price is two cents per dose.

3 The commonly used drug groups of neurologic
4 agents, sedatives, musculoskeletal therapy agents,
5 ophthalmological agents, and local anesthetics all include
6 an option that lists at less than \$1 per dose.

7 We are not asserting that all of the drugs on
8 this list are interchangeable. When prescribers pick which
9 ones to use for individual patients, they should not always
10 pick the two-cent choice. But there is no clear indication
11 that Medicare's inpatient or outpatient prospective payment
12 system provides systematic payment incentives that promote
13 the use of opioid analgesics over non-opioid analgesics.
14 Both opioids and non-opioids are available at a range of
15 list prices, and there are options for either type of drug
16 that list at less than \$1 per dose.

17 You'll see that there are some non-opioid options
18 that are much more expensive, but this is true for the
19 opioid drugs as well.

20 Turning now to the third item from the mandate on
21 monitoring, as we discussed in October, CMS tracks opioid
22 use through data available in the Part D program. To

1 briefly review, CMS monitors opioid use in Part D in
2 multiple ways. The three categories shown here might be
3 the most relevant for Part A and B.

4 First, the Overutilization Monitoring System
5 shares feedback securely with Part D plan sponsors and
6 ensures that they implement opioid overutilization policies
7 effectively.

8 Second, CMS uses quality measures to track trends
9 in opioid overuse across the Medicare Part D program and
10 drive performance improvement among plan sponsors. These
11 include publicly available display measures and
12 confidential patient safety reports that are sent to plan
13 sponsors.

14 And, third, CMS makes data on clinicians' opioid
15 prescribing patterns publicly available on the website
16 through the Medicare Part D opioid prescribing mapping tool
17 that shows comparisons at various geographic levels.

18 All three efforts rely on prescription drug
19 event, or PDE, data. These data are summary records that
20 prescription drug plan sponsors must submit every time an
21 enrollee fills a prescription under Medicare Part D. The
22 PDE data are not the same as individual drug claims, but

1 are summary extracts using CMS-defined standard fields.
2 The distinction is important, and I'll come back to it in a
3 bit. And the agency does not operate opioid tracking
4 programs in either Part A or Part B.

5 In our last discussion, the sense of the
6 Commission was that there are compelling patient safety and
7 public health reasons for Medicare to track the use of pain
8 drugs in hospital settings.

9 Reasons for undertaking a tracking program
10 include the severity of the opioid epidemic, the gap in
11 knowledge about the degree to which Medicare beneficiaries
12 are exposed to opioids while in the hospital, and the
13 opportunity for program oversight of hospitals' use of
14 opioids versus non-opioids.

15 Last time we discussed some existing programs
16 that might serve as alternative oversight programs in lieu
17 of Medicare taking on this role. Other federal agencies
18 besides CMS have jurisdiction over some aspects of opioid
19 use, such as FDA, CDC, and SAMHSA, but none has programs
20 that track opioid overutilization in the hospital setting.

21 States have also taken on a role through the use
22 of prescription drug monitoring programs, or PDMPs, which

1 are electronic databases that track a state's controlled
2 substance prescriptions. Along with some other features
3 that affect the utility of the state PDMPs, hospital
4 inpatient pharmacies are not required to report to them.

5 So that brings us to options for implementing a
6 Medicare tracking program.

7 First, we could require hospitals to report PDE-
8 type data. If Medicare were required to undertake an
9 opioid monitoring program in hospitals, structural
10 differences would require CMS to adapt its current program
11 under Part D, which relies on plan sponsors to report the
12 PDE data. CMS also relies on the plan sponsors to use
13 analytic results to implement drug management programs and
14 clinical contact with prescribers. While there are no drug
15 plan sponsors in Parts A and B, prescribing clinicians or
16 hospitals could be required to report summary information
17 (similar to the PDE) about pain management drugs.

18 Second, we could require hospitals to report
19 prescribed drugs on Part A and Part B claims, which
20 currently do not include information on the pain management
21 drugs included in bundled payments. CMS could take steps
22 to incorporate these data into the claims and then require

1 hospitals to include it. This would require decisions
2 about how best to proceed and would likely require a multi-
3 year effort to implement.

4 And, third, CMS could incorporate opioid use
5 disorder, or OUD, in its Hospital-Acquired Condition
6 Reduction Program or any replacement program.

7 Last time we discussed that the existing program
8 could provide a platform for tracking the effects of opioid
9 use that originated in hospital settings. The program
10 sends confidential hospital-specific reports and reduces
11 payments to poor-performing hospitals. It includes six
12 hospital-acquired condition quality measures such as rates
13 of C. difficile infection.

14 Incorporating OUD and other opioid-related
15 adverse events into the program would require the
16 development and adoption of a measure, a source of
17 documentation for use with the measure, (such as the PDE-
18 type or claims options we just discussed), a longitudinal
19 tracking effort to identify eventual OUD and other opioid-
20 related adverse events, and, finally, a mechanism to link
21 the outcome to the responsible hospital. Tracking of OUD
22 and related diagnoses could defer identification and

1 feedback and also underestimate the effects of opioid use
2 in hospital settings, as clinicians could delay or avoid
3 diagnosing OUD because of its associated stigma and
4 patients could similarly avoid receiving health care
5 services and diagnoses.

6 I also want to note that I mentioned any
7 replacement program here, if the Commission has discussed
8 concerns with the design of the current hospital-acquired
9 condition reduction program, and later today you will vote
10 on eliminating the program and implementing aspects of it
11 in an improved hospital value incentive program.

12 So I'll conclude here. Please let me know if you
13 have any questions on the presentation or material in the
14 paper. The paper will become the final mandated report and
15 included as a chapter in our upcoming March report.

16 DR. CHRISTIANSON: Thank you, Jennifer.

17 Are there any questions of clarification? Brian,
18 Marge, and Amy.

19 DR. DeBUSK: First of all, thank you for a great
20 report and for choking through that. I'll ask you a really
21 long-answer question.

22 On Chart 12, the center bullet here, you talked

1 about requiring hospitals to report prescribed drugs on
2 Part A and Part B claims. Do we have a feel for what the
3 administrative burden of that would look like? Is that
4 flipping a switch on an EMR? Or is that an overhaul of how
5 coding and claims are handled?

6 MS. PODULKA: We did specifically talk to CMS
7 about what this would entail. They wanted to convey that
8 it's not instantaneous. There would need to be some
9 modifications. They stand ready, if asked by the Congress,
10 to modify. As usual, CMS responds to congressional
11 requests and action. So we do mention that it would
12 require some effort. It couldn't happen right away. It
13 may be months before it could be implemented. I don't have
14 a specific time frame for you, though.

15 DR. DeBUSK: Will we get a chance to talk to some
16 hospitals and get some feedback on just how big of an
17 administrative hurdle that might be?

18 DR. MATHEWS: Brian, I think that would depend on
19 the extent to which we want to pursue this body of work
20 after the mandate at hand. We're trying to dispatch this
21 to comply with the statutory deadline of March 15th. So if
22 there are lingering issues or additional items we want to

1 pursue, we could have that discussion. But the short
2 answer is not before we end up publishing this material.

3 DR. DeBUSK: One other question. I had two here.
4 In the mandate, the mandate reads that we're supposed to
5 report, I think it is, any incentives for opioid versus
6 non-opioid use. And I like the fact that we focused on the
7 cost. I mean, that is the obvious one, the cost incentive.
8 But what about the effect on length of stay or on patient
9 satisfaction? I would think those might be incentives,
10 too, that we would want to explore. I realize that would
11 require chart review, and none of this is available
12 currently. I get all that. But I was going to ask, is
13 cost the only incentive that we're going to explore to meet
14 this deadline?

15 DR. MATHEWS: That is the only one that we
16 contemplated in the conduct of the work thus far.

17 DR. DeBUSK: Even though the mandate is somewhat
18 open-ended, any incentive versus any financial incentive.

19 DR. MATHEWS: That is true, but the financial
20 incentives seem to be the most pressing, and to get into
21 things like efficacy or patient satisfaction, we start
22 getting into very idiosyncratic issues that do invoke chart

1 review and things like that.

2 I would also point out that we were given a
3 fairly limited amount of time in which to conduct this
4 work. I think the final legislation was passed in October-
5 ish. We were given a heads-up a couple of months before
6 then, and so we started on this work. But it's not a lot
7 of time to do an extremely comprehensive scope, and so we
8 focused on the aspect that seemed to be of most relevance
9 to us and do the Congress.

10 DR. DeBUSK: Okay. When I saw the chapter, the
11 one lingering thought or the one that really stood out was
12 length of stay because I thought if these opioids are
13 perhaps getting them out of the hospital sooner or more
14 confidently -- and even if we can't collect that data, that
15 might be something we want to mention. That it's hard to
16 measure.

17 DR. MATHEWS: We will talk when we get back, but
18 I think it is something that we could at least acknowledge
19 as an additional incentive that we didn't deal with at
20 length in the analysis.

21 DR. CHRISTIANSON: Marge.

22 MS. MARJORIE GINSBURG: Two questions or

1 comments.

2 The first one, is there any tracking of discharge
3 meds? I didn't see any reference in the report, but if one
4 is interested in finding out how the opioid epidemic gets
5 started, I would imagine that looking at discharge meds
6 from the hospital would be an important piece.

7 I don't know. Are discharge meds under Part A or
8 Part D?

9 MS. PODULKA: They get switched to Part D. So
10 even if you take something, say, in the emergency
11 department, they can't send you home with something that
12 gets charged to Part D.

13 Specifically, we're trying to scope everything
14 down to be responsive and meet the mandate, and the mandate
15 is focused on A and B, which includes the discharge meds.

16 MS. MARJORIE GINSBURG: Okay.

17 My second comment -- and I confess my husband
18 works for the Medical Board of California and does review
19 of bad doctors, a lot of opioid cases. So I asked him to
20 look it over.

21 This may not be anything we can do because if CMS
22 is already doing it.

1 So, in the report itself on page 1, it talks
2 about the things that CMS is tracking, and one was
3 prescriptions of opioids from four or more prescribers and
4 four or more pharmacies. And based on a whole lot of
5 reviews he's done, he has never seen anybody with four or
6 more and thinks that should be reduced to three.

7 Also, it says four or more prescribers. I think
8 that should be changed to "practices" because often you
9 might have nurse practitioners working under a physician.
10 So you might end up with more prescribers than you actually
11 have practices.

12 Anyway, I don't know what the status is of CMS
13 doing this review, and I wonder if you could mention that
14 and whether it's too late for any comments on that.

15 MS. PODULKA: CMS has actually just newly rolled
16 out some refinements to the Part D tracking program, and I
17 can't remember specifically if the four was one of the ones
18 that changed most recently or not.

19 Basically, they've implemented a lot more
20 requirements and more tracking efforts and changed some of
21 the criteria. It's just gotten started, and so sometimes
22 when that happens, we like to see what the effect is before

1 we comment again.

2 DR. CROSSON: Amy.

3 MS. BRICKER: Similar to where I thought Marge
4 might be going was around -- so the concern is someone has
5 started on an opioid -- I think this is the concern.
6 Someone started on an opioid in the hospital and then
7 maintained and then becomes addicted to the opioid they
8 were started on.

9 So I'm wondering. Is there a role that retail
10 pharmacy could play in tracking of the initiation of the
11 drug?

12 Again, I know you mentioned we could hook in A
13 and B or hospitals could hook into what's been established
14 in D. Then we have a complete picture of the patient and
15 the prescribing of the opioid. When the discharge
16 prescription is written, there are additional questions
17 about when was the patient started, what was the patient
18 started on, what was the patient started for. I don't
19 know. Just additional information.

20 I fear if we're trying to build an infrastructure
21 for every hospital in America, we'll never get there. So
22 can we hook into what's already established?

1 MS. PODULKA: So this would contemplate having --
2 tell me if I'm getting this wrong, though -- having a
3 prescriber who writes a prescription that would then be
4 filled under Part D to include information about what that
5 prescriber knows the patient did while in the hospital.

6 MS. BRICKER: Just an idea because --

7 MS. PODULKA: Yeah.

8 MS. BRICKER: -- everyone that has D has A and B,
9 so some way to then just tie this together in some sort of
10 historical context because where the breakdown occurs is
11 that you can leverage pharmacy benefit managers for all of
12 the Part D information in the universe, but A and B, to
13 your point you were making very well in the chapter, we
14 just don't have this level of insight on the drug level in
15 the hospital.

16 So given the health crisis, can we shift sort of
17 the protocol to ensure that when you're dispensing a
18 script, you have to get that information if it's on
19 discharge, for instance?

20 MS. PODULKA: It's something we could definitely
21 add a discussion and explore.

22 Totally off the top of my head, I think it's

1 intriguing. I'm sure there might be some limitations if
2 the discharge is different from the team or something, but
3 definitely worth considering. Thank you.

4 DR. GRABOWSKI: I like the idea, Amy, and another
5 part of this is those individuals discharged from the
6 hospital to a skilled nursing facility would be through a
7 long-term care pharmacy under the Part A. I'm just
8 thinking how, just in general, post-acute would play into
9 this, and then do you want to bring in the long-term care
10 pharmacies as well to be a part of this?

11 Thanks.

12 DR. CROSSON: Jonathan.

13 DR. JAFFERY: Two quick questions, but actually,
14 before that, also to Amy's question, maybe one way you
15 could think about it, without having -- well, perhaps if a
16 beneficiary had a first-time fill for an opioid linked very
17 closely to a hospitalization discharge, to a discharge, you
18 might be able to get around trying to link some other
19 things, if that makes sense.

20 So if somebody's first fill comes within a week
21 of being discharge, that might be an indication at least of
22 what happened at the inpatient stay.

1 But my questions, in terms of bullet point 2, if
2 we were to require hospitals to report this in Part A and
3 Part B, would we be missing any MA beneficiaries? That
4 would be one question.

5 MS. PODULKA: For the MA beneficiaries, we might
6 need to capture this information through encounter data,
7 which we'll be discussing later this spring --

8 DR. JAFFERY: Yeah.

9 MS. PODULKA: -- which has its own issues, but
10 since we're missing exact claims there, we would either
11 have a mechanism for the prescribers under MA to report
12 summary or claim-type information or report it as encounter
13 data to the plan to translate to Medicare.

14 DR. JAFFERY: Okay. So maybe a couple extra
15 barriers there too for that.

16 The other question, do all states currently have
17 functioning PDMPs, and if so, is there any precedent or
18 opportunity to tie into those?

19 MS. PODULKA: Forty-nine states do. One
20 additional state is in the process, but doesn't have a
21 complete one.

22 PDMPs do have a role to play, but right now, in

1 addition to some other technical limitations, the hospital
2 inpatient pharmacies aren't required to report to the state
3 PDMPs, so they're kind of facing the same blind spot that
4 Medicare is.

5 DR. JAFFERY: I guess I'm wondering if we could
6 move in the direction of that be the requirement because
7 PDMPs seem to be functioning. At least in Wisconsin,
8 they're functioning, functioning pretty well.

9 MS. PODULKA: It could be a requirement. I'm not
10 sure that we're the right body to --

11 DR. JAFFERY: Yeah.

12 MS. PODULKA: Yeah.

13 DR. CROSSON: Okay. Seeing no further questions,
14 we'll proceed to Round 2.

15 Jon is going to start us off.

16 DR. PERLIN: First, Jennifer, let me thank you
17 very much for a thoughtful response to this congressional
18 mandate.

19 It's interesting that just this week, the
20 National Safety Foundation identified opioid use disorder
21 as the number one preventable cause of death in the United
22 States, and that's quite a statement. That supersedes car

1 accidents and everything else, so obviously, this is a
2 crisis.

3 I think the data are that too many of these late-
4 term consequences start with exposure to opioids in
5 clinical settings, including the hospital.

6 We also know at a very fundamental level that the
7 dose and duration of opioids contribute to the propensity
8 to later dependence.

9 In terms of the questions that we were asked, the
10 description of payment is factual, and I appreciate the
11 very thoughtful outline of that. I think on a financial
12 basis, the data that you outlined suggest that there are no
13 dollar incentives that drive to a particular use of one
14 versus the other.

15 But I think there are two points here worth
16 noting. First, I think the overwhelming evidence in
17 prescribing generally is that bad prescribing isn't driven
18 by cost sensitivity. In fact, it's just the opposite.
19 That the history of bad prescribing, be it overuse of
20 antibiotics, for example, is done with incredible
21 insensitivity to cost. So I think that's further evidence
22 that that's probably not the key component of choice there.

1 I think Brian and others point, that there may be
2 other incentives at work, I think are particularly
3 important. Ironically, it may be that opioids, depending
4 on the circumstance, can either shorten your life, then,
5 and certain non-steroidals and/or other agents can shorten
6 your life.

7 I think the other issue is to really get at the
8 question that I think is behind the nominal question, is
9 how do we improve prescribing and reduce bad or avoidable
10 outcomes and unintended consequences.

11 When you factor in the unintended consequences,
12 some of the approaches now to avoiding opioids made
13 themselves have additional liabilities. First, at a sort
14 of social, financial level, some of them are very
15 expensive. They're like preparations of drugs, that
16 they're long-acting forms and things that are dirt cheap,
17 that put in a particular preparation are literally four to
18 five orders of magnitude more expensive. That's obviously
19 problematic.

20 Second, the substitutions of some of the
21 analgesics, opioids in particular, by other things that
22 aren't necessarily analgesics can lead to unintended

1 consequences. For example, some of the drugs that might be
2 used for nausea or a headache actually are in the category
3 of atypical antipsychotics and can cause lifelong
4 complications like Tardive dyskinesia and the like. So
5 these are not necessarily good outcomes either, and so
6 don't want to inadvertently drive other problems.

7 So let me just dissect a couple of pieces first,
8 and I'll offer some comments on each of the categories.
9 What about the question of requiring prescription drug
10 events reporting by hospitals? I would offer that the
11 question is what are the relevant outcomes, and do they
12 occur within the window of hospitalization? I think the
13 issue here is are you creating a situation in which there
14 are long-term dependence or complications that derive from
15 that, and so the window of insight into those events may
16 not necessarily be during the hospitalization, just that I
17 mention the dose and duration are predictors.

18 So I just note that that's relevant on part two,
19 which is require hospitals to report on prescribed drugs on
20 Part A and Part B claims. I would offer that is actually
21 going to be quite burdensome. We mentioned the limitations
22 for MA patients in terms of a lack of structure at the

1 outset.

2 But here's the other problem. It may not be the
3 best relevant data. It may neither be the best data in
4 terms of in-hospital data because it's inadequately
5 clinical, and it may be the wrong window of time because
6 you're really looking for the propensity to a later
7 liability.

8 Third -- and I feel a little guilty about this
9 one in terms of incorporate opioid use disorder into CMS's
10 hospital-acquired conditions program. I think in theory,
11 that's a great idea. I think in theory, it is because I
12 have to be consistent with myself. Authors Mike Schlosser,
13 Ravi Chari, and Jon Perlin posted a blog to Health Affairs
14 on considering opioid use disorder as a late-occurring
15 complication.

16 And it was really meant to spark debate about
17 dose and duration and alternatives to opioid therapy in
18 hospital, and while in the social sense, we need to be
19 paying attention to that in a sort of practicable time
20 limited sense, it's probably not operational for the
21 reasons I have mentioned.

22 So let me just dive down into a couple of other

1 comments in each of these areas. First, it may not be
2 beyond the scope to comment on achieving best prescribing
3 and reduction of opioids through programs that we want
4 hospitals to do, alternatives to opioid therapy at
5 emergency departments, or ALTO, as how some of these
6 programs are named. Enhanced surgical recovery programs
7 are programs that systematically reduce the need for larger
8 doses of opioids and can be beneficial.

9 In the area of incentives, I would note that
10 beyond the question of length of stay, which may go in
11 either direction on both opioid and non-opioid classes of
12 drugs, while the Patient Experience Survey, or HCAHPs, has
13 been changed from questions that really implied an absolute
14 elimination of pain, there are still discussions of pain.
15 And I think further education is needed in the provider
16 community because that still operates, if not an explicit,
17 certainly an implicit incentive toward use of maximal pain
18 therapy.

19 Second, you had noted in the chapter, which is
20 really so well written -- and thank you for that -- the
21 need for prescribing guidelines. One of the problems in
22 adoption of prescribing guidelines is the variation. I am

1 pleased to report further progress from the National
2 Academy of Medicine. I mentioned the Action Collaborative
3 that's bringing together professional and provider
4 organizations in both care and addiction.

5 But under the aegis of that and in collaboration,
6 the FDA is actually promulgating new prescribing guidelines
7 for pain management, suggests that that be identified as a
8 benchmark when they're published later this year for
9 appropriate use.

10 There are incentives against the use of certain
11 agents that may have less opioid addiction liability.
12 Buprenorphine, for example, requires additional education.
13 Ironically, other agents that have been implicated in
14 addiction do not, and that may fall under the aegis of
15 incentives.

16 Finally, let me just close with some other
17 suggestions on how to get at the best possible data, best
18 outcomes. I think the thread of conversation and the round
19 of clarifying questions about the use of Part D for
20 discharge prescriptions is really a good telegraph into
21 whether a patient is going home with a high dose of
22 opioids, whether they're going home with a dose of opioids

1 that they didn't have prior to hospitalization. They think
2 that could be potentially reconciled pre- and post-
3 hospital, and in the context of the indications, the
4 patient has certain diagnoses, as particular prescription
5 may make more sense than some of the other diagnoses. So
6 think about -- toward answering Congress' inquiry, a
7 direction there may be of some benefit.

8 In terms of the events tracking, there may be
9 some hospital data in terms of rescue drug use for
10 overdoses. That's been discussed in the clinical
11 literature.

12 We now have ubiquitous electronic record system.
13 I would encourage the use of the clinical systems, as the
14 administrative systems really don't have the sensitivity to
15 articulate what the context was in which particular choices
16 of cocktails, opioids were used. And there still is a very
17 appropriate role -- and the shortage of certain opioids for
18 surgical other procedures.

19 There is in the clarifying round the question
20 that Jonathan and others raised about the utility of the
21 prescription drug monitoring programs, and with the
22 increased requirements for e-prescribing, the ability to

1 ping the PDMP, even inpatient might be something that could
2 be encouraged. So that prescriptions aren't started if one
3 had indication that a particular patient was at risk for
4 overuse or had different sorts of opioid prescription
5 history.

6 Finally, the use of other technologies may be of
7 merit. The FDA has sponsored the use of the Sentinel
8 programs. The Sentinel has a database of the actual drugs
9 that are used during hospitalization. That may provide a
10 basis for surveillance -- I'm getting further afield --
11 chain of custody of all opioids. Distribute the literature
12 aka blockchain may be a way of tracking opioids throughout
13 the entire cycle.

14 So I hope those comments are helpful and again
15 commend for a terrific chapter and then back to the
16 question's factual response on the payments, that's there.
17 The incentives, probably not financial. There may be
18 stronger incentives related to experience, maybe some
19 implicit incentives related to finance and tracking.

20 I don't think the administrative systems offer
21 the best data in terms of trying to force Part B into the
22 hospital, but the post-hospitalization Part D may offer the

1 highest utility.

2 Thanks so much.

3 DR. CROSSON: Thank you, Jon. Very
4 comprehensive. I was particularly impressed with your
5 ability to debate with yourself, and win.

6 Further comments for Jennifer? I see Jonathan,
7 Amy.

8 Jonathan.

9 DR. JAFFERY: All right. I hadn't raised my
10 hand.

11 DR. CROSSON: Oh. Not your hand. Was that
12 Kathy's hand?

13 MS. BUTO: It was.

14 DR. JAFFERY: Go ahead.

15 MS. BUTO: It was my hand but I was disguised as
16 Jonathan.

17 DR. CROSSON: You just snuck it up under his
18 shoulder or what?

19 MS. BUTO: Sorry about that.

20 So I really want to just endorse a lot of what
21 Jon was saying about prescribing guidelines and using not
22 financial incentives so much or data requirements to try to

1 get at the issue of really the long-term dependency on
2 opioids by patients post hospital discharge. I think using
3 Part D as a way to track those prescriptions longer term
4 would be a good way to go at it without adding new
5 requirements.

6 I'm also wondering -- and this is really out of
7 ignorance -- whether we can look at either MA or MA and
8 ACOs, which are intended to try to manage or coordinate
9 care across the continuum as a way to get at some of the
10 data on opioids and use of prescribing guidelines, and find
11 a way to provide incentives within that structure. And
12 this may not be the only issue. But I realize that the
13 argument against that is you don't want to develop too many
14 sort of site-specific or entity-specific requirements that
15 then take you far afield from making comparable assessments
16 across fee-for-service and managed care.

17 But I just feel like that we ought to be, in
18 those entities, able to track more of this kind of issue,
19 which is longer-term dependency on opioids and other issues
20 that cut across provider settings.

21 DR. CROSSON: Thank you, Kathy. Amy.

22 DR. BRICKER: I'm going to go a little bit of a

1 different angle for just a moment. So I was thinking about
2 a couple of things. One, my own personal experience and,
3 one, just the crisis that this country is in relative to
4 opioid misuse.

5 There is never a conversation in the hospital
6 about your care plan relative to pain management, from my
7 experience. I've had surgery. I've had children. No one
8 has ever said to me, "We're going to discharge you. You're
9 going to be in the recovery room on morphine." There's
10 never been that explicit sort of explanation of the drugs
11 that are going to be administered.

12 Why I think this is important is within the
13 number of people that will likely enter our health system,
14 our hospitals, our ERs, that have struggled with opioid
15 addiction, who absolutely fear being reintroduced to an
16 opioid, it's incredible.

17 So is there a way for us to require the screening
18 of, have you ever, you know, had an opioid-related
19 addiction or have you ever sought treatment for, or some
20 sort of screening? We put on the walls of hospital beds
21 "this is a fall-risk," right, so take care. We don't say
22 "this patient has struggled with an opioid so don't give

1 them one," or this patient doesn't ever want one if we can,
2 at all costs, not give them one, you know, all other
3 treatment options should be sought.

4 So maybe it's not practical, but I think we've
5 got to figure out a way to support people that are coming
6 out of recovery, and when they're at the hospital thinking
7 that they're getting the best care that's available to them
8 it not be price, it not be cost, but it be about the health
9 and well-being of that patient and us ensuring that we're
10 doing the best that we can by them.

11 DR. CROSSON: It's interesting because, actually,
12 I thought where you were going to go was requiring informed
13 consent, which, of course, is done for procedures.

14 DR. BRICKER: Similar. I think that's exactly
15 what I'm suggesting.

16 DR. CROSSON: Jon has a comment.

17 DR. PERLIN: Yeah, just briefly on this point.

18 Great comments, Amy. In that legislation, if I'm not
19 mistaken, it includes a requirement, at least annually,
20 Medicare beneficiaries be screened for opioid use disorder.
21 My only qualm with that screening is that it should be
22 broadly for any substance use disorder. Putting that

1 aside, I think your thoughts are really well taken about a
2 care plan discussion.

3 DR. CROSSON: Okay. Did I see anybody else?

4 Now -- yes, Karen.

5 DR. DeSALVO: I'm sorry. I was trying to find
6 that there was some legislation based on a death that
7 happened just in that circumstance, a woman named Jessica
8 Grubb, who had an addiction disorder, and when she was
9 admitted they failed to ask and she subsequently died.

10 So I just want to relate also to the demand side
11 of the equation. I want to add on to what Amy is saying,
12 because I think, first, as we've described, it's a very
13 complex scenario in the hospital setting about whether
14 someone gets prescribed and then actually takes opioids for
15 pain, and that may happen sometimes in the middle of the
16 night without a lot of forethought because somebody is
17 awake and you want them to sleep, et cetera. So many
18 hospitals are taking matters into their own hands and
19 they're leveraging their pharmacies as the gatekeeper to
20 it. And I don't know if there's an opportunity, Jennifer,
21 for pharmacy data to inform some of this, if it's so
22 outside of the sphere. But that's a way that they're

1 trying to track not just prescribing but actual
2 administration of drugs to folks.

3 So the demand side may be something to consider
4 if there's still time, before we send the report to
5 Congress, which is are there ways that the Medicare program
6 could better inform beneficiaries at the time -- required
7 at the time of admission to the hospital, during
8 hospitalization, on discharge, at the time of enrollment in
9 Medicare, just to increase awareness that there are
10 multiple ways to manage pain, that there's good science
11 around addition, even short-term treatment with opioids can
12 lead to addiction, because that education would probably
13 help empower them even further than they've already been.

14 DR. CROSSON: Thank you, Karen. Bruce.

15 MR. PYENSON: I think this is a fascinating topic
16 and this group is so smart and interested, but I'm worried
17 about whether this is best venue or whether MedPAC has the
18 means to contribute to this beyond the many other federal
19 organizations and private organizations that are addressing
20 the topic.

21 So I just have a concern about that. As we go
22 forward, we had a fairly specific charter to address on

1 payment issues, and wonderful discussion but I'm
2 uncomfortable going too far out without having a full view
3 of what the CDC is doing, or what other organizations are
4 doing on this issue, with some of the topics.

5 DR. CROSSON: So, Bruce, that's a good point, and
6 just let me sort of be clear. Given the specificity of the
7 mandate, as you point out, and also the time frame to get
8 this report done, we have stopped short of, and will stop
9 short of trying to adjudicate, you know, what's the best
10 solution, you know, to the tracking or even interdiction of
11 inappropriate use in the hospital. But I think it is
12 within the mandate, and it is the intention, given the time
13 frame that we have, to mention ideas that have come up
14 through the staff or that have come up through the
15 Commission discussion. And I think that's the intent.

16 MS. MARJORIE GINSBURG: Is the point you're
17 making, Bruce, is we can present ideas but we don't want to
18 own it? Or is this report going to make any reference to
19 what our future role might or might not be?

20 DR. CROSSON: At the moment, no. We're
21 fulfilling a mandate right now. That doesn't mean that
22 based on other internal or external pressures that we might

1 not come back to this issue. But this is circumscribed at
2 the moment.

3 Okay. Thank you. It was a very good discussion,
4 Jennifer. Thank you for this work. Very important stuff.

5 We are now finished with this morning's
6 discussion. We now have an opportunity for a public
7 comment period. If there are any of our guests who wish to
8 make a public comment please come up to the microphone,
9 line up, and I'll give you an opportunity in a second. I
10 just want to see who is there.

11 [Pause.]

12 DR. CROSSON: So this is an opportunity to make a
13 public comment on matters before the Commission this
14 morning. We would remind you that there are other
15 opportunities to interface with MedPAC staff, both online
16 and in person.

17 As you come to the microphone please identify
18 yourself and any organization that you're affiliated with,
19 and we would ask you to limit your remarks to two minutes.
20 When this light returns, the two minutes will have expired.

21 Thank you.

22 MR. BLACKMAN: Good morning. Test. Good

1 morning. My name is Scott Blackman. I'm an associate of
2 Jerry Stringham at Medical Technology Partners, a Bethesda,
3 Maryland, consulting firm.

4 There is a problem with the benefit design in
5 federal programs. Some opioid pain mitigation technologies
6 have no benefit category where they can be reimbursed by
7 government insurers. An example of this flaw in the system
8 is noninvasive vagus nerve stimulators. The Pain
9 Management Best Practices Interagency Task Force, which was
10 required to be formed by CARA, indicated in their draft
11 report that, quote, "There are now multiple Level 1 studies
12 and multiple Level 2 studies demonstrating that noninvasive
13 vagus nerve stimulation can be effective in ameliorating
14 pain in various types of cluster headaches and migraines.
15 These therapies provide an electric field to the brain,
16 cranial nerves, or peripheral nerves without actually
17 requiring a surgical procedure or implant."

18 Unfortunately, noninvasive neuromodulation
19 technologies, which are self-administered, do not meet any
20 current benefit category definitions, including medical,
21 drug, or DME.

22 We would like MedPAC to propose a minor change in

1 the definition of a Part D drug so that non-opioid
2 technologies like this could be covered for patients under
3 government programs, should the program administrators deem
4 that they meet the reasonable and necessary criteria for
5 coverage. Without some legislative change, there is no
6 pathway for coverage for technologies like this, and
7 opioids will be prescribed for many of these patients.

8 I have some legally prepared draft legislation
9 and would ask MedPAC to recommend its enactment.

10 Thank you.

11 DR. CROSSON: Thank you for your comment.

12 MS. DORSEY: Good morning. DeChone Dorsey and
13 I'm representing AvaMed, a medical device association. And
14 I wanted to raise for the Commission one of the concerns we
15 have related to opioid alternative device payments, namely
16 something that wasn't brought out in today's discussion
17 related to language in Section 6082 of the support bill,
18 where it speaks to non-opioid alternatives which, to our
19 understanding, could also include devices.

20 So we support consideration of payment and
21 coverage policies that reduce bias in selecting the devices
22 used to treat chronic and acute pain. In some cases, this

1 may mean paying separately for opioid alternative
2 technologies and in others it may mean simply paying more
3 to address inadequate payments.

4 While these changes are important, we would ask
5 the Commission and others to consider payment revisions
6 that do not force patients to choose between a potentially
7 addictive opioid and a non-opioid alternative device due to
8 financial concerns, by promulgating policies that maintain
9 the same copay for both types of treatments.

10 Thank you.

11 DR. CROSSON: Thank you for your comment.

12 MR. INGOGLIA: Hi. Good morning. My name is
13 Chuck Ingoglia. I'm the Executive Director of the
14 Partnership for Part D Access. And I'd like to talk a
15 little bit this morning about an issue that the Commission
16 has discussed before, mainly Medicare's six protected
17 classes. And this issue is especially relevant today as
18 the Commission, in 2016, made recommendations on the
19 protected classes that have been incorporated into a
20 proposed rule that was recently released by CMS.

21 Our partnership represents patients from all over
22 the six relevant classes, and we've been curious to --

1 there's been a lot of discussion that the six protected
2 classes prevent management of the drugs within these
3 classes, and so we commissioned Avalere to take a look at
4 this. And despite the statutory requirements that all
5 drugs in the protected classes be covered, the analysis
6 conducted by Avalere, based on 2016 Part D claims data,
7 showed that, on average, just 67 percent of available drugs
8 from protected classes are actually being covered, and just
9 60 percent of brand drugs.

10 Also, contrary to the notion that plans are
11 limited in their ability to manage utilization, the data
12 shows that plans consistently use prior authorization, step
13 therapy, and tiering to encourage the use of lower-cost
14 drugs. In fact, Avalere found that 39 percent of
15 medications in the protected classes are subject to some
16 form of medication management, and the data also show that
17 91 percent of prescriptions filled within the Part D
18 program are for generic products.

19 We believe the data compiled by Avalere calls
20 into the question the MedPAC recommendations to eliminate
21 coverage for certain classes of medications within the
22 protected classes, as well as the administration's recently

1 proposed change to the policy.

2 On behalf of the patient communities who rely on
3 the protected class policies, we ask you to consider this
4 data and to rescind your previous recommendation.

5 Thank you.

6 DR. CROSSON: Thank you for your comment. Seeing
7 no further guests at the microphone we are adjourned until
8 1:15.

9 [Whereupon, at 11:54 a.m., the meeting was
10 recessed, to reconvene at 1:15 p.m. this same day.]

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AFTERNOON SESSION

[1:15 p.m.]

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3 DR. CROSSON: Okay. I think we can sit down and
4 get going now. For the benefit of our guests, this is the
5 portion of our meeting in January, actually it is the
6 portion of our year where the Commission votes on
7 recommendations primarily to the Congress for updates to
8 various portions of the Medicare provider world for fiscal
9 year 2020.

10 For those of you who were not present at our
11 December meeting or have been here before, we will have two
12 sorts of presentations and votes based upon the December
13 discussion to the extent that the draft recommendation that
14 was presented at that time was broadly accepted by the
15 Commission. We'll have short presentations and proceed
16 without debate to vote.

17 In the case where the Commissioners had a
18 prolonged discussion and in many cases asked for more
19 information to be presented, the presentation will be
20 longer. There will be a discussion and then the vote
21 following that.

22 So we're going to proceed with the first

1 presentation, which is on the update to hospital inpatient
2 and outpatient payments, as well as a discussion about a
3 way of rewarding hospital performance. And Stephanie,
4 Ledia, and Jeff are here, and Stephanie has got that look
5 in her eye like she's going to start.

6 MS. CAMERON: Good afternoon. We are back today
7 to continue our discussion of the adequacy of Medicare
8 payments to short-term acute-care hospitals and review our
9 work in redesigning Medicare's hospital quality incentive
10 programs. We will provide you with a draft recommendation
11 for hospital quality reporting and updating the hospital
12 payment rates for 2020.

13 To start with our assessment of hospital payment
14 adequacy, as you'll recall, using MedPAC's common framework
15 we examine beneficiaries' access to care, providers' access
16 to capital, and the quality of care provided in hospitals.
17 We also examine hospital payments and costs, including
18 Medicare and efficient provider margins for 2017, and we
19 project an aggregate Medicare margin for 2019.

20 As we discussed in December and included in your
21 mailing materials, the draft update recommendation would
22 affect about \$190 billion in Medicare fee-for-service

1 spending. This includes \$118.6 billion in inpatient
2 payments and about \$65.5 billion in outpatient payments.
3 Forty-seven hundred hospitals account for about 10 million
4 inpatient admissions and about 2 million outpatient visits.

5 To summarize our payment adequacy findings that
6 we provided in detail last month and also, again, included
7 in your mailing materials, access to care is good. Use has
8 increased since 2016, and there is excess hospital capacity
9 in aggregate.

10 Access to capital remains strong with close to
11 record-high all-payer margins and high levels of bond
12 issuance.

13 At the same time, quality metrics are improving,
14 with mortality rates declining and patient experience
15 improving.

16 Medicare margins were negative 9.9 percent in
17 2017, and if current law holds, we would expect slightly
18 more negative Medicare margins in 2019 compared with 2017,
19 even for the relatively efficient providers.

20 Based on the payment adequacy analysis, the draft
21 recommendation seeks to balance several imperatives. This
22 includes: maintaining pressure on providers to constrain

1 costs to improve long-term program sustainability,
2 minimizing differences in payment rates across sites of
3 care consistent with our site-neutral work, moving Medicare
4 payments toward the cost of efficiently providing high-
5 quality care, and rewarding high-performing hospitals.
6 Clearly there are tensions between these objectives that
7 require a careful balance in the draft recommendation.

8 The draft recommendation thus includes two parts:
9 first, providing acute-care hospitals with a substantial
10 payment update, relative to prior years; and, second,
11 provide additional funds to hospitals for their performance
12 under the hospital value incentive program which Ledia will
13 now discuss.

14 MS. TABOR: The Commission contends that Medicare
15 payments should not be made without considering the quality
16 of care delivered to beneficiaries and has recently
17 formalized a set of principles for quality measurement in
18 the Medicare program.

19 Based on these principles, in our June 2018
20 report to the Congress we examined the potential to create
21 a single outcomes-focused, quality-based payment program
22 for hospitals -- that is, the hospital value incentive

1 program, or HVIP. The HVIP links payment to quality of
2 care to reward hospitals for providing high-quality care to
3 beneficiaries.

4 Last month, the Commission discussed recommending
5 to the Congress to implement the HVIP with increased
6 payments from the difference between the Commission's
7 update recommendation for acute-care hospitals and the
8 amount specified in current law. This approach rewards
9 hospitals providing higher-quality care, as opposed to all
10 hospitals.

11 The HVIP design and modeling I'll review today
12 includes the enhanced HVIP payments that are part of the
13 draft recommendation you'll review at the end of the
14 presentation.

15 Over the past cycle and a half, the Commission
16 has overall supported the HVIP and asked that we continue
17 to move forward with a recommendation to the Congress. As
18 some of the Commissioners have described, the devil will be
19 in the details of how policymakers implement the HVIP, but
20 in general, the HVIP should align with the Commission's
21 principles for quality measurement.

22 As illustrated on the left-hand side of the

1 slide, the HVIP would combine the current HRRP, VBP, and
2 HACRP into one program, and eliminate the IQRP which is an
3 obsolete pay-for-reporting program. Two of these programs
4 reduce hospital payments for poor performance with design
5 elements that do not align with the Commission's
6 principles. Removing these two programs would increase
7 payments to hospitals by about a billion dollars in
8 aggregate. Instead, the new and improved payment program
9 would increase or decrease hospital payments using the
10 design elements described on the right-hand side of the
11 slide.

12 The HVIP would incorporate population-based
13 outcome, patient experience and value measures. We modeled
14 the HVIP using five existing, all-condition quality measure
15 domains: readmissions, mortality, spending, patient
16 experience, and hospital-acquired conditions (or infection
17 rates).

18 Per the Commission's principles, the HVIP would
19 translate quality measure performance to payment using
20 clear, prospectively set performance standards. The HVIP
21 also accounts for differences in provider populations
22 through peer grouping.

1 Similar to the current VBP, the HVIP would
2 redistribute a pool of dollars to hospitals based on their
3 performance.

4 I'll briefly review the scoring methodology we
5 used to model the HVIP, starting with how measure
6 performance is converted to HVIP points.

7 One of the Commission's principles is that
8 Medicare quality programs should reward providers based on
9 clear and prospectively set performance targets. So
10 hospitals will know ahead of time what performance they
11 need to achieve on each measure to receive HVIP points and
12 payments.

13 In our HVIP modeling, hospitals earn points for
14 their performance on quality metrics based on a continuous
15 scale, starting at zero points and up to ten points.

16 Medicare can define the performance scale using
17 different methods. For our modeling we set the scale along
18 a broad distribution of historical data so that most
19 entities have the opportunity to earn credit for their
20 performance. A hospital's total HVIP score is the average
21 of all of its points across the five measure domains.

22 We accounted for differences in the social risk

1 factors of different hospital patient populations through
2 peer grouping as opposed to adjusting measure results
3 because adjusting measure results can mask disparities in
4 clinical performances.

5 In peer grouping, to convert HVIP points to
6 payment adjustments, we use the same performance-to-points
7 scale across all groups, but each peer group has its own
8 pool of dollars and has its own multiplier, which is the
9 "percentage adjustment to payment per HVIP point." Like
10 the performance-to-points scale from the previous slide,
11 each peer group's payment multiplier is prospectively set
12 and known by hospitals.

13 We modeled the HVIP where quality-based payments
14 are distributed to hospitals within ten peer groups. Each
15 peer group has about the same number of hospitals, and
16 those hospitals have about the same share of Medicare
17 patients that are fully dual-eligible beneficiaries.

18 In our model, the hospitals in the group serving
19 more dual-eligible beneficiaries have a larger percentage
20 increase in payments per HVIP point, so those hospitals
21 receive a larger adjustment to their points for higher
22 performance.

1 Each peer group has an enhanced pool of dollars
2 which is distributed to hospitals within the peer group
3 based on the HVIP points each hospital earns.

4 The pool of dollars will be made up of two
5 sources. First, the HVIP would be built on a withhold
6 amount from each of the hospitals in the peer group. The
7 VBP currently uses a 2 percent total base payment withhold,
8 but the Commission has also discussed transitioning or
9 beginning with a 5 percent withhold amount.

10 The second source for the pool of dollars is part
11 of the current law payment update. For modeling the HVIP,
12 we assumed that 0.8 percent of the total hospital payment
13 update, which applies to both inpatient and outpatient,
14 would be added to the HVIP pool. This 0.8 percent roughly
15 translates to a little more than 1 percent of inpatient
16 spending.

17 So for the chapter, we modeled hospital
18 performance using a pool of dollars based on a 2 percent
19 withhold and 1 percent of total base inpatient spending (or
20 a 3 percent pool), as well as a 5 percent withhold and 1
21 percent of total base spending (or a 6 percent pool).

22 Using either a 3 percent or 6 percent pool of

1 dollars in our modeling, the vast majority of hospitals
2 would receive more than their withhold because the pool of
3 dollars is enhanced by a portion of the hospital payment
4 update. Also, our HVIP modeling scores hospitals using a
5 continuous performance-to-points scale based on almost the
6 entire distribution of performance, so each hospital has
7 the potential to earn some points and be rewarded.
8 Policymakers can define the HVIP performance scale using
9 different methods, for example, around a desired value,
10 which can change the distribution of hospitals being
11 rewarded.

12 Compared with the existing programs, the HVIP we
13 modeled enhances payment adjustments for hospitals serving
14 more fully dual-eligible beneficiaries. Also, relatively
15 efficient providers receive more of a reward from the HVIP
16 compared with other hospitals.

17 So, in summary, consistent with the Commission's
18 principles, the HVIP links payment to quality of care to
19 reward providers for offering high-quality care. It also
20 rewards hospitals that efficiently deliver higher-quality
21 care.

22 The HVIP is simpler than the current four

1 overlapping programs. It uses a small set of population-
2 based outcome, patient experience, and value measures that
3 encourage providers to collaborate across the delivery
4 system.

5 Finally, the HVIP reduces the differences in
6 payment adjustments between groups of providers serving
7 populations with different social risk factors.

8 I'll now turn it back to Stephanie to discuss the
9 recommendation.

10 MS. CAMERON: Beneficiaries maintained good
11 access to care and providers continued to have strong
12 access to capital, while quality improvement continued,
13 despite negative Medicare margins for most providers.
14 Given this, the draft recommendation provides the following
15 program improvements.

16 First, the HVIP eliminates the complexity of
17 overlapping program requirements, focuses on outcomes, and
18 promotes coordination of care.

19 Second, the program accounts for differences in
20 the social risk of hospitals' patient population through
21 peer grouping.

22 Third, because the current readmissions and

1 hospital-acquired infection programs are eliminated,
2 hospital payments would increase and payments to relatively
3 efficient providers would also increase.

4 And, fourth, the update recommendation balances
5 the need to maintain access to care while maintaining
6 fiscal pressure on hospitals to control their costs, with
7 the expectation that margins will begin to increase over
8 time.

9 With that, the draft recommendation reads:

10 Congress should replace Medicare's current
11 hospital quality programs with a new hospital value
12 incentive program (HVIP) that:

13 Includes a small set of population-based outcome,
14 patient experience, and value measures;

15 Scores all hospitals based on the same absolute
16 and prospectively set performance targets;

17 Accounts for differences in patient's social risk
18 factors by distributing payment adjustments through peer
19 grouping;

20 And, for 2020, update the 2019 base payment rate
21 for acute-care hospitals by 2 percent.

22 The difference between the update recommendation

1 and the amount specified in current law should be used to
2 increase payments in a new HVIP.

3 The recommended update of 2 percent with an
4 increase in quality incentive payments would result in
5 total hospital payments that are equal to current law.
6 However, eliminating the current readmissions and hospital-
7 acquired conditions programs would remove penalties from
8 hospital payment rates and thus increase spending by
9 between \$750 million and \$2 billion in 2020 and by between
10 \$5 to \$10 billion over five years.

11 We expect the recommendation to reduce providers'
12 burden and, relative to current law, makes adjustments more
13 equitable among hospitals that serve populations with
14 different social risk factors.

15 To provide context for the draft recommendation,
16 the left-hand column of the slide reflects current law. As
17 you can see, the estimated update for inpatient and
18 outpatient rates for 2020 would be 2.8 percent if the
19 current estimates of the market basket and productivity
20 remain at the current estimated levels. Note that the 2020
21 current law update is expected to be the highest in a
22 decade as this is the first year since 2010 that hospitals

1 have not received an additional downward adjustment to the
2 update factor, as specified in law. The right-hand side of
3 this slide reflects the draft recommendation where the
4 update would be 2 percent, then an additional 0.8 percent
5 from the HVIP, and an addition 0.5 percent from the
6 elimination of the current readmissions and hospital-
7 acquired condition program. This results in an increase in
8 the Medicare payment rates to hospitals of 3.3 percent for
9 fiscal year 2020.

10 And with that, I turn it back to Jay.

11 DR. CROSSON: Thank you. Stephanie, good work.
12 Long time coming. I thank Ledia and Jeff as well.

13 We're now open for clarifying questions. Paul.

14 DR. PAUL GINSBURG: You know, given that you have
15 a precise estimate there of what the draft recommendation
16 will do as far as payment rates, how does that reconcile
17 with the range between 750 million and 2 billion in the
18 additional payments to hospitals? Or what's the basis of
19 that range?

20 MS. CAMERON: So the basis of that range comes
21 from the elimination of the current quality penalty
22 programs. We send our recommendations to the Congressional

1 Budget Office, and they provide us with those buckets. We
2 estimated kind of, you know, the fee-for-service effect to
3 be close to \$1 billion, but that is the range that we were
4 provided with. And that comes from the 0.5 percent.

5 MS. TABOR: I'd say there is a range because the
6 HAC reduction program takes away 1 percent from the lowest-
7 performing quarter of hospitals. So it depends what that 1
8 percent like what group of hospitals are actually taking
9 from, and that's true for the readmissions program, too,
10 which takes 3 percent from lowest-performing hospitals. So
11 which hospitals are which could vary by year.

12 DR. CROSSON: Is everybody clear on that? There
13 are standard ranges that we use, so if the number roughly
14 falls into a standard range, we use the standard range.

15 Okay. Other clarifying questions? Warner.

16 MR. THOMAS: Just two quick questions, and, once
17 again, I apologize. I missed the presentation you did last
18 month.

19 First of all, in the materials that were
20 provided, there's still a 0.5 percent productivity
21 reduction. Is that correct?

22 MS. CAMERON: Yes. That's the current estimate.

1 That could change as the proposed and final rules for
2 fiscal year 2020 come out. CMS uses the most recent
3 estimates at that time. Today the most recent estimate is
4 that 0.5.

5 MR. THOMAS: Was there any thought given to
6 proposing to reduce that or eliminate it given the
7 continued trend you see in the efficient hospital and total
8 inpatient margin?

9 DR. STENSLAND: Current law has the productivity
10 adjustment, but our recommendations for several years
11 haven't had a productivity adjustment. We have just said
12 the update should be X, and I think the discussion last
13 December was saying, given where we're at with all these
14 indicators, we should have a bigger increase in payments in
15 aggregate than the current law of 2.8. And that's how we
16 got down to this 3.3 percent increase in payments, which
17 is, you know, much bigger than anything that's happened in
18 recent years.

19 DR. CROSSON: So, in effect, Warner, what was
20 done is what you asked. What we have is what you asked.

21 MR. THOMAS: Yeah. I mean, I guess by
22 eliminating the current penalties, but did you think about

1 or do you know how many entities or organizations would be
2 impacted? I mean, some do not have the deducts on
3 readmission and whatnot, and you would think there would
4 probably be efficient hospitals that you reference. So
5 they wouldn't necessarily get a pickup with the elimination
6 of those programs, or would they? I mean, I'm making
7 assumptions.

8 DR. STENSLAND: If you don't have any quality
9 penalties against you now, you will not get a pickup when
10 those are eliminated, but you will benefit from the HVIP
11 because we're putting new money into HVIP.

12 MR. THOMAS: The 0.8.

13 DR. STENSLAND: The 0.8 plus the up to 5 percent
14 in the HVIP. So you could have 5.8 percent in the HVIP,
15 which would then be redistributed, and those that do well
16 no quality would get a disproportionate share of those
17 dollars because the HVIP is a pool of money where you take
18 a little bit from everybody and you distribute to the good
19 performers.

20 MR. THOMAS: Through that withhold?

21 DR. STENSLAND: Yes.

22 So the good performers are going to do better

1 under the HVIP.

2 DR. MATHEWS: The withhold and the 0.8.

3 DR. CROSSON: Brian.

4 DR. DeBUSK: Thank you for a really well-written
5 chapter and a great presentation as well.

6 I was going to ask about page 35 of the reading
7 materials. You cited some studies about this notion that
8 creating fiscal pressure constrains costs, and I noticed
9 you had a number of studies that you cited, some of them as
10 recently as 2017. It made a really compelling argument.
11 I've heard this, the cost shift argument versus the fiscal
12 constraint argument. It made a really compelling argument
13 for the fiscal constraint argument and seemed to debunk the
14 cost-shifting argument.

15 Is there a similar body of literature out there?
16 I mean, if we wanted to make the opposite argument, are
17 there a set of articles we could use that are sort of in
18 the equal and opposite direction here, or is this being
19 presented to us as largely settled research now? That the
20 fiscal constraint argument has won out over the cost-
21 shifting argument?

22 DR. STENSLAND: There was one recent cost-shift

1 paper -- and I can't remember -- that came out recently
2 arguing that there was some cost shift.

3 But for a long time, most of the economics
4 literature has suggested that there isn't a cost-shift
5 effect. Most of the economics literature has said that
6 basically it kind of comes down to the providers would
7 rather have the money go to them than stay with the
8 insurance company, and so if they can get a higher rate,
9 they generally will like that.

10 DR. DeBUSK: So it's largely settled research
11 now, at least in the opinion of this Commission?

12 DR. STENSLAND: I think so. You can ask
13 everybody else around the table. I don't know if everybody
14 would agree, but I think at least the literature is kind of
15 going in that way. Maybe David would have comments on that
16 too.

17 DR. GRABOWSKI: I agree with Jeff here that most
18 of the economic research on this topic is sort of debunked,
19 but cost-shifting stories, I'm not a big believer in that.
20 I know Jon sort of touched on this as well earlier.

21 DR. DeBUSK: Okay, great.

22 Then the second question I had, these relatively

1 efficient hospitals -- and I think David actually mentioned
2 this in our last public meeting, we set up a screener that
3 includes things like cost, and then on the next page, on
4 page 38, we report, lo and behold, these efficient
5 hospitals have lower costs. Well, they were screened on
6 having lower costs. It's a circular reference.

7 I was sort of critical of that. David, I think
8 you were the one who mentioned that in the last public
9 meeting.

10 When I got my reading materials, I was playing
11 with something. If you look at your screener and you just
12 assume by random chance, these 2,151 hospitals are going to
13 fall in a spectrum.

14 Statistically speaking, 476 of them should
15 qualify, if these were just random variables based on your
16 screen, and in practice, we only get, I want to say, 291
17 that qualify.

18 I'm really warming up to the screener. I mean, I
19 really like what you're doing here, but I think in future
20 work -- I'm thinking through. Have we looked at the
21 deviation from the statistical expectations of what we
22 should see from this group?

1 For example, if we said, well, we screened on
2 cost, we would expect them to be 8 percent lower, and
3 they're not 8 percent lower. They're 13 percent lower.
4 Have we looked at the statistics around the bias that we've
5 introduced into our screener?

6 Perhaps the longest Round 1 question ever. Sorry
7 about that.

8 DR. STENSLAND: Not recently.

9 We could do something like that. It would be
10 somewhat complicated because the screener says you can't be
11 bad on any of these things in any of the prior three years.

12 What we do that's differently from a lot of the
13 other analysis you'll see that will come out in kind of the
14 more popular press and they'll say these are the best
15 hospitals or the most efficient hospitals -- and they'll
16 look for the hospitals in 2018, which they say are the most
17 efficient. They'll look at 2018 costs and say these are
18 the most efficient hospitals.

19 That's not what we do. We say, well, let's look
20 at who looks good from '14 to '16, and if they looked good
21 in '14 to '16, we'll call them the efficient group. And
22 then we'll look at their 2017 costs. So the costs that

1 we're judging them on are from a year that are different
2 from the costs that we screen them on in order to avoid
3 them getting into the good group just by random variation.

4 So if they were in that good group just by random
5 variation and there wasn't any serial correlation, you
6 would expect them in the next year not to be anything
7 different from the average, but that's not what we find.
8 So the whole idea is to screen on one set of years and then
9 look at the performance in a different set of years that's
10 separate.

11 DR. DeBUSK: So is this a relatively stable group
12 of 291 hospitals, then? Do the members change that much
13 from year to year?

14 DR. STENSLAND: I would call it relatively
15 stable, but there are definitely people that are going to
16 go in and out because you only need one bad year to go out.

17 So if you're a hospital and you close a wing one
18 year and so you write off all that expense for that wing,
19 you're not going to make it in the efficient group just for
20 that one thing that you did in that one year.

21 We're not really trying to be definitive of
22 saying this exact group is the best hospitals. We're just

1 trying to say that if you do operate relatively
2 efficiently, what kind of indicator do we have in terms of
3 what kind of margins you would end up with?

4 DR. DeBUSK: Okay.

5 And with Warner's observation -- I guess it was a
6 year ago -- that the relatively efficient providers had
7 slipped into negative margins, do we have any way of
8 assessing? Does HVIP fix that? Is it close? Have we
9 modeled it?

10 DR. STENSLAND: I think what we expect to happen
11 is their margins have been going down, and we think between
12 the total increase in money that we have going in of 3.3
13 percent, we think it will start moving their margins back
14 up, maybe not up to zero for the efficient providers, but
15 they should be moving upward, start moving upward in 2020
16 because that's when this would take effect.

17 In terms of the HVIP, the HVIP dollars, we're
18 redistributing all these dollars, and the top performers,
19 the efficient providers are going to do better under the
20 redistribution because they just tend to have mortality,
21 lower readmission. They do better on HVIP. So they do
22 better on that, but they're also the ones, as Warner put it

1 out, that aren't going to gain as much from the elimination
2 of the current penalties because these efficient providers
3 are also the ones that aren't getting so much of the
4 current penalties that we're eliminating. So, on net, they
5 do a little bit better, but it's not a huge movement for
6 the efficient providers. So that makes sense.

7 DR. MATHEWS: Brian, if I could just add one
8 thing to what Jeff said -- and I agree completely with
9 everything that he just recited, but to your initial point
10 about whether or not there is something of a tautology here
11 and that we're identifying low-cost providers and -- or
12 relatively low-cost providers and relatively high-quality
13 providers and calling them efficient and then we say, lo
14 and behold, they happen to be relatively low cost and
15 relatively high quality, there's a little bit of that.

16 But the main point of the exercise is to
17 demonstrate the range of performance and to sort of scope
18 out what we can expect in a best-case scenario, even under
19 current levels of Medicare payments.

20 So this is saying that within the 4,000
21 hospitals, the 2,100, whichever composes our base group for
22 this analysis, that there is a subset that can, indeed,

1 perform X percent better on quality and with Y percent
2 lower cost, relative to other hospitals, even at current
3 levels of Medicare payments.

4 DR. DeBUSK: Again, we're really warmed up to
5 this concept because, at first, I had dismissed it as a
6 circular reference, and I get it now.

7 DR. MATHEWS: Yeah.

8 DR. DeBUSK: That as long as you're looking at
9 how they deviate versus the statistical expected value,
10 then you've got something.

11 It would be interesting to see how this group
12 stratifies by SES too, though, just to make sure they're
13 not all rich.

14 DR. CROSSON: Did I saw Jaewon? Then Pat and
15 Bruce.

16 DR. RYU: Yeah. I just had a confirming question
17 as far as how this impacts ACO benchmarking. I think the
18 benchmarking is always normalized for payment updates. Is
19 that right? But given that you're changing the HVIP with
20 the peer grouping, if you move to a regional benchmark, the
21 mix of what kinds of peer-group hospitals are in your
22 region, now that payment update changes.

1 So I'm just wondering how that would impact, or
2 have we thought that through?

3 DR. STENSLAND: Yeah. The dollars will be -- the
4 relative benchmarks for each of the region will reflect
5 these things. So you'll have a higher benchmark, to a
6 degree, in the regions, where they're getting more HVIP
7 payments.

8 But all the ACOs, the payments that they are
9 going to be giving to the hospitals are all going to be
10 higher. So the benchmarks and the payments, they'll
11 synchronize, so there won't be any ill effects.

12 DR. CROSSON: Pat.

13 MS. WANG: You went through this in December, but
14 can you again just talk about cash flow and revenue
15 certainty in this?

16 So this is the recommendation for 2020. If I'm a
17 hospital and I'm budgeting, I know I'm getting 2 percent.
18 When is my performance on HVIP known to me? Is what's
19 being recommended for 2020 based on a past period but under
20 a new formulation? Do you know what I'm saying? It's
21 like, How do I know how much money I'm actually going to
22 have?

1 MS. TABOR: I'll start off.

2 So with the HVIP, as far as having these clear,
3 absolutely, prospectively set performance targets, Congress
4 and CMS would have to act pretty fast to get this
5 implemented in a way that gives hospitals enough time to
6 know what their targets are and what their payment
7 adjustment would be before it's implemented.

8 MS. WANG: So the new HVIP would be perspective,
9 but a hospital wouldn't know how they would perform until
10 after the measurement period is completed, right? What are
11 they getting paid until an actual HVIP award is calculated?

12 DR. STENSLAND: Yeah. You would know what your
13 payments are at the start of the year, but what your
14 payments are at the start of the year would be based on
15 some prior year's performance under the HVIP.

16 So you're kind of thinking, "I'm coming up to
17 this Year X," and CMS would say, "To reach whatever HVIP
18 performance number of points are, you're going to have to
19 score this big in this coming year." So you know how much
20 you have to score to get a certain number of points and
21 then have a certain adjustment in your payments, but that
22 adjustment in your payments will happen in a future year.

1 So there's kind of like two things that are
2 looking forward. You're looking forward in the short range
3 to say how well do I have to score to get a certain number
4 of points, and then you'll know once I get those points in
5 this year, then in a future year that will affect my
6 payments.

7 So they'll know their payments at the beginning
8 of the year. They'll know their rates.

9 MS. WANG: But for startups, since this is a
10 recommendation for 2020, there will be a lag in that
11 certainty until the new HVIP program catches up. Yeah?

12 MS. TABOR: There would be, but I guess we'll
13 just have to use more historical data.

14 But the way we kind of played it out, again, if
15 Congress and CMS acted fast, this could be implemented by
16 2020. But it would have to be done fast.

17 DR. CROSSON: Bruce.

18 DR. PYENSON: A related question. The withhold
19 could be administered on a prospective basis, so everybody
20 would have a 2 percent or 5 percent lower payment for the
21 year. And that would flow into some future year
22 distribution.

1 MS. TABOR: That's right.

2 The VBP currently functions this way. It uses
3 what 2 percent of prospective spending is and applies it to
4 all the claims going forward for that year.

5 DR. PYENSON: Great. Thanks.

6 Now, I wonder if you could talk a little bit
7 about the 2 percent versus the 5 percent relative to the
8 fluctuations that you see in hospitals' revenue or margin,
9 anyway. Is that consistent with the year-to-year
10 fluctuations?

11 I'm trying to get a sense of whether this is a
12 risk and fluctuations of the sort that hospitals often see,
13 or is this remarkable?

14 DR. STENSLAND: One thing to remember is we're
15 talking about 2 percent or 5 percent of the inpatient pool
16 only, so maybe this is like a 1 to 3 percent, equivalent to
17 a 1 to 3 percent shift in your margin. And that is
18 something that we see happening fairly often.

19 But I think this is enough money for the
20 hospitals to take seriously. For lots of hospitals, 2
21 percent of inpatient is still serious money. We could look
22 at our hospital people, and they'll tell you.

1 DR. PYENSON: Just a follow-up question on that,
2 if I could. I noticed the draft recommendation doesn't use
3 the 2 or 5 percent on the withhold. I'm curious. Would
4 that be decided outside the recommendation? I'm curious
5 why we didn't do that.

6 DR. MATHEWS: Yeah. I think the last time we
7 talked about this, there was no clear consensus among the
8 Commissioners as to what the right level was. There was a
9 discussion of 2. There was a discussion of 5. There was a
10 discussion of starting at 2 and moving to 5. So we've left
11 the bold-faced recommendation language a little ambiguous,
12 but we would lay this out in the supporting narrative and
13 rationale underneath the recommendation. You could do it
14 this way; you could do it that way. Here's what some of
15 the impacts might look like.

16 DR. CROSSON: Dana.

17 DR. SAFRAN: Thanks.

18 Just a terrific chapter and a great presentation.

19 I just want to go back to where Pat was going and
20 make sure I understand. Let's say we're in the scenario
21 you describe. Congress moves quickly. This gets
22 implemented. It starts in 2020. Can you just talk us

1 through if I'm a hospital, what I understand on January
2 1st, 2020, about my performance, about my payment for this
3 year, and about my incentives for performance to enhance my
4 payment for 2021?

5 MS. TABOR: So we include this as part of the
6 normal rulemaking process. Like this summer when inpatient
7 IPPS rules come out, CMS could put in place or release,
8 "Here the targets that you need to meet. Here's the
9 performance adjustment. Here's the list of all the
10 hospitals and which peer group you're in."

11 And then that would be implemented into final law
12 that fall, affecting that fall's fiscal year payment.

13 DR. CROSSON: Paul.

14 DR. PAUL GINSBURG: A question. I think this is
15 a great system, and it will hopefully incent even better
16 performance by hospitals.

17 So what happens if the performance improvement is
18 greater than what's envisioned? Do we wind up paying the
19 hospitals more and saying it was worth it because quality
20 is better, or does it somehow -- sets it budget-neutral?

21 MS. TABOR: That's a great point. So the way
22 that it is defined, again, since it is a prospective

1 system, is that if hospitals do perform better, Medicare
2 will end up paying more.

3 But one thing that we do touch on in the paper is
4 that CMS should regularly monitor what these targets are,
5 and if one year there is a lot more improvement than was
6 anticipated, they can revise the targets the following
7 year. So there is kind of a checks-and-balance system on
8 this.

9 MS. CAMERON: And I think the flip side is also
10 true. If they don't hit the performance targets, then less
11 would be paid out. So the goal is for budget neutrality.
12 The expected value there is zero, but it could go on either
13 side of that equation, depending on performance.

14 DR. CROSSON: Jaewon.

15 DR. RYU: I just wanted to follow up on the
16 earlier question on timing and mechanics of how this would
17 go. So if it got implemented on the timeline that you
18 would set, the payment would hit that next prospective
19 year, but it would be based on quality measurement that
20 would be performance year two years ago, correct? So that
21 would still be retro. The payment would be.

22 So, in some respect, you'd have a period of a

1 couple years before a hospital could really do anything to
2 change what they would be getting paid under the new HVIP.

3 MS. TABOR: That's correct.

4 But one thing I will say is that we selected
5 measures that hospitals have been paid on. We're changing
6 how they're paid on it and trying to make it a little more
7 fair and to drive improvement, but these are not brand-new
8 topics for hospitals.

9 DR. CROSSON: Okay. I saw a half a hand. Oh,
10 Round 2.

11 So we'll move into the discussion period. Put up
12 the recommendations up there. So we are on the path to
13 vote. What I'd like to do is ask those of you who want to
14 make comments to do it in the context of the
15 recommendation, support and not support; if so, reasons
16 why, as we traditionally do.

17 Warner, you're up.

18 MR. THOMAS: So, directionally, I think the HVIP
19 is a good program. I guess I -- it just comments to me,
20 and I'm not sure what it will go and the specificity behind
21 this, because obviously more details need to be worked out.
22 But I do think having some flexibility, if you need to

1 change a measure out, would be important, because obviously
2 things evolve over time.

3 I also question whether cost is a quality
4 measure, but we can probably debate that one the rest of
5 the day, so it's just really a comment.

6 I think a comment that Jim made earlier, that,
7 you know, the 0.8 is new money being put in, but it's
8 really not new money. It's taking dollars from the update
9 factor and reassigning it. So, you know -- and I think
10 that's fine, but it's not necessarily, you know, new
11 dollars that are tied to specifically this program. It's
12 taking dollars that, statutorily, we were recommending.
13 We're just allocating it in a different fashion versus just
14 giving folks an update. And I just worry about that, given
15 the information in the chapter of the trend of how Medicare
16 payments are doing versus, you know, inflation factors and
17 input factors that go into hospitals, such as drug pricing,
18 labor pricing, et cetera.

19 So I think that the concept, moving this
20 direction, is a good one. I'm just concerned about taking
21 pieces of the update factor versus, you know, maybe we take
22 the 0.5 percent that's a deduct and add that back, you

1 know, versus taking something that's the update factor and
2 reallocating it in a different way.

3 So it's not necessarily I'm against the proposal,
4 but I also think doing this for 2020 seems quick, just
5 given how we deal with other issues. This seems like it's
6 a pretty quick move. So not that it can't be done, but I'm
7 not sure actually that CMS could move quick enough to get
8 this put in place, going to Jaewon's comment that you're
9 going to be dealing with a lot of historical data, and will
10 hospitals really be able to make an impact in that short a
11 period of time, almost most are tracking all these measures
12 anyway. It's just that are the clear about what the
13 baseline is kind of going into a new program like this.

14 DR. CROSSON: Comments. Paul.

15 DR. PAUL GINSBURG: Actually, I interpreted it
16 differently, Warner. I interpreted this as yet the 0.8 is
17 going into the HVIP, but also the elimination of the
18 current quality penalties. That, to me, is, in a sense, an
19 extra half percentage point increase in the update in the
20 aggregate. So this is not just current law. This is
21 really current law plus 0.5, from my perspective.

22 MR. THOMAS: Yeah, I don't disagree with that,

1 but I think Jim's point was but the new money, the 0.8 is
2 new money. That's really not new money. That's part of
3 the updates being reallocated differently. And I get that,
4 you know, reduction of the -- or elimination of these
5 reductions, I think that that's fine. And once again, I
6 think hospitals should have to earn the dollars. There's
7 no doubt about that. I also look at -- if you look at the
8 performance of what's happening in this category,
9 especially as you compare it to the rest of the categories
10 we have that we evaluate, that we're going to be talking
11 about the rest of the afternoon, you know, I think we just
12 need to really be mindful of that when we're making these
13 types of changes.

14 DR. CROSSON: Further comments. Bruce.

15 MR. PYENSON: I want to comment the authors for
16 this. I think the tiering was really well done and I
17 support the recommendation.

18 I'm hoping we might be able to get a consensus on
19 recommending an aggressive withhold, because I think what
20 we have here is right, it creates the right incentives, it
21 has the right protections, so why not be aggressive with
22 recommendation for an attention-getting withhold.

1 DR. CROSSON: So let me hear other responses to
2 that. Dana.

3 DR. SAFRAN: So I'm really excited about this
4 program, and understanding Warner's point that this does
5 involve moving pretty fast. I guess I think that's
6 appropriate in this case because we're removing some
7 programs and complexity that really aren't producing so
8 much value and are in the way. We're adding, you know, the
9 social risk factor stratification that, you know, I think
10 really solves problems that folks have been pretty vocal
11 about. And it's really good for beneficiaries and I think
12 better for providers.

13 So I think there's a lot here that really is an
14 enormous step forward and good model for both Medicare and
15 other payers, in terms of how to structure value-based
16 payment, and I'd love to see us move it quickly.

17 DR. CROSSON: Jon.

18 DR. PERLIN: Let me begin by thanking the group
19 for really thoughtful work. I want to really associate
20 with Warner's comment. I like it directionally. As
21 always, the devil is in the details, and particularly if
22 you're looking at an operating environment.

1 The way the cash flow plays out, to Pat's point,
2 I think is tremendously important, obviously, if there's a
3 lag. And the problem with the lag is that it decouples the
4 actual improvement from the reimbursement for the
5 improvement, by necessity. And so these are the things
6 that would hope we pay attention to as we figure out what
7 the implementation characteristics are.

8 So if you look at the five measure domains, we
9 had some discussion earlier today about the challenges of
10 readmission measures, generally. And, you know, we talked
11 through socioeconomic circumstances that there may be
12 difficulties for placement, and some of that gets evened
13 out, perhaps, in the dual-eligible stratification by band.
14 That's the theory.

15 But that can operate sort of like the challenge
16 with mortality, that may be insensitive to that particular
17 banding. So, for example, the hospital is a referral
18 hospital. Even if it's in an upper band it actually may
19 get patients from hospitals with much more complex
20 patients, complex socioeconomic circumstances, that have
21 one trajectory, and that trajectory is unfortunately going
22 to be death or advanced complex disease that could lead to

1 remission, my point being that it may be less amenable to
2 the management than possible.

3 The spending per Medicare beneficiary is -- you
4 know, I'm not sure what it is. It's an index but it's not
5 a quality measure and it may or may not be, for those
6 reasons, controllable. Measures generally that have been
7 in these buckets have suffered from the challenges of
8 clustering, and I think part of our guidance will have to
9 be that there's decompression. Otherwise, you can both win
10 and lose with virtually the same performance on that.

11 And in terms of the final measure, the hospital-
12 acquired conditions, we've had discussion, we had
13 discussion last time about these being extremely,
14 fortunately, rare events, but in order to have enough data
15 to have statistical validity we go further back.

16 The comment was made that in terms of linking the
17 actual performance with the reimbursement schedule that you
18 would sort of weight that nearer, but either way it's still
19 driving while taking information from the rear-view mirror.

20 So I think this is laudable but I think we really
21 have to pay attention to the components of each of the
22 measures, and step away from some of the pratfalls that

1 we're already aware of, in the context of support for the
2 general direction and the involvement of that.

3 The second is that I agree with Warner as well
4 and Pat, in the sense that we have data in our own report
5 that shows that, you know, we've got a 9.9 aggregate
6 Medicare margin -- negative 9.9 percent aggregate Medicare
7 margin, and anticipating negative 11 percent this year.
8 And so I think as this goes forward -- I see heads nodding
9 as well -- that there has to be a vehicle to fund this that
10 is different than the vehicle of updates to control for
11 cost of labor and cost of supplies, et cetera. So got
12 support on this, but I think the onus is on us, and
13 ultimately CMS, to finesse that implementation along those
14 lines. Thanks.

15 DR. CROSSON: Just a quick comment, Jon. I mean,
16 you've identified some of the natural problems in doing any
17 kind of quality assessment. The only point I'd add is that
18 the mortality is risk-adjusted. Now it may not be risk-
19 adjusted adequately but it is risk-adjusted.

20 DR. PERLIN: I mean as Lisa Iezonni wrote many
21 years ago, that's 20 percent of the variation, but there
22 are some systematic complexities. I'm a strong endorser

1 here of measures, of the buckets measurement, but, you
2 know, need to really get to the evidence base for which
3 measures -- the statistical means to actually differentiate
4 appropriately. Thanks.

5 DR. CROSSON: Further comments.

6 Seeing none, we will proceed to the vote. All
7 Commissioners in favor of the recommendation please raise
8 your hands.

9 [Show of hands.]

10 DR. CROSSON: All opposed.

11 [No response.]

12 DR. CROSSON: Abstentions.

13 [No response.]

14 DR. CROSSON: The recommendation passes
15 unanimously.

16 Stephanie, Ledia, Jeff, thank you for this work
17 and all the work that has preceded it. It's really
18 excellent. Thank you very much.

19 [Pause.]

20 DR. CROSSON: Okay. We're now going to proceed
21 to the second update recommendation. That's on payment to
22 physicians and other health professionals, and we have

1 additional recommendations relating to the payment of
2 advanced practice registered nurses and physician
3 assistants. Ariel, Brian, and Kate are here. Ariel, it
4 looks like you're going to begin.

5 MR. WINTER: Good afternoon. As Jay said, I will
6 discuss the payment adequacy assessment for physician and
7 other health professional services and present the draft
8 update recommendation for your vote.

9 Then Brian will present two draft recommendations
10 on payment policies for advanced practice registered nurses
11 and physician assistants, which you will also be voting on.
12 You saw all three of these draft recommendations last
13 month.

14 We'd like to thank Kevin Hayes, Carolyn San
15 Soucie, and Emma Achola for their help with this work.

16 We discussed our assessment of payment adequacy
17 extensively at the December meeting, so today I will be
18 focusing on highlighting some key points. There are more
19 details in your mailing paper.

20 First, some background on this sector. Medicare
21 pays for services provided by physicians and other health
22 professionals using a fee schedule. Total spending for

1 these services was about \$69 billion in 2017, or 14 percent
2 of fee-for-service spending.

3 Nine hundred eight-five thousand clinicians
4 billed Medicare in 2017. Under current law, there will be
5 no update to the fee schedule conversion factor for 2020.
6 But there is a 5 percent incentive payment for certain
7 clinician participants in Advanced Alternative Payment
8 Models.

9 We received several comments from Commissioners
10 at the December meeting, which we have addressed in the
11 paper. In addition, we have updated some of the numbers in
12 the paper.

13 I do want to focus on one issue that Kathy raised
14 at the December meeting, which is how we calculate changes
15 in the volume of clinician services. Volume growth is a
16 function of two things: changes in the number of services,
17 such as the number of imaging tests; and changes in the
18 intensity or complexity of services, as measured by RVUs,
19 or relative value units. For example, the substitution of
20 a CT scan for a plain X-ray represents an increase in
21 intensity.

22 This table shows each factor separately. From

1 2016 to 2017, across all fee schedule services, which is
2 the top row, the number of services per beneficiary grew by
3 1.3 percent, and intensity per beneficiary increased by 0.3
4 percent. The sum of these variables gives us the change in
5 volume per beneficiary of 1.6 percent.

6 The rest of the table includes examples of
7 service categories that had relatively large changes in
8 intensity. For example, the second row is the category of
9 major vascular procedures. There was no change in the
10 number of services per beneficiary, but intensity per
11 beneficiary grew by 9.5 percent. So all of the volume
12 growth was related to an increase in intensity.

13 This was because certain vascular procedures with
14 relatively high RVUs had rapid growth in the number of
15 services, and there was a corresponding decrease in the
16 number of procedures with lower RVUs.

17 To summarize our analysis, payments appear to be
18 adequate. Access indicators are generally stable. Our
19 annual telephone survey indicates that beneficiaries have
20 comparable or slightly better access to clinician services
21 than privately insured individuals ages 50 to 64. The
22 share of providers enrolled in Medicare's participating

1 provider program remains high, and the number of clinicians
2 billing Medicare per beneficiary is stable.

3 Quality is indeterminate; the ratio of Medicare's
4 payment rates to private PPO rates did not change; and
5 there was an increase in the volume of services.

6 So the draft update recommendation reads: For
7 calendar year 2020, the Congress should increase the
8 calendar year 2019 Medicare payment rates for physician and
9 other health professional services by the amount specified
10 in current law.

11 In terms of implications, there would be no
12 change in spending compared with current law, and this
13 should maintain beneficiaries' access to care and
14 providers' willingness and ability to furnish care.

15 And now I'll hand things over to Brian.

16 MR. O'DONNELL: So, switching gears a bit, I'll
17 now discuss Medicare's payment policies for NPs and PAs.
18 The Commission discussed this topic in depth in October and
19 December. What follows today is a brief summary of the
20 materials discussed in those meetings.

21 NPs are the largest subgroup of APRNs and are
22 registered nurses who have additional training, most

1 commonly a master's degree.

2 Similarly, PAs must graduate from a PA
3 educational program, which is generally a post-
4 baccalaureate master's.

5 The number of NPs and PAs billing Medicare has
6 increased rapidly over the last several years.

7 For example, from 2010 to 2017, the number of NPs
8 that billed the Medicare program increased from
9 approximately 52,000 to 130,000, an average annual increase
10 of 14 percent.

11 In addition to their growing number, NPs and PAs
12 increasingly practice in specialties other than primary
13 care.

14 The result of these two trends is that NPs and
15 PAs perform a larger number and a greater variety of
16 services for Medicare beneficiaries than in the past.

17 NP and PA services can be billed in two different
18 ways under Medicare.

19 They can be billed directly. Under this option,
20 NP and PA services are billed under their own NPIs, and
21 Medicare pays 85 percent of fee schedule rates.

22 The same services can also be billed under

1 Medicare's "incident to" rules. In this case, NP and PA
2 services are billed under a physician's NPI, and Medicare
3 pays 100 percent of fee schedule rates.

4 In your mailing materials, we walk through a list
5 of potential motivations to eliminate "incident to" billing
6 for NPs and PAs, and it's worth noting a few here.

7 At a very basic level, "incident to" billing
8 limits transparency by obscuring policymakers' knowledge of
9 who is actually providing care for Medicare beneficiaries.

10 "Incident to" billing could also inhibit accurate
11 valuation of fee schedule services and increase Medicare
12 and beneficiary spending.

13 It's also worth noting that eliminating "incident
14 to" billing would not affect the services NPs and PAs can
15 perform. Even if "incident to" billing were eliminated,
16 the decision about what services these clinicians can
17 perform would continue to be the province of states and the
18 physicians with whom they practice.

19 Given these issues with "incident to," the first
20 draft recommendation related to APRNs and PAs reads: The
21 Congress should require APRNs and PAs to bill the Medicare
22 program directly, eliminating "incident to" billing for

1 services they provide.

2 In terms of implications for spending, the draft
3 recommendation is expected to reduce program spending
4 between \$50 million and \$250 million over one year and
5 between \$1 billion and \$5 billion over five years compared
6 with current law.

7 The draft recommendation would also reduce
8 beneficiaries' financial liabilities and is not expected to
9 adversely affect their access to care.

10 In terms of effects on providers, revenues for
11 some practices that employ APRNs and PAs would decline.

12 In addition, APRN and PA services would be billed
13 under their own NPIs instead of physicians' NPIs, which
14 would improve Medicare's data on who furnishes care to
15 beneficiaries.

16 The next issue to discuss is the specialties in
17 which NPs and PAs practice.

18 NPs and PAs have historically been concentrated
19 in primary care. However, they increasingly practice
20 outside of primary care, in specialties such as dermatology
21 and orthopedics. Recent estimates suggest that only half
22 of NPs and around a quarter of PAs practice in primary

1 care.

2 Despite the variety of specialties in which they
3 practice, Medicare has limited specialty information for
4 these clinicians. For instance, Medicare groups all NPs
5 into one specialty.

6 This lack of specialty information can create
7 issues, such as limiting Medicare's ability to target
8 resources towards areas of concern, such as primary care,
9 and inhibits the operation of programs that rely on
10 identifying primary care providers.

11 Given these issues, the next draft recommendation
12 reads: The Secretary should refine Medicare's specialty
13 designations for APRNs and PAs.

14 The draft recommendation is not expected to
15 substantially affect program spending, beneficiaries'
16 access to care or financial liabilities, or provider
17 revenues.

18 This last slide summarizes the three draft
19 recommendations that Ariel, Kate, and I discussed today.

20 With that, we look forward to your comments, and
21 I turn it back to Jay.

22 DR. CROSSON: Thank you. Very clear.

1 I think for purposes of efficiency and also based
2 on my memory of a reasonable degree of consensus here,
3 we'll take all of these recommendations together, both in
4 terms of Round 1 and Round 2. So clarifying questions?
5 Marge.

6 MS. MARJORIE GINSBURG: I think this is a
7 clarifying question. One of the arguments made for getting
8 rid of the "incident to" is that it was sort of mucking up
9 the information about who do we attribute this service to
10 in terms of checking for quality of care and things like
11 that. Isn't there a way of changing -- or is there a way
12 of changing the recording so you're actually separating out
13 the provider who provided the care from the billing for
14 that particular care? Maybe I'll throw this all together.
15 The reason I say that is I'm a little concerned about doing
16 away with the "incident to" for primary care providers, and
17 the reason is solely a financial one. We're all struggling
18 with how do we maintain adequate income for primary care
19 physicians, and if they're possibly making a little money
20 by hiring NPs to do the work and that's fattening their
21 pocketbook a little bit, that may not necessarily be a bad
22 thing. So I'm sorry, I sort of have two comments here.

1 The first one is: Isn't there a way of
2 separating out who's providing the service from how the
3 service is being billed?

4 MS. BLONJARZ: Sure, you could do that. You
5 could have like a performing provider, rendering provider,
6 billing provider, have it be all separate, and have the
7 payment amount attached to one of the other categories.

8 MR. WINTER: The other thing I would say is that
9 -- so one of the arguments we make is that if you're
10 looking to kind of put money into primary care, this is a
11 really inefficient way to do it, because a lot of them
12 practice outside of primary care. But I think putting our
13 two recommendations together, we're saying, okay, we're
14 getting rid of "incident to," but we're also allowing the
15 program to identify, let's say, NPs that work in primary
16 care. So that if in the future the program wanted to put
17 money into primary care more accurately, it could do so.

18 DR. CROSSON: Other questions?

19 [No response.]

20 DR. CROSSON: We'll move on then to comments,
21 again, directed towards the slide, comments of support,
22 lack of support, for any or all of the recommendations?

1 [No response.]

2 DR. CROSSON: Seeing no comments -- and I think,
3 again, for purposes of efficiency, since there doesn't
4 appear to be a significant amount of debate, we'll take all
5 of the recommendations together. So all Commissioners in
6 favor of the recommendations, please signify by raising
7 your hand?

8 [Show of hands.]

9 DR. CROSSON: All opposed?

10 [No response.]

11 DR. CROSSON: Abstentions?

12 [No response.]

13 DR. CROSSON: The recommendations collectively
14 pass unanimously. Thank you, Ariel, Kate, and Brian, for
15 excellent work again.

16 [Pause.]

17 DR. CROSSON: Now we're going to proceed into the
18 part of the afternoon where we do update recommendations
19 and voting based on expedited presentations and expedited
20 voting. And we've got Dan and Zach here. Three of you?

21 Okay. Kim, are you just visiting or are you --

22 MS. NEUMAN: No. Hospice will be next.

1 DR. CROSSON: Oh, wait a minute. Did I mess up
2 something here?

3 DR. MATHEWS: No. You're good.

4 DR. CROSSON: Yeah. Wait a minute. Oh, we're
5 doing both? Hang on. Sorry. Sorry. Oh, and hospice.
6 All right. Sorry about that.

7 Yes, well, getting back to it, Dan, are you going
8 to present the ASC recommendation?

9 MR. ZABINSKI: I am.

10 All right. At the December 2018 meeting, we
11 presented update information for ambulatory surgical
12 centers and provided draft recommendations. In your
13 updated draft chapter we have added text in response to
14 Commissioner comments from the December meeting. For Sue,
15 we added text about the rate at which rural beneficiaries
16 receive care in ASCs. Bruce, we added a discussion about
17 which services covered under the ASC payment system are
18 often provide in physician offices. Dana, we added text
19 that the measures in the ASC quality reporting program
20 should be synchronized with the measures in the hospital
21 outpatient quality reporting program. And for Kathy we
22 added discussion about developing new quality measures that

1 rely on specialty-specific clinical guidelines to assess
2 the appropriateness of specific services provided in ASCs.

3 Facts about ASCs in 2017, are that Medicare
4 payments to ASCs were nearly \$4.6 billion, the number of
5 Medicare-certified ASCs was about 5,600, and 3.4 million
6 fee-for-service beneficiaries were served in ASCs.

7 We find that beneficiaries' access to ASC
8 services is improving. In 2017, we found a volume per fee-
9 for-service beneficiary increased 1.7 percent, the number
10 of fee-for-service beneficiaries served increased by 0.4
11 percent, and the number of ASCs increased by 2.4 percent.
12 In addition, Medicare payments per fee-for-service
13 beneficiary increased by a healthy 7.7 percent.

14 The growth in the number of ASCs suggests that
15 the access to capital is good. Also, there has been a fair
16 amount of acquisitions and partnerships with ASCs by
17 hospital groups and other health care companies, which
18 requires access to capital.

19 The measures of payment adequacy showed slight
20 improvement from 2013 through 2016, but issues with the
21 quality measures remain. We believe that CMS should add
22 more claims-based outcomes measures, and we are concerned

1 about CMS's decision to delay use of the CAHPS-based
2 patient experience measures.

3 Finally, a limitation of our analysis is that we
4 cannot assess margins or other cost-based measures because
5 ASCs don't submit cost data. Even though the Commission has
6 recommended on several occasions that these data should be
7 submitted.

8 So for the Commission's consideration today we
9 have the following draft recommendation: The Congress
10 should eliminate the calendar year 2020 update to the
11 conversion factor for ambulatory surgical centers.

12 Given our findings of payment adequacy and our
13 stated goals, eliminating the update is warranted. This is
14 consistent with our general position of recommending
15 updates only when needed. The implication of this
16 recommendation for the Medicare program is that it would
17 decrease spending relative to current law by \$50 million to
18 \$250 million in the first year and by less than \$1 billion
19 over five years.

20 We anticipate this recommendation having no
21 effect on beneficiaries' access to ASC services or
22 providers' willingness or ability to furnish those

1 services.

2 In a second draft recommendation, we have that
3 the Secretary should require ambulatory surgical centers to
4 report cost data.

5 The importance of this recommendation is that the
6 Commission has recommended this policy several times. In
7 contrast, CMS has implemented a policy of replacing the
8 CPI-U as the basis for updating ASC conversion factor with
9 the usually higher hospital market basket for a five-year
10 period, without a firm commitment to collecting cost data
11 from ASCs.

12 Collecting cost data, as Medicare does for other
13 providers, would improve the accuracy of the ASC payment
14 system. The Secretary could limit the burden on ASCs by
15 using a streamlined system of cost submission. Implementing
16 this recommendation would not change Medicare program
17 spending. We also anticipate no effect on beneficiaries.
18 However, ASCs would incur some added administrative costs.

19 Now Kim will cover hospice.

20 DR. CROSSON: Yeah, if I'd ask you to hold, I
21 mean, I think -- I'd like to do one at a time, if we could.
22 Sorry.

1 So based on the judgment we made in December
2 about the relative degree of support here and the decision
3 to use expedited voting, I would invite questions or
4 comments specifically on the changes that were delineated,
5 or the additions that were delineated in the beginning of
6 the presentation.

7 [No response.]

8 Seeing none, we will proceed to vote and we'll
9 vote on both recommendations simultaneous.

10 All in favor of draft recommendation 1 and 2
11 please raise your hand.

12 [Show of hands.]

13 DR. CROSSON: All opposed.

14 [No response.]

15 DR. CROSSON: Abstentions.

16 [No response.]

17 DR. CROSSON: Seeing none, both pass unanimously.

18 Okay. Sorry, Kim. Now we can -- yeah.

19 MS. NEUMAN: Good afternoon. I'm going to review
20 indicators of hospice payment adequacy that we discussed at
21 the December meeting and that's described in detail in your
22 mailing materials.

1 We revised the materials based on your December
2 conversation. For example, Jonathan, we added information
3 on hospice days by level of care and hospice provider
4 characteristics. David, we added the issue of higher
5 margins among providers treating patients in nursing
6 facilities and assisted living facilities.

7 So a few key facts about hospice. In 2017, about
8 1.5 million Medicare beneficiaries used hospice services,
9 including more than half of beneficiaries that died that
10 year. Nearly 4,500 Medicare hospice providers furnished
11 services to those beneficiaries, and Medicare paid those
12 hospices about \$17.9 billion.

13 So now we'll look at our indicators of payment
14 adequacy which are strong. The supply of hospice providers
15 continues to grow, increasing about 2.4 percent in 2017.
16 For-profit providers account entirely for the net growth in
17 the number of providers.

18 Hospice use also increased. The share of Medicare
19 decedents using hospice exceeded 50 percent for the first
20 time in 2017. The number of hospice users, number of
21 hospice days, and average length of stay among decedents
22 also increased. Marginal profit in 2016 was 14 percent,

1 which suggests providers have an incentive to accept new
2 Medicare patients.

3 Quality data are available and scores are high,
4 but there is concern that the process measures are topped
5 out. In terms of access to capital, the continued growth
6 in the number of providers suggests that capital is
7 accessible.

8 So this brings us to margins, and as you will
9 recall, margin estimates assume cap overpayments are fully
10 returned to the government and exclude non-reimbursable
11 bereavement and volunteer costs. For 2016, we estimate an
12 aggregate Medicare margin of 10.9 percent. For 2019, we
13 project an aggregate Medicare margin of 10.1 percent.

14 On the basis of these positive payment adequacy
15 indicators, we have the draft recommendation, which reads:
16 For 2020, Congress should reduce the fiscal year 2019
17 Medicare base payment rates for hospice providers by 2
18 percent.

19 The implications of this recommendation are a
20 decrease in spending relative to the statutory update of
21 between \$750 million and \$2 billion over one year and
22 between \$5 billion and \$10 billion over five years.

1 In terms of implications for providers and
2 beneficiaries, given the margin in the industry and our
3 other payment adequacy indicators, we anticipate that the
4 aggregate level of payments could be reduced by 2 percent
5 in 2020 and would still be sufficient to cover providers'
6 costs. So this draft recommendation is not expected to have
7 an adverse impact on beneficiaries' access to care.

8 Consistent with the Commission's principle that
9 it is incumbent on Medicare to maintain financial pressure
10 on providers to constrain costs, this draft recommendation
11 would increase financial pressure on providers but it is
12 not expected to affect their willingness or ability to care
13 for beneficiaries.

14 So with that I'll turn it back to Jay.

15 DR. CROSSON: Thank you, Kim. Before we proceed
16 with voting I want to correct the record. The previous
17 recommendation was not passed unanimously. A Commissioner
18 was absent. Sixteen members voted in the affirmative, one
19 will be recorded as not voting.

20 We will proceed to vote on the draft
21 recommendation for hospice services. All Commissioners in
22 favor of the recommendation please raise your hand.

1 [Show of hands.]

2 DR. CROSSON: All opposed.

3 [No response.]

4 MS. MARJORIE GINSBURG: I was talking.

5 DR. CROSSON: Okay. Abstentions, other than
6 that.

7 [No response.]

8 So we have 16 votes in the affirmative and one
9 talking, which I will count as an affirmative. Thanks very
10 much.

11 Thank you, Kim.

12 [Pause.]

13 DR. CROSSON: Just to be clear, Carol, you're
14 going to present the SNF one, and then we're going to
15 rotate presenters; is that right?

16 DR. CARTER: Yes.

17 DR. CROSSON: Okay. Sorry.

18 DR. CARTER: Are we ready?

19 DR. CROSSON: We're ready.

20 DR. CARTER: Okay.

21 In this block of presentations, we'll consider
22 the adequacy of payments for thee PAC settings: skilled

1 nursing facilities, home health agencies, and inpatient
2 rehabilitation facilities. We discussed the full
3 information for each setting in December, and you have the
4 complete papers. So each of these presentations will be
5 short. I'll start with the analysis of Medicare's payments
6 to SNFs.

7 In 2017 there were about 15,000 providers that
8 furnished services to 2.3 million beneficiaries. About 4
9 percent of fee-for-service beneficiaries used SNF services.
10 Medicare spending on fee-for-service totaled \$28.4 billion.

11 Our analysis of the adequacy of payments found
12 that indicators are mostly positive. In 2017, supply was
13 steady. Even though covered admissions and days decreased
14 between '16 and '17, these trends are consistent with the
15 decline in inpatient hospital stays that were three days or
16 longer, which is required for Medicare coverage, and with
17 expanded MA enrollment and alternative payment models,
18 which are likely to use fewer SNF services. The marginal
19 profit, an indicator of the financial incentive to treat
20 Medicare beneficiaries, was 19.1 percent.

21 Quality performance was mixed, with small changes
22 from 2016.

1 Access to capital is adequate and expected to
2 remain so. Medicare remains the providers' preferred
3 payer.

4 In terms of payments and costs, the Medicare
5 margin for 2017 was 11.2 percent, and this was the
6 eighteenth year in a row that the average was above 10
7 percent.

8 For efficient providers, those with relatively
9 low cost and high quality, the average Medicare margin was
10 18 percent, further evidence that Medicare overpays for SNF
11 care. We project the 2019 margin to be 10 percent.

12 The Commission's analysis of payment adequacy
13 often considers revisions to the payment system that would
14 improve its accuracy and equity. CMS is poised to
15 implement a revised PPS that will base payments on patient
16 characteristics, not the amount of therapy furnished.

17 The revised design is consistent with MedPAC's
18 recommendations for a SNF PPS and the PAC PPS. The changes
19 are likely to prompt many providers to revise their mix of
20 cases and cost structures, which would change the relative
21 costs of different types of stays and indicate the need for
22 the relative weights to be recalibrated.

1 In considering how payments should change for
2 2020, there are two takeaways. First, the SNF PPS
3 continues to favor the provision of therapy and needs to be
4 revised. Further, to keep payments and costs aligned, the
5 relative weights of the case-mix groups should be updated
6 annually.

7 Second, the level of payments is too high, given
8 the costs of treating beneficiaries.

9 The first draft recommendation reads: "The
10 Secretary should proceed to revise the skilled nursing
11 facility prospective payment system in fiscal year 2020 and
12 should annually recalibrate the relative weights of the
13 case-mix groups to maintain alignment of payments and
14 costs."

15 In terms of implications, relative to current
16 law, this recommendation would not change program spending.
17 The recommendation is budget-neutral to the current level
18 of spending.

19 For beneficiaries and providers, a revised PPS
20 will increase the equity of Medicare's payments for all
21 case types and help ensure access for all beneficiaries,
22 including those with medically complex conditions. We do

1 not expect the recommendation to affect providers'
2 willingness or ability to care for Medicare beneficiaries.

3 Turning to the level of spending, the second
4 draft recommendation reads: "The Congress should eliminate
5 the fiscal year 2020 update to the Medicare base payment
6 rates for skilled nursing facilities."

7 In terms of implications, spending would decrease
8 relative to current law by between \$750 million and \$2
9 billion for fiscal year 2020 and between \$5 billion and \$10
10 billion over five years.

11 For the beneficiary and provider, "Given the high
12 level of Medicare's payments, we do not expect adverse
13 impacts on beneficiaries. Providers should continue to be
14 willing and able to treat beneficiaries."

15 Now I'll turn the voting over to Jay and put up
16 both recommendations.

17 DR. CROSSON: Thank you, Carol.

18 Based again on our discussion in December and the
19 decision to proceed to expedited voting, I'll now ask for a
20 vote on these recommendations together.

21 You have the recommendations before you. All
22 Commissioners voting in favor of the recommendations,

1 please raise your hand.

2 [Show of hands.]

3 DR. CROSSON: All opposed?

4 [No response.]

5 DR. CROSSON: Abstentions?

6 [No response.]

7 DR. CROSSON: Seeing none, the recommendations
8 passed unanimously.

9 Thank you, Carol.

10 [Pause.]

11 DR. CROSSON: Okay. Evan, are you going to take
12 us through the update for home health?

13 MR. CHRISTMAN: Yes.

14 Good afternoon. We're going to look at home
15 health next. As Carol mentioned, we had a longer
16 presentation, going to summarize a longer presentation we
17 presented in December, and you also have the paper that
18 includes some revisions you requested. Please let me know
19 if you have any questions about the revisions.

20 As a reminder, Medicare spent \$17.7 billion on
21 home health services in 2017. There were over 11,800
22 agencies, and the program provided about 6.3 million

1 episodes to 3.4 million beneficiaries. And about 8.8 fee-
2 for-service beneficiaries used home health in 2017.

3 As you may recall, our indicators for home health
4 were mostly positive. Beneficiaries have good access to
5 care. The number of agencies has declined slightly, and
6 the number of episodes declined slightly in 2017. But both
7 remain relatively high, and the marginal profit in 2017 was
8 17.5 percent, indicating that home health agencies have an
9 incentive to serve Medicare beneficiaries.

10 For quality measures, we saw trends consistent
11 with earlier years. The rates of hospitalization and
12 emergency department use were unchanged.

13 The functional measures showed improvement in
14 2017, but as we discussed in December and note in the
15 paper, agency coding practices may contribute to this
16 trend.

17 Access to capital is adequate. The all-payer
18 margins in 2017 were 4.5 percent, and the financial
19 performance of this sector under Medicare is strong. And
20 these are the highest margins of any fee-for-service
21 provider you've seen this cycle.

22 Home health agencies had Medicare margins of 15.2

1 percent in 2017, and we project margins of 16 percent in
2 2019. The median margin for the efficient provider in 2016
3 was 24 percent.

4 Based on these findings, we offer the following
5 draft recommendation. The recommendation reads: "For
6 2020, the Congress should reduce the calendar year 2019
7 Medicare base payment rate for home health agencies by 5
8 percent."

9 The impact of this change would be to lower
10 spending by \$750 million to \$2 billion in 2020 and 5- to
11 \$10 billion over five years.

12 The impact to beneficiaries should be limited,
13 and we do not expect it to affect beneficiary access to
14 care, and it should not affect provider willing to serve
15 beneficiaries.

16 This completes my presentation.

17 DR. CROSSON: Thank you, Evan.

18 We'll now invite comments or questions on any of
19 the Commissioner-requested changes to the text.

20 [No response.]

21 DR. CROSSON: Seeing none, we'll proceed to the
22 vote. The recommendation is before you. All Commissioners

1 in favor of the recommendation, please signify by raising
2 your hand.

3 [Show of hands.]

4 DR. CROSSON: All opposed?

5 [No response.]

6 DR. CROSSON: Abstentions?

7 [No response.]

8 DR. CROSSON: The recommendation passes
9 unanimously.

10 Thank you, Evan.

11 I would point out parenthetically here, we've
12 made this point in general. I think after these last two
13 presentations, it's important to note that the
14 recommendation we made for acute care hospitals increases -
15 - if it's adopted, increases Medicare payment. It's more
16 than made up for -- or would be more than made up for by
17 our recommendations here in a number of post-acute care
18 settings.

19 Okay. Craig and --

20 MR. LISK: All right. What?

21 DR. CROSSON: Craig and Dana are here to talk
22 about an update to IRFs.

1 MR. LISK: Okay. Good afternoon.

2 So, last month, the Commission discussed the
3 findings from our update analysis of inpatient
4 rehabilitation facilities, and we will review those
5 findings briefly and then present the draft recommendation
6 for your consideration.

7 Just as a reminder, here is a bit of background
8 information on inpatient rehab facilities.

9 In 2017, Medicare spent \$7.9 billion on care
10 provided in about 1,180 IRFs nationwide, most of which were
11 hospital-based units that are part of acute care hospitals.

12 There were about 380,000 fee-for-service
13 beneficiary IRF stays in 2017, but because freestanding
14 IRFs tend to be larger and have higher occupancy rates,
15 slightly more than half of all cases are in freestanding
16 facilities. Slightly less than 1 percent of fee-for-
17 service Medicare beneficiaries had an IRF stay in 2017.

18 Overall, our indicators of payment adequacy are
19 positive.

20 Let's start with access. Overall, capacity
21 appears adequate to meet demand. While we saw a slight
22 decrease in the number of IRFs in 2017, the total bed

1 supply actually increased slightly.

2 The average IRF occupancy rate was 65 percent,
3 indicating that capacity was more than adequate to handle
4 current demand for services. The number of IRF discharges
5 per fee-for-service beneficiary did fall 2.4 percent in
6 2017 from 2016, however, but we see strong marginal profits
7 for both freestanding and hospital-based IRFs, indicating
8 that IRFs have an incentive to take more Medicare
9 beneficiaries that qualify for IRF-level care.

10 To assess quality of care in IRFs, we looked at
11 discharges to the community and to SNFs and readmissions to
12 the acute care hospitals. We also looked at measures of
13 improvement of motor function and cognition. We have seen
14 slight improvement in all of these measures since 2012.

15 We then considered access to capital. Hospital-
16 based IRFs have good access to capital through their parent
17 institutions. Large chains also have very good access to
18 capital. We were not able to determine the ability of
19 other freestanding facilities to raise capital, however.

20 All payer margins, though, in freestanding IRFs
21 were robust, 10.4 percent in 2017.

22 Finally, we looked at payments and costs.

1 Payments have been rising faster than costs on average over
2 the past five years, leading to a health Medicare aggregate
3 margin in 2017 of 13.8 percent. We expect the cost growth
4 is likely to exceed payment growth in 2018 and 2019, and so
5 we've projected that the aggregate margin will fall to 11.6
6 percent in 2019.

7 In 2020, IRF-based payment rates are slated to
8 increase by 2.7 percent, and so we lead to the draft
9 recommendation, which reads: "For 2020, Congress should
10 reduce the fiscal year 2019 Medicare-based payment rate for
11 inpatient rehabilitation facilities by 5 percent."

12 The implication for spending is it would decrease
13 Medicare spending by between \$250 million and \$500 million
14 in fiscal year 2020, and by between \$5 billion and \$10
15 billion over five years.

16 For the implications on beneficiaries and
17 providers, we anticipate no adverse effect on Medicare
18 beneficiaries' access to care. The recommendation, though,
19 may increase financial pressure on some providers.

20 So that concludes our presentation, and we'll
21 turn it back to Jay.

22 DR. CROSSON: Thank you, Craig.

1 Based on our discussion in December and our
2 decision to go to expedited voting in January, we have the
3 draft recommendation before us. All Commissioners in favor
4 of the draft recommendation, please raise your hands.

5 [Show of hands.]

6 DR. CROSSON: All opposed?

7 [No response.]

8 DR. CROSSON: Abstentions?

9 [No response.]

10 DR. CROSSON: Seeing none, the recommendation
11 passes unanimously.

12 Thank you, Craig and Dana.

13 [Pause.]

14 DR. CROSSON: Okay. We'll now return to the
15 regular order. We're going to have a discussion of the
16 recommendation for updating payments to long-term care
17 hospitals. Commissioners should note that this
18 recommendation is slightly different than the one we
19 discussed in December.

20 Stephanie?

21 MS. CAMERON: Thank you. Good afternoon. Today
22 we are here to discuss how payments to LTCHs should be

1 updated for fiscal year 2020. We will be reviewing our
2 full analysis today because, as you'll recall from
3 December, the Commission was concerned about the adequacy
4 of Medicare payments for this sector and the Chairman's
5 draft recommendation.

6 Based on your feedback, our review of the payment
7 adequacy indicators, and to ensure equitability with other
8 sectors, we will be presenting a revised draft
9 recommendation at the end of my presentation.

10 However, before I go on, I'd like to note a few
11 other changes in your mailing materials based on your
12 feedback in December.

13 Kathy and Marge, we added a discussion regarding
14 LTCH use compared with other PAC use following discharge
15 from an acute-care hospital.

16 Jonathan and David, we provided additional detail
17 regarding the use of ICU days as a proxy for defining the
18 chronically critically ill.

19 And, Kathy, we added a new table and discussion
20 in response to your questions about LTCH mortality.

21 Today I start by summarizing some background
22 information that was included in your mailing materials.

1 To qualify as an LTCH under Medicare, a facility must meet
2 Medicare's conditions of participation for acute-care
3 hospitals and have an average length of stay for certain
4 Medicare cases of greater than 25 days.

5 Medicare spent \$4.5 billion for about 116,000
6 LTCH cases. These cases are expensive with an average
7 payment per case of about \$38,000. Given the high cost of
8 LTCH care, the Commission has sought to understand the
9 level of care and cases most appropriate for this sector.

10 However, MedPAC, other researchers, and
11 policymakers have struggled with how to define the patients
12 most appropriate for LTCH care over the past several
13 decades. LTCH medical staff, administrators, and case
14 managers have been unable to reach consensus on describing
15 patients most appropriate for LTCH care during
16 conversations with the Commission.

17 The literature describes the chronically
18 critically ill as patients with multiple-body system
19 failures; requiring heavy ICU use; being ventilator
20 dependent with major co-morbidities; multiple organ
21 failures; or with septicemia and other complex infections.
22 Research has found that ICU days are an indicator of case

1 complexity and are readily available in administrative
2 data.

3 With that in mind, in 2014 the Commission
4 recommended that standard LTCH payment rates be paid only
5 for LTCH patients who meet certain criteria at the point of
6 transfer from an acute-care hospital. Such cases should be
7 those that spent eight or more days in an ICU or received
8 mechanical ventilation for 96 hours or more. The
9 Commission recommended that Medicare pay for all other
10 cases admitted to LTCHs using an IPPS-based payment rate.

11 The Pathway for SGR Reform Act of 2013
12 established a dual-payment rate structure. Cases meeting
13 the criteria, those preceded by an acute-care hospital
14 discharge that either spent three or more days in the ICU
15 of the referring acute-care hospital or received prolonged
16 mechanical ventilation in the LTCH are paid under the LTCH
17 PPS and will be the focus of a lot of the analysis I will
18 walk through. The policy began in fiscal year 2016 and,
19 until 2020, cases that do not meet the criteria are paid a
20 rate equal to 50 percent of the site-neutral rate and 50
21 percent of the much higher standard LTCH payment rate.

22 I will now turn to the question of how payments

1 to LTCHs should be updated for fiscal year 2020. To
2 determine the update recommendation, we will review payment
3 adequacy using our established framework.

4 While we apply our established framework in the
5 same manner for LTCHs, we expect substantial changes from
6 the implementation of the dual-payment rate structure given
7 the financial disincentive for LTCHs to continue taking
8 Medicare beneficiaries not meeting the criteria. Because
9 of the reduction in payment, the extent to which LTCHs are
10 able to alter their admission patterns toward cases meeting
11 the criteria determines facilities' financial performance
12 under Medicare.

13 Because some LTCHs have dramatically altered
14 their admission patterns in response to the policy
15 consistent with the goals of the dual-payment rate
16 structure, some of our analyses focus on LTCHs with more
17 than 85 percent of their cases meeting the criteria. I
18 will specify when we consider this subset of providers
19 during this presentation.

20 With that, we have no direct indicators of
21 beneficiaries' access to needed LTCH services, so we focus
22 on changes in use, capacity, and occupancy. Starting with

1 use, the number of LTCH cases declined starting in 2012.
2 The volume of cases meeting the criteria decreased slightly
3 from 2012 to 2015. Starting in 2016, the volume of cases
4 meeting the criteria increased, as expected by the
5 implementation of the dual-payment rate structure.

6 In contrast, cases not meeting the criteria
7 declined more rapidly from 2015 to 2017 compared with THE
8 prior years. As a result, the share of LTCH discharges
9 meeting the criteria has increased since 2012. Just over
10 half of LTCH cases met the criteria prior to the
11 implementation of the dual-payment rate structure; however,
12 this share increased to about 64 percent in 2017.

13 Moving to other indicators of access, supply has
14 decreased since 2012, and we expect addition reductions in
15 2018. Occupancy has decreased by about two percentage
16 points from 2016 to 2017; however, despite these trends,
17 Medicare marginal profit remains strong. Therefore, we
18 contend that LTCHs have a financial incentive to increase
19 their occupancy rates with Medicare beneficiaries who meet
20 the criteria.

21 Now, quality. Not unexpectedly, given
22 differences in patient severity, unadjusted rates of LTCH

1 readmissions and morality varied depending on whether or
2 not the case met the criteria, but were stable over time.
3 In 2017, for cases meeting the criteria, 10 percent were
4 readmitted to the acute-care hospital directly from the
5 LTCH, 16 percent died in the LTCH, and another 13 percent
6 died within 30 days of discharge from the LTCH. This means
7 that, combined, close to 40 percent of LTCH cases meeting
8 the criteria in 2017 were readmitted or died within 30 days
9 of LTCH discharge. By comparison, cases not meeting the
10 criteria have lower rates of readmission and mortality.

11 We have begun to provide information for several
12 outcomes measures reported publicly by CMS that we
13 discussed in December and were included in your mailing
14 materials. As you'll recall, these measures have not been
15 in place long enough for a time-series analysis, and we
16 will continue to monitor them.

17 Moving now to access to capital, access to
18 capital allows LTCHs to maintain and modernize their
19 facilities; however, given the last decade of policies that
20 have limited industry growth, which include moratoria on
21 new facilities and the implementation of the dual-payment
22 rate structure, the availability of capital is limited

1 across the industry.

2 LTCHs' access to capital also depends on their
3 all-payer profitability which was 0.2 percent in 2017 down
4 from 3.1 percent in 2016 resulting from reduced payments
5 for cases not meeting the criteria. LTCHs with more than
6 85 percent of their Medicare cases meeting the criteria had
7 an aggregate all-payer margin of 4.2 percent in 2017.

8 In 2017, the aggregate Medicare margin fell to
9 negative 2.2 percent down from 3.9 percent in 2016.
10 However, the aggregate Medicare margin for LTCHs with more
11 than 85 percent of Medicare cases meeting the criteria was
12 4.6 percent, indicating that facilities with a high share
13 of these cases can have positive financial performance
14 under Medicare.

15 We project that the 2017 Medicare margin for
16 LTCHs with a high share of cases meeting the criteria will
17 decline in 2019. Our projection of the LTCH margin for
18 fiscal year 2019 focuses on LTCHs with more than 85 percent
19 of their Medicare cases meeting the criteria. We expect
20 significant changes in LTCHs' costs as the dual-payment
21 rate structure is fully implemented and LTCHs continue to
22 increase their Medicare admissions toward cases that meet

1 the criteria.

2 However, once an LTCH has reached a threshold of
3 Medicare cases that meet the criteria, we expect changes in
4 cost will become increasingly stable and reflect cost
5 growth levels consistent with those prior to 2016. Using
6 these historical levels of cost growth, we project a 1.2
7 percent Medicare margin for LTCHs with a high share of
8 cases meeting the criteria for 2019.

9 In sum, measures of beneficiary access, quality
10 of care, and the industry's access to capital are mixed as
11 is expected from an industry in flux. Focusing on
12 financial performance under Medicare, we project that the
13 2019 margin for LTCHs with a high share of cases meeting
14 the criteria will be 1.2 percent, down from 4.6 percent in
15 2017.

16 As I mentioned, the Chairman's draft
17 recommendation presented in November was for no update to
18 LTCH payment rates; however, based on concerns about
19 payment adequacy and equity with other sectors, we re-
20 evaluated our indicators and, given the trends we observed
21 for LTCHs, focused on cases meeting the criteria.

22 The revised draft recommendation reads: For

1 2020, the Secretary should increase the fiscal year 2019
2 base payment rates for long-term care hospitals by 2
3 percent.

4 A 2 percent update for 2020 will decrease federal
5 program spending relative to the expected regulatory update
6 of 2.8 percent by less than \$50 million in 2020 and by less
7 than \$1 billion over 5 years.

8 We anticipate that LTCHs can continue to provide
9 Medicare beneficiaries who meet the criteria with access to
10 safe and effective care.

11 And, with that, I turn it back to Jay.

12 DR. CROSSON: Thank you, Stephanie.

13 We'll proceed to clarifying questions. Yes,
14 Jonathan, and then Warner.

15 DR. JAFFERY: Thanks, Stephanie. This is a great
16 report on the updates. Just a quick question. In the
17 mailing materials on page 23 in the table, you have Table
18 11-5, which gives the different kinds of readmission rates
19 and in-LTCH mortality and three-day post-discharge for a
20 number of conditions. I wonder if we have the ability to
21 dig a little deeper on that in the future around some other
22 factors. Age comes to mind, and other co-morbidities. It

1 seems like there's a real opportunity for understanding a
2 little bit better prognoses in some of these situations.
3 So just a thought for a future -- unless you know some of
4 those things off the top of your head.

5 MS. CAMERON: Absolutely. I think, you know, for
6 a long time we have been providing unadjusted measures and
7 unadjusted rates because for quite some times LTCHs did not
8 have an assessment instrument that allowed for risk
9 adjustment. The LTCH care database has now been used, and
10 assessment data is becoming increasingly available in this
11 sector. So I think as we move forward, we will be able to
12 certainly start thinking about better risk adjustments for
13 this population and see kind of how we can incorporate that
14 data. I think starting with age is certainly a
15 possibility.

16 If you'll recall, there is a much higher share of
17 Medicare beneficiaries in LTCHs that are under 65. So, you
18 know, that's actually kind of an interesting difference
19 from the other post-acute-care settings where some of these
20 younger patients are actually very, very sick. And so, you
21 know, we can certainly look at some of these by those
22 factors, and it will be interesting to see what we find in

1 the future.

2 DR. JAFFERY: Thank you.

3 DR. CROSSON: Warner.

4 MR. THOMAS: This may be more of a question for
5 Jim. When we look at all-payer margins, are we -- is that
6 cash flow? Is that operating income? Are we excluding any
7 expenses? Is it pre-taxing -- like what exactly are we
8 looking at when we look at all-payer income?

9 DR. MATHEWS: Yeah. So we look at overall net
10 profit margins here, if I'm getting this right, and we only
11 take into account Medicare allowable costs, which vary by
12 sector. So earlier this afternoon Kim mentioned that with
13 respect to calculation of hospice margins, there are a
14 couple of cost categories that we do not consider in our
15 Medicare margin. And, similarly, when we are going to talk
16 about ESRD, there are cost categories that we exclude for
17 this purpose.

18 MR. THOMAS: I mean, so are there -- it may be
19 just interesting to know what is -- I mean, I have no idea
20 like what would be excluded or how material that is just on
21 a go-forward -- I mean, it's not necessarily related just
22 to LTCH, but just in general, how material is it? Is it a

1 half a percent? Is it multiple percent? Just so we
2 understand.

3 DR. MATHEWS: In hospice where there are distinct
4 categories, we do quantify --

5 MR. THOMAS: Right.

6 DR. MATHEWS: -- the impact on margins of
7 including versus excluding those costs. I don't think in
8 the LTCH sector we are dealing with the same issue of
9 Medicare allowable costs the way we are in these couple of
10 other --

11 MR. THOMAS: What about in other areas? In all
12 the disciplines we've looked at, I mean, would there be
13 excluded costs that would not be in the all-payer margin
14 numbers?

15 DR. CROSSON: I thought -- I may be wrong, but I
16 thought when we were dealing with hospice bereavement
17 costs, we were talking about something around 1 percent.

18 MR. THOMAS: Okay.

19 DR. CROSSON: Is that right? Something like
20 that.

21 MR. THOMAS: But consistently in other categories
22 we've approved during the day today, I mean, the same sort

1 of thing, there would be excluded costs that are outside of
2 the all-payer margin. Is that correct?

3 MS. CAMERON: No. For the all-payer margin,
4 we're looking at a total revenue calculation and a total
5 cost calculation that comes into the hospital. So I think
6 what Jim was speaking to was the Medicare margin. The all-
7 payer margin, we're looking at the cost reports at the
8 bottom line, what costs have gone out and what revenues
9 have come in.

10 MR. THOMAS: So there's no excluded costs or
11 revenue. So if you're looking at proprietary, it would
12 include -- it would be pre-tax or post-tax or -- I'm just
13 trying to us what the --

14 DR. STENSLAND: There's a schedule in the cost
15 report where they're just supposed to take the information
16 from your audited financial statement and just stick it on
17 there.

18 MR. THOMAS: Okay.

19 DR. STENSLAND: So it's going to include
20 everything on there. You might -- but it's supposed to be
21 at the individual hospital level.

22 MR. THOMAS: I got it.

1 DR. STENSLAND: So you could have an individual
2 hospital level that has its profit and cost, and then you
3 have it's owned by a system and you wouldn't always include
4 all like the system's taxes and things.

5 MR. THOMAS: What about in the other areas like
6 home health and, you know, rehab and others? The same sort
7 of thing?

8 DR. STENSLAND: I'm not familiar with those cost
9 reports, but I'm assuming it's the same thing.

10 DR. CROSSON: Other clarifying questions?

11 [No response.]

12 DR. CROSSON: Let's put the recommendation -- it
13 is up. We'll now have discussion of the recommendation.
14 In favor, or opposed, other ideas? Kathy.

15 MS. BUTO: So I'm in favor of the recommendation,
16 and I think it was a good discussion that led us to this
17 point. It must have led to some pretty good staff
18 discussions that led to this revised recommendation.

19 I wanted to just mention something that -- to me,
20 LTCHs are almost like the poster child for this issue that
21 has been rattling around in my brain about PAC, unified
22 PAC, and directionally going forward, and that is that I

1 think we've tended to think of unified PAC as sort of the
2 place we're going and we have to deal with issues like
3 different criteria for entering those facilities or for
4 being a patient who qualifies for service in that facility
5 or whatever, or even in home health. And I've been
6 struggling with how do we reconcile those differences and
7 standards, and in a unified PAC, are we going to get to a
8 place where you have just a standard set of conditions of
9 participation.

10 The LTCH presentation kind of brought home to me
11 that there truly are some patients that won't easily fit
12 into other sites of care. And so what I'm thinking of --
13 and this is a longer discussion -- is that, yes, we can
14 achieve a greater degree of equity and comparability and
15 site-neutral payment based on clinical characteristics of
16 patients, but there may be patients like ventilator-
17 dependent patients, patients with long ICU stays and so on
18 who somehow in this unified PAC we want to make sure we're
19 not discouraging care, specialized care for those kinds of
20 individuals. And I think that helps us also address the
21 issue of different standards for institutions or for
22 programs within institutions to deal with these different

1 kinds of patients. And I know the staff has been thinking
2 of different ways to address this, but I just wanted to get
3 that out there because I think we tend to think of, you
4 know, our eventual path leading us to a much more unified
5 system, but this one brings home to me that there really
6 are some patients who -- and I'm not historically a great
7 fan of LTCHs. I think I was part of the group that
8 recommended we just eliminate the category when I was at
9 CMS. But I do think it's important to recognize that, as
10 we move forward, there be some way to address both the
11 differences in the criteria to qualify, and it may help us
12 with all these different things like three-day prior
13 hospitalization and long ICU stays and stuff like that, and
14 also to recognize that patients need different things.

15 So I just wanted to get that out there.

16 DR. CROSSON: Carol, would you care to comment,
17 or is it fine? And then we'll go to Brian.

18 DR. CARTER: So the way I would think about this
19 is to make sure in the risk adjustment model, we have
20 indicators of things that we think are really important for
21 identifying really high-cost patients.

22 So, for example, you might want to include an

1 indicator for ventilator patients, so that they pull enough
2 of the payments towards them, or severe wounds or ICU
3 lengths of stay of eight or more days or severity level No.
4 4. So all those things are going to be pulling in
5 resources, resource requirements to those patients, and the
6 payments for those patients would go up. So that's on the
7 payment side, making sure that we're directing our dollars
8 towards patients we think have high-care needs.

9 On the other side, we've talked about having
10 regulatory requirements that are patient condition-
11 specific. So instead of licensing by shingle on the door,
12 it would be licensing by the types of patients you're
13 opting to treat.

14 So for ventilator cases, for example, you might
15 pull in requirements that some of which might be current
16 LTCH requirements. I don't know. We're going through
17 that.

18 You might have minimum staffing levels. You
19 might have certain training requirements. It's not just
20 what are the care needs, but what are the staffing and
21 equipment needs to take care of patients? Ventilator
22 patients and severe wound cases are, for example, patients

1 where it's not just that you have the right equipment, but
2 you need to have staffing that's adequately trained.

3 So I think of like ventilator cases and patients
4 that really meet the LTCH requirements as having -- trying
5 to identify who those patients are and having requirements
6 that meet them, so that's how we're thinking about it.

7 Does that help?

8 MS. BUTO: That helps.

9 You and I talked also about stroke patients and
10 IRFs and things like that.

11 DR. CARTER: Yes, that's right.

12 MS. BUTO: Again, SNFs might be able to treat
13 stroke patients just as effectively, but the issue whether
14 there should be certain criteria associated with that --

15 DR. CARTER: Right. I mean, sometimes Stephanie
16 and I talk about maybe LTCHs. We want to think of them as
17 almost regional referral centers for certain types of
18 cases, and that might be a useful model.

19 DR. CROSSON: Okay. Thank you, Carol.

20 Brian, and then I saw Jon and Paul and Jaewon.

21 DR. DeBUSK: To Kathy's point, I do think the
22 unified -- the PAC PPS does fix a lot of issues with the

1 prospective payment. But I do think as we build that or
2 recalibrate that model -- and, Carol, this is sort of a
3 technical, I guess, question/comment combined -- when we go
4 to calibrate that model, you're going to have 2.3 million
5 SNF stays. Then you're calibrating the same model with
6 116,000 LTCH visits.

7 The contribution of the LTCH to this regression
8 model that we're going to do is beyond negligible. I mean,
9 it's probably two or three orders of magnitude beyond
10 negligible.

11 So one of the concerns would be to make sure that
12 the LTCH cases that are these true high cost, I mean these
13 long-term mechanical ventilation cases or you hear about
14 these stories about beneficiaries who are going to be there
15 for six months, we're going to have to figure out a way to
16 make sure that their costs don't get completely run over in
17 the model.

18 And just like we had that dichotomous variable
19 that made a home health adjustment, we may have to have a
20 lingering or at least a transitioning dichotomous variable
21 that accounts for the fact that some of these LTCH cases
22 are just fundamentally different and more expensive.

1 And I do love your idea, Carol, of different
2 levels of certification too. That's complementary because
3 what we may want to do is let the dichotomous variable
4 relate to the level of certification that the facility has,
5 not just the fact that this happens to be an LTCH and
6 something else happens to be a SNF.

7 So I think, Kathy, you and I are directionally
8 going in the same direction. I just don't want the LTCHs
9 to get completely run over in the calibration.

10 DR. CROSSON: Jonathan.

11 DR. JAFFERY: Yeah. Thanks.

12 This actually also builds on that a little bit.
13 I made some comments about this in December, but when we
14 think about the unified PAC PPS, I think about the IRFs and
15 the SNFs and the home health as being a pretty clear
16 continuum, and I do like the idea of trying to base it on
17 what the patient needs are.

18 But I still wonder if LTCHs, the level of care
19 for patients who go to LTCHs is actually close to acute
20 care hospitals than these other areas.

21 Even adding to Brian's point about how it's such
22 a small number, that it's going to get kind of swamped up

1 by all the SNF and other stays and home health stays, how
2 you account for that. I just wonder if we should be
3 thinking about is there a unified PAC PPS for those three
4 other areas and that LTCHs are somehow close to acute care
5 hospitals.

6 Then the other comment I want to make, again, I
7 appreciate the update and the history on the ICU stay in
8 the report. So maybe I'm not getting it or maybe I'm just
9 perseverating a bit, but it seems to me that showing that
10 this prolonged ICU stay is a proxy for LTCH-level intensive
11 resource needs isn't exactly the same as saying that
12 patients who had a long ICU stay are going to benefit from
13 an LTCH stay.

14 It seems like we've come to the point where we've
15 talked about mechanical ventilation as being sort of the
16 specialty care that an LTCH provides. In fact, that's what
17 sort of drove the recommendation to include that as a
18 criteria, an LTCH criteria.

19 So if that's really the specialty that they have,
20 it's not clear to me why we don't just talk about prolonged
21 mechanical ventilation as the criteria because I'm not
22 seeing a lot of evidence that patients with other complex

1 needs benefit from their LTCH stay.

2 MS. CAMERON: Some of the quality data is still
3 new. With the evolution of this quality data, I am hopeful
4 that in the future, perhaps we can provide more comparisons
5 to the extent that you're discussing.

6 There will be some vent weaning and some
7 ventilator-associated quality metrics coming online that I
8 hope we'll be able to talk about in the next couple years.
9 Hopefully, those will provide some value.

10 I do just want to circle back. In terms of
11 thinking about some of these populations within the PPS,
12 Carol mentioned ventilator, and as we dig deeper on how we
13 define ventilator in the post-acute care setting and
14 compare it across, what we're finding is well upward of --
15 well over 95 percent of beneficiaries who receive an
16 invasive mechanical ventilation in a post-acute care
17 setting are in fact in LTCHs.

18 And I think as our analysis is updated and as we
19 are better able to refine invasive versus non-invasive
20 vents because they're two very different things, as many of
21 you are well aware, when we look at those invasive vents,
22 the vast, vast majority of them in the post-acute care

1 setting are in LTCH, and therefore, the model will
2 calibrate appropriately to reflect primarily LTCH costs for
3 that category, which will far outweigh other PAC provider
4 costs.

5 So, Brian, you're absolutely right with your
6 example of the 2.3 million SNF relative to the 116,000
7 LTCH. When we look at this very small category, it is so
8 heavily weighted LTCH that we are finding that's what's
9 carrying that predictive cost in the model.

10 DR. CROSSON: Okay. Paul? Pass.

11 Jaewon.

12 DR. RYU: Just on the unified PAC PPS, I thought
13 -- and I may not be remembering this right, but from one of
14 our earlier discussions in the fall when we talked about
15 LTCH, there were markets where LTCHs has never been very
16 present, and somehow the care got absorbed through the
17 other categories. I just think as we delve deeper into
18 that discussion, it may be informative to look at those
19 markets around how did that happen, how did they get
20 absorbed, and what was it about the cost structure of
21 whether it was the SNFs or wherever?

22 The care got met somehow. It's not clear to me

1 how because I agree with Kathy and Brian and others.
2 There's clearly a subset of patients where the category
3 makes sense. So I'm curious how those markets address that
4 and what happened to the care because the need clearly
5 couldn't have gone away, but what happened? I think that
6 would be an informative exercise.

7 MS. CAMERON: Do you want me to respond to that?

8 DR. CROSSON: Are you going to answer?

9 MS. CAMERON: So I think as we look at different
10 markets, there are a few things, and one is even when we
11 look at markets across the country, there is an LTCH
12 available to a vast majority of Medicare beneficiaries
13 within about 90 miles.

14 Now, that's not all beneficiaries, but for
15 certain beneficiaries who are willing to travel for their
16 needs, they do travel.

17 Although the median travel distance, I believe,
18 is between 15 and 20 miles, the range is huge. That's a
19 median, and it's a very, very large range.

20 We have found in some of our work that especially
21 for things like ventilator-associated conditions, those
22 people are more willing to travel, and for those that do

1 travel outside of their market area for an LTCH, it's more
2 likely for a ventilator issue.

3 Because of the numbers and because these patients
4 other than the vent are so difficult to define, it's very
5 hard to see them and tease them out of the data on a market
6 basis. Many of these beneficiaries have very long lengths
7 of stay in the acute care hospital, and I think some of our
8 hospital people we spoke with during our site visits have
9 spoken about the long, long length of stay.

10 Some folks in New York were citing 180-day
11 lengths of stay in their acute care hospital, but finding
12 the folks who are longer than the average, 5.3-day average
13 length of day, they could stay 30 days in the acute care
14 hospital. And that might mimic more of their length of
15 stay in the LTCH, and it's very difficult to tease out.

16 So I think LTCHs are unevenly distributed
17 throughout the country, but they are often in markets with
18 a critical population mass. And that represents a vast
19 majority of Medicare beneficiaries, at least within kind of
20 an hour-and-a-half travel area. To the extent that those
21 folks are able to get to an LTCH, I think they do use it.

22 There are SNFs, not a lot, but there are SNFs

1 that do provide that care. And we spoke with markets like
2 that who do have some SNFs that provide this care.

3 Now, I think that's still fairly rare in the
4 industry. SNF payment is changing, and one of the parts of
5 that payment change, we don't expect it to happen
6 overnight. But will SNFs over time be able to increase
7 their staffing capital in such a way that could support
8 this population? There needs to be a critical mass of
9 patients on vent for a facility to pay for a respiratory
10 therapist and have these physicians do rounds more
11 frequently. So a one- or two-off patient at a SNF is not
12 going to carry that threshold.

13 So there are a lot of dynamics changing here, and
14 when we've looked at it, that's what we've found.

15 DR. CROSSON: Thank you.

16 Jon.

17 DR. PERLIN: Right on this point, there's that
18 triangulating between Jaewon's comments and Jonathan's
19 earlier about the similarity perhaps more to certain
20 hospitalized than SNF patients.

21 Self-service research may already be done, but I
22 knew you were really skirting to it -- is that if you look

1 at those areas without SNFs within X number of miles or X
2 number of hours of drive time, it would seem that one
3 potentially calibrating population would be those extreme
4 outlier ventilated patients with excessively long lengths
5 of stay.

6 And that may help with Brian's point about the
7 asymmetry of the groups in terms of modeling out that group
8 of patients.

9 DR. CROSSON: Do you have a comment, Brian?

10 DR. DeBUSK: On that, that may be one of the
11 reasons.

12 Actually, last week, I exchanged some emails with
13 Jim. We were speculating -- or I was speculating. One of
14 the reasons we were having some trouble separating out
15 these, teasing apart these populations is there may be some
16 LTCH patients that are legitimate PAC patients and will be
17 well addressed by the PAC PPS.

18 There may be some outliers that are really just
19 levels of MS-DRGs that we don't currently account for.

20 I mean, it would be interesting to see if you
21 could take the IPPS, selectively add a few severity levels
22 to some existing DRGs to accommodate for those, peel those

1 patients off, and then let the balance of them go into the
2 PAC PPS, because I was looking at the ventilator, the
3 patients within the ventilator criteria. It's only like
4 19,000 Medicare discharges out of 116,000. So the vent
5 isn't quite the bright white line that we were looking for.

6 And when you think about this whole definition of
7 CIRCADIAN and three days in ICU, I mean, it starts to sound
8 a little bit like a poor man's grouper. In the IPPS, we've
9 solved that with the DRG grouper.

10 And so, again, I do wonder if some of those cases
11 that Kathy was mentioning earlier, they may be better fit
12 by adding a couple of MS-DRGs on the high end of the
13 severity.

14 MS. BUTO: Didn't we recommend some increase to
15 the outlier payments for hospitals to account for some --
16 in some kind of combined policy, I think last year in our
17 paper?

18 MS. CAMERON: That's right.

19 Many of these patients -- and when we talk about
20 this, I'm mainly focused on the patients that kind of meet
21 the criteria because I think the way the patients are
22 defined, those that don't meet the criteria are likely to

1 be those that could be seen at other post-acute care
2 settings.

3 Maybe kind of what's your definition and what
4 you're thinking about as, they're more able to be treated
5 in a SNF or in another post-acute care setting.

6 But when we think about the patients meeting the
7 criteria, those patients are extremely expensive, whether
8 they're treated in an LTCH or -- and they're very costly, I
9 should say. They are very costly to treat, whether it's in
10 an LTCH or in an acute-care hospital.

11 Many of these patients are financial losers for
12 the hospital, regardless of whether they end up getting an
13 outlier payment, and so part of our March 2014
14 recommendation was -- in addition to putting this in place
15 in the LTCH, was to provide the additional money from the
16 LTCHs to the acute care hospital in the form of an outlier
17 pool that addresses the financial losses that hospitals are
18 taking on this type of patient because they're not
19 typically profitable.

20 DR. CROSSON: Okay. Thank you, Stephanie.

21 I think we are ready to proceed with the vote.
22 So the draft recommendation is before you. It's amended

1 from December. All Commissioners in favor of the draft
2 recommended, please raise your hand.

3 [Show of hands.]

4 DR. CROSSON: All opposed?

5 [No response.]

6 DR. CROSSON: Abstentions?

7 [No response.]

8 DR. CROSSON: Passes unanimously.

9 Thank you very much, Stephanie.

10 We'll move on to the final presentation for the
11 day.

12 [Pause.]

13 DR. CROSSON: Okay. Our final presentation for
14 the day is going to be on the update for outpatient
15 dialysis services. Nancy and Andy are here, and take it
16 away.

17 MS. RAY: Good afternoon. Today's presentation
18 on assessing the payment adequacy of outpatient dialysis
19 services consists of three sections. First, we will answer
20 some questions raised during the December meeting. Recall
21 during last month's session, Commissioners asked for
22 additional information to help in their deliberation of the

1 draft update recommendation. Then I will summarize the
2 indicators of payment adequacy that we reviewed in
3 December. Lastly, I will present the draft update
4 recommendation.

5 So as background, in 2017, there were about
6 394,000 Medicare fee-for-service dialysis beneficiaries
7 treated at approximately 7,000 facilities. Total Medicare
8 fee-for-service spending was about \$11.4 billion for
9 outpatient dialysis services.

10 So now I'm going to move to answer some of the
11 questions raised during the December meeting.

12 Bruce, in 2017, fee-for-service Medicare
13 accounted for roughly 45 percent of revenues, according to
14 public SEC filings and our preliminary analysis of cost
15 reports.

16 Jonathan, we have added additional discussion
17 about the use of chronic kidney disease care coordination
18 and patient education efforts, and some of these have been
19 sponsored by payers in addition to providers.

20 Kathy and others, we have added additional
21 discussion about CMS's revision to the transitional drug
22 add-on payment adjustment, including our strong objection

1 to the policy. In addition, the broader issue of drug
2 pass-throughs is on the list of items that we will discuss
3 tomorrow during the drug session.

4 Jon and others, we have added additional
5 discussion about how CMS adjusts payment in the dialysis
6 PPS for rural and low-volume facilities and our concern
7 that these adjustments are not well-targeted for low-volume
8 and isolated facilities.

9 Now let's review the payment adequacy analysis.
10 The indicators assessing adequacy are generally positive,
11 and you have seen all of this material in December.

12 Regarding access, there is a net increase of
13 about 250 facilities between 2016 and 2017. Our analysis
14 suggests that there were few facility closures in 2016, and
15 the few beneficiaries who were affected were able to obtain
16 care elsewhere.

17 Regarding capacity, the growth in dialysis
18 treatment stations has exceeded the growth in the number of
19 fee-for-service dialysis beneficiaries between 2016 and
20 2017.

21 Looking at volume changes, between 2016 and 2017
22 the growth in the number of dialysis fee-for-service

1 beneficiaries and Medicare-covered treatments remained
2 steady. The 17 percent marginal profit suggests that
3 providers have a financial incentive to continue to serve
4 Medicare beneficiaries.

5 So here are trends in quality that we discussed
6 lath month. Between 2012 and 2017, mortality admissions
7 per beneficiary and the percent of hospitalized
8 beneficiaries with a readmission are trending down. The
9 percent of dialysis beneficiaries using home dialysis,
10 which is associated with improved quality of life and
11 patient satisfaction, has increased. These are all good
12 trends. On the other hand, the percent of dialysis
13 beneficiaries with at least one ED visit has increased
14 between 2012 and 2017.

15 Regarding access to capital, indicators suggest
16 it is robust. An increasing number of facilities are for
17 profit and freestanding, and private capital appears to be
18 available to the large and smaller-sized multi-facility
19 organizations.

20 Moving to our analysis of payments and costs, in
21 2017, the Medicare margin is -1.1 percent. The Medicare
22 margin is higher for high-volume facilities compared to

1 low-volume facilities. That is, the margin increases as
2 total treatments increase. The lower Medicare margin for
3 rural facilities is related to treatment volume. Rural
4 facilities are on average smaller than urban ones.

5 So the factors that the 2019 projection accounts
6 for include the statutory payment increases in 2018 and
7 2019; regulatory changes by CMS that are expected to
8 increase total payments in both years; and the small
9 estimated reduction in total payments due to the ESRD
10 Quality Incentive Program in both years.

11 Based on these factors, the 2019 projected
12 Medicare margin is -0.4 percent, a small increase from the
13 2017 margin.

14 Here are the policy changes in 2020 that will
15 affect spending. I'd like to highlight the third item. As
16 discussed earlier, CMS will begin to pay facilities
17 separately under its revised TDAPA policy for all new
18 dialysis drugs without any offset to the PPS base payment
19 rate. We expect this will increase Medicare payments to
20 dialysis facilities.

21 So here is a quick summary of the payment
22 adequacy findings. Access to care indicators are

1 favorable. Quality is improving for some measures.
2 However, the 2019 Medicare margin is projected at -0.4
3 percent.

4 So here is the draft recommendation: For
5 calendar year 2020 the Congress should update the calendar
6 year 2019 Medicare ESRD PPS base rate by the amount
7 determined in current law.

8 In terms of spending implications, this draft
9 recommendation has no effect on spending relative to
10 current law. Regarding implications for beneficiaries and
11 providers, we anticipate that beneficiaries will continue
12 to have good access to care, and we also expect providers'
13 continued willingness to furnish care.

14 With that we turn it back to Jay.

15 DR. CROSSON: Thank you, Nancy. We will take
16 clarifying questions. I see Brian, Jon, and Dana.

17 DR. DeBUSK: The -- and I think this was Bruce's
18 question earlier and I'm sure I can produce it in the
19 materials, but what percentage of their treatments go to
20 Medicare fee-for-service beneficiaries?

21 MS. RAY: It's roughly 60 percent. So 60 percent
22 of all treatments are fee-for-service treatments, and

1 roughly 45 percent of total revenues is from fee-for-
2 service.

3 DR. DeBUSK: Okay. So there are about 60 percent
4 -- I'm just trying to do a back-of-the-envelope
5 calculation. I think in the materials we said their all-
6 payer margin was maybe 20 percent.

7 MS. RAY: Right. It's about 20 percent. And I
8 just want to -- that the 45 percent and 60 percent, those
9 are averages and it could vary from facility to facility.

10 DR. DeBUSK: Okay. I agree it's an aggregate. I
11 was just trying to back into what it would take to get a 20
12 percent -- you know, if 60 percent or more of your business
13 is at zero margin, effectively -- you know, zero -- what do
14 you need to be -- would that mean commercial rates are
15 \$550, \$600 a treatment? I'm just trying to think of how
16 you get to 20 percent if 60 percent of your business is
17 sitting at zero.

18 DR. CROSSON: You charge a lot.

19 DR. DeBUSK: Well, that's what I'm saying. No,
20 no, I'm with you. I'm thinking the non-Medicare treatments
21 are going to be 20 percent more. They're going to have to
22 be 100 percent more. I mean, are we talking roughly 100

1 percent?

2 DR. JOHNSON: We don't have an exact number but
3 it's in that ballpark, and the type of math you're doing
4 makes sense.

5 DR. DeBUSK: Okay.

6 DR. CROSSON: I recently reviewed, or in the
7 process of reviewing a paper that suggests that your
8 estimate is correct.

9 DR. DeBUSK: Okay. Thank you.

10 DR. CROSSON: Other questions? We've got Jon.

11 DR. CHRISTIANSON: In your presentation you noted
12 that there was an increasing proportion of dialysis
13 beneficiaries using the ER, and it's increasing but it's
14 not huge.

15 MS. RAY: It's not huge but there is a modest
16 increase.

17 DR. CHRISTIANSON: So my question is, does that
18 come predominantly from home- versus facility-based, or did
19 you look at that?

20 MS. RAY: I have not looked at that.

21 DR. CHRISTIANSON: Okay.

22 DR. CROSSON: Dana.

1 DR. SAFRAN: I forgot I had my hand up before.

2 DR. CROSSON: You did, didn't you?

3 DR. SAFRAN: I did. Yeah.

4 DR. CROSSON: It's late but go ahead.

5 DR. SAFRAN: I'm curious, how does the thinking
6 about home dialysis get factored into our thinking about
7 payment rates for facilities, including, you know, the
8 desire, if we have one, to motivate the use of home
9 dialysis where it's appropriate, since it's so much better
10 quality of life and convenient and all that? So how does
11 that fit together with this?

12 MS. RAY: So when CMS developed the PPS, and it
13 was implemented in 2011, one of the issues was whether to
14 pay -- have a separate payment for home dialysis or include
15 home dialysis with in-center. And the decision that CMS
16 made at that time, based on cost report data, was to not
17 have a separate adjustment for home dialysis, because,
18 historically, home dialysis costs were less than in-center
19 costs.

20 DR. SAFRAN: So if I'm a provider I will get paid
21 the same regardless of the setting.

22 MS. RAY: For patients over the age of 18, that's

1 correct.

2 DR. SAFRAN: Thank you.

3 DR. CROSSON: Kathy.

4 MS. BUTO: So as I'm reading this, Nancy, the
5 transitional drug add-on payment adjustment is completely
6 administrative. In other words, it's not dictated per se,
7 this policy, by statute, or is it part of the statute on
8 the PPS?

9 MS. RAY: So in some law passed, I think it was
10 in PAMA perhaps, instructed the agency to develop
11 regulations on how new drugs would be paid for under the
12 PPS. And so the agency did that and they finalized that in
13 2016, I think.

14 MS. BUTO: Yeah.

15 MS. RAY: And those regulations -- based -- what
16 those regulations said was, well, if you have a new drug
17 and if it fits any of the existing dialysis drug
18 categories, we're going to just put it right into the
19 bundle.

20 MS. BUTO: Right. They changed that in this
21 latest decision.

22 MS. RAY: Right. That's correct.

1 MS. BUTO: That's the change.

2 MS. RAY: Yes.

3 MS. BUTO: But even the original interpretation
4 was their interpretation. They could have said all new
5 drugs are covered under the bundle and we'll recalibrate
6 the rates accordingly, from time to time.

7 MS. RAY: That's correct.

8 MS. BUTO: Okay. I just wanted to be clear on
9 that.

10 DR. CROSSON: Okay. Seeing no further questions,
11 you have the recommendation before you. We will proceed to
12 comments, support, oppose, other comments with respect to
13 the recommendation.

14 [No response.]

15 DR. CROSSON: Seeing none, I'd ask for a vote on
16 the recommendation. All Commissioners in favor of the
17 recommendation before you raise your hand.

18 [Show of hands.]

19 DR. CROSSON: All those opposed.

20 [No response.]

21 DR. CROSSON: Abstentions.

22 [No response.]

1 DR. CROSSON: The recommendation passes
2 unanimously.

3 DR. CROSSON: Thank you, Andy. Thank you, Nancy.
4 We have come to the end of this day, and it's now
5 time for a public comment period. If there are any
6 members, any of our guests who wish to make a public
7 comment please proceed to the microphone. Just wait for my
8 instructions for one second, if you would.

9 I'll just make a note that there are other
10 mechanisms to provide information to the Commission,
11 through the staff, either online or in person, that this is
12 an opportunity. We'd ask you to state your name and any
13 organization you're affiliated with, and please limit your
14 comments to two minutes. When this light returns, that's
15 two minutes. Thanks.

16 MS. DREW: Good afternoon. My name is Lauren
17 Drew, and I am the senior manager of advocacy and state
18 relations at NHPCO, the National Hospice and Palliative
19 Care Organization. On behalf of our president and CEO, Edo
20 Banach, I respectfully submit comments on the MedPAC
21 Chair's recommendation to Congress that you reduce fiscal
22 year 2020 Medicare base payment rates for hospice by 2

1 percent.

2 The National Hospice and Palliative Care
3 Organization is the oldest and largest nonprofit membership
4 organization representing hospice and palliative care
5 programs and professionals. We represent almost 4,000
6 unique programs nationwide.

7 The organization is committed to improving
8 serious illness and end-of-life care and expanding access
9 to hospice and palliative care with the goal of profoundly
10 enhancing quality of life for the seriously ill, the dying,
11 and their loved ones.

12 We believe we bear a special responsibility both
13 to ensure that the Medicare hospice benefit is available to
14 all Americans and that it continues to deliver the value
15 that patients, their families, and all taxpayers deserve.

16 It is for that reason that we are deeply
17 concerned about the Chair's recommendation and look forward
18 to discussing opportunities to strengthen the hospice
19 program and ensure adequate hospice reimbursement.

20 NHPCO's value agenda is designed to achieve a
21 seamless delivery model from patient diagnosis through
22 family bereavement. Featuring common-sense reforms for

1 person-centered care, our agenda is designed to advance
2 patient choice and access to care, particularly in
3 underresourced areas; improve provider education and
4 training; enhance accountability; and improve program
5 integrity.

6 Importantly, our vision also unified hospice and
7 palliative care, including their payment systems, under a
8 single person-centered care umbrella for enhanced
9 transparency and predictability. We look forward to
10 meeting with Dr. Jim Mathews, Kim Neuman, and staff at our
11 scheduled meeting later this month. We are excited to
12 share our improved data analytics capabilities and to
13 receive your valuable perspective on our work.

14 We look forward to offering our assistance to
15 MedPAC in their important role in advising Congress.

16 Thank you.

17 DR. CROSSON: Thank you for your comments.

18 Seeing no one else at the microphone, today's
19 session is concluded. We will reconvene tomorrow at 8:30.
20 Thanks, everybody, for the work.

21 [Whereupon, at 3:45 p.m., the meeting was
22 recessed, to reconvene at 8:30 a.m. on Friday, January 18,

1 2019.]

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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, January 18, 2019
8:30 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
BRIAN DeBUSK, PhD
KAREN DeSALVO, MD, MPH, Msc
MARJORIE GINSBURG, BSN, MPH
PAUL GINSBURG, PhD
DAVID GRABOWSKI, PhD
JONATHAN JAFFERY, MD, MS, MMM
JONATHAN PERLIN, MD, PhD, MSHA
BRUCE PYENSON, FSA, MAAA
JAEWON RYU, MD, JD
DANA GELB SAFRAN, ScD
WARNER THOMAS, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

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AGENDA	PAGE
Future policy directions to address Medicare prescription drug spending	
- Kim Neuman, Nancy Ray, Rachel Schmidt, Shinobu Suzuki.....	3
Analysis of Medicare Shared Savings Program (MSSP) performance	
- David Glass, Luis Serna, Jeff Stensland.....	77
Public Comment.....	155

P R O C E E D I N G S

[8:30 a.m.]

1
2
3 DR. CROSSON: Okay. We can be seated and get
4 going. Welcome to the Friday morning session.

5 It comes as no particular surprise that the
6 country is wrestling with the problem of increasing drug
7 costs taking place now in the popular literature as well
8 as, of course, with policymakers and in Congress and in the
9 administration. This Commission has been working on this
10 issue for some time. We intend to continue to do that, and
11 so today's presentation is intended to be a review of the
12 recommendations and ideas that have come out of this
13 Commission in recent years, as well as a discussion -- a
14 presentation and discussion among the Commissioners about
15 priorities for continued and future work of the Commission.

16 Today we have Kim and Nancy and Rachel and
17 Shinobu in the bull pen to help us think through these
18 issues, and, Kim, it looks like you are going to start out.

19 MS. NEUMAN: Good morning. So today's session
20 focuses on Medicare policy concerning drugs and biologics.
21 As you know, Medicare spending on these products is
22 substantial. In 2017, Medicare and enrollees paid Part D

1 plans \$94 billion, and Medicare fee-for-service spending on
2 Part B drugs, including cost sharing, was \$32 billion.

3 As Jay mentioned, today we're going to explore
4 potential future policy directions to address concerns
5 about growth in drug prices and Medicare spending. This
6 session is in response to Commissioners' requests to take a
7 broad look at Medicare drug policy, starting with the
8 Commission's past work, and then outlining a variety of
9 ideas offered by others that could be explored.

10 As we'll discuss, work is already underway on
11 several specific topics for spring presentations that will
12 be potentially included in the June 2019 report. We hope
13 that today's session will spark discussion about which
14 additional ideas you're interested in exploring further and
15 help set priorities for our research agenda going into the
16 fall and beyond.

17 This next slide provides an outline of the
18 presentation. We'll briefly discuss the scope of the
19 presentation and then, as I mentioned, discuss the
20 Commission's past recommendations, other ideas the
21 Commission has explored but not moved forward on to date,
22 work planned for the spring, and then other ideas in the

1 environment that we could consider exploring further.
2 Since there are many policy ideas in the environment, this
3 presentation will by necessity be relatively high level,
4 but we aim to give you enough descriptive information so
5 that you can set initial priorities.

6 Clearly, there are a number of policies beyond
7 Medicare that have important implications for drug prices,
8 but since these areas are outside of MedPAC's purview, this
9 presentation won't be covering them. Examples include:
10 government funding of research and development by NIH;
11 patent policy and the FTC's anticompetitiveness enforcement
12 policy; FDA policies concerning drug approval, exclusivity,
13 and interchangeability; aspects of Medicaid drug policy,
14 such as best price; tax credits and tax incentives for
15 research and development; and state pharmacy law, such as
16 those governing pharmacists' substitution of
17 interchangeable products.

18 So now turning to the Commission's past
19 recommendation, first we have Part B. As you'll recall,
20 Medicare Part B covers drugs that are infused or injected
21 by physicians and outpatient hospitals as well as a few
22 pharmacy-supplied drugs. Medicare pays the average sales

1 price plus 6 percent for most Part B-covered products.

2 In June 2017, the Commission made a three-part
3 recommendation to improve payment for Part B drugs. The
4 first part consisted of four policies aimed at improving
5 the ASP payment system. I'll highlight two.

6 One requires drug manufacturers to pay Medicare a
7 rebate when ASP for their drug grows faster than an
8 inflation benchmark.

9 Another would pay innovator biologics and
10 biosimilars the same rate under a consolidated billing code
11 to promote price competition.

12 The second part of the recommendation was the
13 development of a drug value program, or DVP, which would be
14 a voluntary market-based alternative to the ASP payment
15 system in which physicians and outpatient hospitals could
16 choose to enroll. Medicare would contract with a small
17 number of DVP vendors to negotiate prices for Part B drugs,
18 and these vendors could use tools such as a formulary and,
19 for some drugs, binding arbitration.

20 The third part of the recommendation was reducing
21 the 6 percent add-on under the ASP payment system to
22 encourage DVP enrollment.

1 Next is Part D. As you know, Medicare Part D
2 covers drugs dispensed as pharmacies. Medicare pays Part D
3 plans using a combination of capitated payments based on
4 plan bids and reinsurance subsidies. In June 2016 and
5 March 2018, the Commission made recommendations to address
6 concerns over rising drug prices and Part D spending.

7 To increase plans' incentives to manage spending
8 on high-cost drugs, the recommendations would lower the
9 reinsurance Medicare pays from 80 percent to 20 percent of
10 catastrophic spending while simultaneously increasing
11 capitated payments. At the same time, the recommendation
12 would give plan sponsors greater flexibility to use
13 formulary tools, strengthening their negotiating leverage.

14 Other parts of the Commission's recommendation
15 would modify cost sharing for low-income subsidy
16 beneficiaries to improve incentives for use of generics and
17 biosimilars. The recommendation would also eliminate cost
18 sharing above the out-of-pocket threshold, increasing
19 insurance protection in the catastrophic phase of the
20 benefit.

21 This next slide highlights some other past drug
22 recommendations the Commission has made. I won't go into a

1 lot of detail now, but we'd be happy to discuss on
2 question. These include: a 2016 recommendation to reduce
3 the Part B drugs' dispensing and supplying fees paid to
4 pharmacies for inhalation drugs and certain oral drugs to
5 rates similar to those of other payers.

6 In 2007, out of concern that there is not enough
7 credible, empirically based information on the comparative
8 effectiveness of alternative treatments, the Commission
9 recommended Congress charge an independent entity with
10 sponsoring research on the comparative effectiveness of
11 health care services, including drugs, and disseminate that
12 information.

13 In 2007, the Commission also recommended moving
14 coverage of new preventive vaccines from Part D to Part B
15 to facilitate easier access in physician offices. Also in
16 2007, the Commission recommended the Secretary clarify
17 average sales price reporting requirements for drugs that
18 are subject to bundled price concessions.

19 Over the years, the Commission has discussed
20 several other strategies aimed at increasing the value of
21 Medicare spending for drugs and biologics. The Commission
22 has not pursued recommendations in these areas to date, but

1 the issues could be revisited depending upon interest.

2 The first relates to coverage with evidence
3 development, or CED. Under CED, Medicare links the
4 coverage of an item or service to the collection of
5 clinical evidence. Although Medicare applies CED in the
6 national coverage determination process, some researchers
7 argue that Medicare's use of CED has been limited.

8 We have also discussed several policies that are
9 based on comparative clinical effectiveness research, which
10 compares the clinical effectiveness of two or more
11 treatment options for the same condition.

12 The first three noted on the slide -- least
13 costly alternative, Pearson-Bach, and combined billing
14 codes -- are all variants of reference pricing where the
15 amount Medicare pays for products with similar health
16 effects are based on a benchmark such as the lowest-cost
17 comparable alternative or the average cost.

18 The fourth approach is cost-effectiveness
19 analysis, which starts with information on comparative
20 clinical effectiveness and compares the incremental cost in
21 dollars of one intervention to another in creating one unit
22 of health outcome. There's increasing interest by

1 commercial payers in using such information in determining
2 a drug's value.

3 Because cancer drugs account for a large share of
4 Part B drug spending, the Commission has also discussed
5 several approaches to improve the efficiency of oncology
6 care. Approaches discussed include oncology medical home,
7 bundling, and accountable care organizations, which are all
8 approaches to increasing provider accountability. We've
9 also discussed oncology clinical pathways which are
10 evidence-based protocols that some providers and commercial
11 payers use.

12 Finally, there is the ASP hybrid model. In June
13 2016, we modeled a policy option that changes part of the 6
14 percent add-on to a flat fee.

15 DR. SCHMIDT: In the spring, we plan to discuss
16 the issues on this slide and, as Kim said, potentially
17 include them in our June report. For now I'll just
18 describe these briefly.

19 Kim just mentioned some variations of reference
20 pricing. It's a general approach that could be used in
21 Part B or Part D in which a purchaser or payer sets a
22 maximum amount that it will reimburse for therapeutically

1 similar drugs. Reference prices can be based on a payer's
2 own pricing data, but under a second approach, the
3 reference price could be based on prices from other
4 countries.

5 Under binding arbitration, two parties would
6 agree to accept the verdict of a neutral third party over a
7 drug's price. As Kim mentioned, the Commission's 2017 Part
8 B drug recommendation included binding arbitration as a
9 tool in the drug value program. In spring, we'll explore
10 using it more broadly for Part B drugs.

11 Yesterday we talked about how in Part D brand
12 manufacturers provide a large price discount in the
13 coverage gap. This lowers enrollee costs but also reduces
14 incentives to manage benefits. We'll come back this spring
15 to discuss a way to restructure the discount in a way that
16 may address this concern.

17 Finally, some enrollees take high-priced
18 specialty drugs that have few therapeutic alternatives.
19 For those patients, Part D cost sharing can also be high
20 and may affect their adherence. We plan to discuss some
21 approaches for addressing this.

22 Over the next few slides, I'll describe some

1 policy ideas that stakeholders, academics, policymakers,
2 and others have raised to address drug prices and spending
3 but that the Commission hasn't yet formally considered.
4 Although we don't have estimates of savings for many of
5 these, we've tried to use the information we have to put
6 the ones that we expect to have the biggest effect towards
7 the top.

8 So the first idea relates to excluding new drugs
9 from coverage or formulary at launch. Launch prices of new
10 drugs have been rising steadily. Part B providers and Part
11 D plan sponsors have little or no ability to negotiate
12 price concessions for a new drug that doesn't have
13 competitors. Excluding a new expensive medication until
14 there is more real-world evidence about its clinical
15 effectiveness could allow room to negotiate more
16 competitive pricing. Some PBMs are already using this
17 approach for commercial clients.

18 Next on the list is Medicaid-like rebates in
19 Medicare. So the Medicaid drug rebate has two components:
20 a flat percentage rebate and an inflation rebate. One or
21 both of those approaches could be used in Medicare. If
22 used in Part D, a Medicaid-like rebate could apply to dual

1 eligibles and others who receive the low-income subsidy.
2 They account for about 30 percent of enrollment and 50
3 percent of spending.

4 In 2006, the duals were moved from Medicaid to
5 Part D's low-income subsidy program. Estimates by
6 government agencies suggest that the average rebates
7 negotiated by private plans in Part D tend to be lower than
8 the mandated ones under Medicaid. With the Medicaid-like
9 approach, manufacturers would pay Medicare the difference
10 between the rebates required under Medicaid and the amounts
11 negotiated by Part D plan sponsors. The Congressional
12 Budget Office estimates that the flat percentage and
13 inflation rebates combined would save \$154 billion over ten
14 years in Part D.

15 In 2013, OIG recommended that CMS explore the
16 effect of applying a Medicaid-like rebate to Part B drugs.
17 The Commission has recommended an inflation rebate for Part
18 B drugs, but has not considered a flat rebate. If applied
19 in either B or D, the Medicaid-like approach would generate
20 savings. However, it could also lead to increased launch
21 prices for new products. To the extent that occurs, the
22 savings to Medicare from the rebate would decline over

1 time.

2 In recent years, manufacturers, payers, and PBMs
3 have entered into outcomes-based agreements that link a
4 drug's payment to measures intended to reflect patient
5 outcomes. These can sometimes be complex to implement and
6 can have high administrative costs. A key issue is how to
7 define a clinically relevant outcome that is observable in
8 a reasonable time period.

9 Control over outcomes data and a data analysis
10 can be sticking points in these agreements. Stakeholders
11 have said that best price reporting requirements can be an
12 impediment. Some payers have questioned whether the
13 approach can really achieve sizable reductions in price.
14 However, other payers like the approach, and the number of
15 outcomes-based contracts is increasing, particularly in
16 drug classes that have competing therapies.

17 Indication-specific pricing has been promoted by
18 experts such as oncologist Peter Bach and is used by PBMs
19 for some commercial clients. This approach stems from the
20 common situation where the FDA approves a drug for an
21 initial indication and then the drug receives subsequent
22 approvals for additional indications. Rather than paying

1 one flat amount for any use of the drug under indication-
2 specific pricing, a PBM might negotiate a lower payment for
3 those indications for which the drug is relatively less
4 effective.

5 Proponents of the approach contend it can expand
6 access by lowering prices. Critics argue that the approach
7 primarily serves to expand manufacturer profits and would
8 only expand access for lower-value uses of a drug.

9 Proponents of direct price negotiations believe
10 that with the federal government's large purchasing power,
11 Medicare could obtain prices from manufacturers that are
12 lower than we see today, particularly for drugs that have
13 no competitors. Opponents of this idea contend that in
14 Part D private plan sponsors are already negotiating for
15 prices and provide access to a wide range of medications.

16 The effectiveness of government negotiations
17 would depend on the specific authority given to the
18 Secretary, such as whether he could establish a formulary,
19 exclude certain drugs, or set prices directly. Even if the
20 Secretary was given authority to establish a formulary or
21 use other tools, it may be difficult to exercise that
22 authority in the presence of strong resistance from

1 stakeholders, including patients and manufacturers.

2 Commercial plan sponsors often try to dispense
3 high-cost specialty drugs through an exclusive network of
4 specialty pharmacies. Many of the largest insurers and
5 PBMs own specialty pharmacies, and some encourage their
6 clients to dispense exclusively through that company.

7 In Part D, plan sponsors cannot set up a narrower
8 network of specialty pharmacies because, under law, plans
9 are subject to the any willing pharmacy provision.
10 Proponents of exclusive networks believe that the approach
11 can provide greater negotiating leverage and lower prices
12 from drug manufacturers. Critics question whether more
13 concentrated delivery by fewer pharmacies could lead to a
14 less competitive specialty pharmacy market.

15 One approach would be to periodically compete
16 contracts to dispense specialty drugs for Part D
17 beneficiaries in part or all of the country, as the
18 Department of Defense does for TRICARE. However, smaller
19 pharmacies and other organizations that today dispense
20 specialty drugs would oppose limits on their ability to
21 share in the revenues of this growing part of the market.

22 Some manufacturers offer coupons to commercially

1 insured patients to reduce patients' cost-sharing
2 liability. Manufacturer coupons are not considered as
3 discounts for the purposes of calculating a product's ASP.
4 If coupons were considered discounts, Medicare ASP+6
5 payment rates would be lower. For example, GAO estimated
6 that the ASP of 18 drugs would be on average seven-tenths
7 of a percent lower if coupons were counted in the
8 calculation.

9 Some stakeholders have expressed interest in
10 moving drugs from Part B to Part D as a way to apply
11 pharmacy management tools to Part B drugs. Shifting drugs
12 from Part B to Part D could increase or decrease a
13 beneficiary's out-of-pocket costs, depending in part on
14 whether the beneficiary has Medigap, other supplemental
15 insurance, or Part D.

16 Part B covers a few pharmacy-supplied drugs that
17 may be relatively easy to provide under Part D, but moving
18 provider-administered drugs, which account for most Part B
19 spending, would be complex and may not necessarily lead to
20 lower prices.

21 The final idea I'll present is a manufacturer
22 rebate for wasted drugs. Infusion drugs are often sold in

1 a single-use vial that's intended for one patient, with any
2 leftover drug discarded. Peter Bach and colleagues found
3 that some manufacturers offer products in limited vial
4 sizes that are not well matched to patient dosing, which
5 leads to waste and higher revenues for the manufacturer.

6 Bach suggests one potential approach to address
7 this could be to require manufacturers to pay a rebate for
8 wasted drugs. The magnitude of savings from this idea
9 relative to the administrative costs is unclear.

10 So that concludes our laundry list of ideas, and
11 we're looking forward to your feedback, your questions,
12 your suggestions, whether we've missed something important,
13 and we look forward to your discussion.

14 DR. CROSSON: Thank you, Rachel, Kim.

15 We'll now take clarifying questions on the
16 presentation. I see Amy and Paul. Amy?

17 MS. BRICKER: On the idea of accounting for
18 coupons in the ASP calculation, what did you say the
19 savings was estimated to be?

20 DR. SCHMIDT: It was seven-tenths of a percent.

21 MS. BRICKER: That seems really, really, really
22 low.

1 MS. NEUMAN: So GAO had data from a sample for 18
2 drugs, and what they found was that there were five that
3 had an effect greater than one percentage point, and the
4 rest, the other 13, were below. And so on average, you get
5 to that 0.7 number. But, clearly, there's differences
6 across products.

7 MS. BRICKER: So these are just the Part B drugs
8 where you looked at this?

9 MS. NEUMAN: Yes, it's just Part B.

10 MS. BRICKER: Okay. So was something done
11 similar on the D side?

12 DR. SCHMIDT: Not that I'm aware of, no.

13 MS. BRICKER: Something to consider. I'll do
14 that maybe next round. Thank you.

15 DR. CROSSON: Paul.

16 DR. PAUL GINSBURG: You know, as far as moving
17 drugs from Part B to Part D, do you have a sense of
18 magnitude of dollars where this might be an
19 administratively feasible thing to consider? In a sense,
20 are people just talking about it with being very few
21 opportunities to actually do it effectively? Or is this
22 something substantial?

1 DR. SCHMIDT: So there is a paper that just came
2 out, and Jay and Jon actually wrote a commentary that goes
3 alongside it. But I'm not sure that's going to directly
4 answer your question. The ones that are administratively
5 easy, no, I haven't seen an estimate as to the magnitude of
6 that spending. The particular paper that just came out was
7 trying to measure overall movement from B to D, and it
8 estimated that savings, but it was using an approach where
9 it was applying some average rebates that are observable to
10 WAC, and one could question some of those assumptions.

11 DR. CROSSON: Jon.

12 DR. CHRISTIANSON: The reference pricing
13 suggestion or topic, does that come from the experience of
14 Germany or other countries; and if so, what has been their
15 experience?

16 MS. RAY: So, in March, we plan to come back to
17 you in greater depth to discuss reference pricing, when the
18 payer does it, using the payer's own pricing data as well
19 as international reference pricing. We do plan to include
20 a case study about Germany, where a part of their system is
21 based on reference pricing.

22 DR. CROSSON: Kathy and then Bruce.

1 MS. BUTO: Do we have sort of magnitude, high,
2 medium, low kind of sense of which ones of these proposals
3 have the biggest impact on spending? Have you done some of
4 that thinking? Are they kind of rank ordered according to
5 that belief that some will have a bigger impact than
6 others?

7 DR. SCHMIDT: Right. There's a whole lot of
8 uncertainty, and it depends a lot on implementation details
9 and things like that, of course.

10 So we did try and rank order them where there was
11 an estimate out there; for example, the Medicaid-like
12 rebates, we could hang our hat on a CBO estimate, that sort
13 of thing.

14 We put excluding at launch at the top just
15 because it seems like that could be very huge.

16 MS. BUTO: That would be very huge.

17 DR. SCHMIDT: Right.

18 Unfortunately, there aren't detailed estimates
19 for a lot of these, and as I said, a lot depends on the
20 details of how it would be implemented.

21 DR. CROSSON: Bruce.

22 DR. PYENSON: In the international comparison of

1 prices, I wonder if you could look at the comparison of the
2 intermediaries that exist in the U.S. that, my
3 understanding don't exist elsewhere in the same level, so
4 the distribution in the intermediary, because I suspect
5 it's not just about we're very different from the rest of
6 the world and not just in prices, but in how we distribute,
7 how we move things around. Do you have any visibility into
8 that?

9 MS. RAY: We can certainly try to take a look at
10 that between now and when we come back to you in March. I
11 think that's an interesting point.

12 DR. CROSSON: Yes, Karen.

13 DR. DeSALVO: Thank you all so much.

14 To this point about laundry list, which I
15 appreciate how much you all have been trying to grab new
16 ideas, I want to build no what Kathy said and ask about
17 whether you've been able to also rank according to impact
18 on beneficiary for their out-of-pocket cost changes.

19 Related to that, I wondered about whether there's
20 an equity issue built into some of this or an inequity
21 issue. Maybe you can help me understand if that is a
22 concern or not; in other words, if you're a low-income

1 subsidy beneficiary, it seems like sometimes there's maybe
2 not a differential impact on your out-of-pocket but on your
3 access to some drugs that might be of best evidence to
4 treat the condition you have. Think about, in the Medicaid
5 world, something like hepatitis C medications. Sometimes
6 we've created this artificial barrier based on the payment
7 methods, so two things in there, but both about impact on
8 beneficiary as we think about ranking.

9 DR. SCHMIDT: Again, I think it's hard to rank
10 because there's so much in the details of the parameters of
11 how you choose to implement something. It's pretty
12 complicated.

13 Moving drugs from B to D issue, for example,
14 might actually benefit low-income subsidy folks or people
15 who qualify for the low-income subsidy, so long as they
16 have Part D, to the extent that a lot of the cost sharing
17 would be covered if they didn't come from having a Medigap
18 and then they moved to LIS coverage, for example.

19 In other situations, yes, potentially access
20 could be denied. An exclusion at launch, for example, that
21 would not only affect low-income subsidy but perhaps others
22 as well.

1 Reference pricing, it's the same sort of idea.
2 The individual will be paying for the difference between
3 the price level that's set by the payer or plan, and it
4 would set a reimbursement rate. If the price is higher,
5 then the patient would be picking that up, and that could
6 be an access problem for low-income subsidy.

7 Each one of these is pretty complicated, and it
8 would be hard to, I think, rank order them, both in terms
9 of -- we wouldn't necessarily have the same rank, I should
10 say, in terms of program savings versus effects on
11 beneficiaries.

12 DR. CROSSON: Warner.

13 MR. THOMAS: First of all, thanks for the ideas
14 and appreciate the great work done here.

15 Just a couple of questions. I'm just not sure
16 what data is or is not available to us as we kind of go
17 through this analysis.

18 Is it possible to take a market basket, say take
19 the top 100 drugs that is in Part D or Part B, and look at
20 those drugs over a period of time to see what has been the
21 -- not just the utilization, because obviously when you're
22 looking at total cost, you look at utilization and price,

1 but to look at the price change over a period of time,
2 three, five, or more years for top drugs that are utilized
3 by those programs and maybe looking at brand and generic
4 because I think historically we thought generic is a much
5 better alternative. But I think more recently, we're
6 seeing a lot of escalation there.

7 Is that something that's possible? I don't know
8 what data is available to us.

9 DR. SCHMIDT: Yeah. In fact, other organizations
10 have put out publications along those lines. I know OIG
11 has, for example, and I think CBO has done some similar
12 sort of work. If you're interested in seeing that, we
13 could present some of that to you.

14 MR. THOMAS: I guess what I'm trying to get at is
15 one of the things that wasn't -- I mean, one of the things
16 I know we bandied around is just this idea of a -- we did
17 the ASP, moved it from 6 to 3, but the idea of an
18 inflationary cap. And I guess my question is, Would that
19 even matter? Would that have an impact? The only way to
20 maybe understand that is to look back and see if you had a
21 cap over a period of time, what impact may that have had?
22 Obviously, it doesn't impact a launch price, but it may

1 impact increases on a go-forward basis. So that is
2 something that is potentially feasible.

3 My second question, maybe it's building off of
4 Bruce's comment.

5 I'm sorry?

6 MS. NEUMAN: I just wanted to add one
7 clarification. In the 2017 recommendation, the Commission
8 did recommend an inflation cap for Part B drugs, and so
9 that would, going forward, if it were implemented, keep
10 payments at an inflation benchmark and not higher. So we
11 don't have a specific estimate because that whole
12 recommendation was scored by CBO, but it is part of what
13 the Commission recommended.

14 MR. THOMAS: Right. Thank you. I appreciate
15 that.

16 I guess my thing is could we make it broader.
17 Could it have a broader impact across multiple areas?

18 The second comment -- I think it's maybe building
19 off of Bruce's comment -- or question -- is just this idea
20 of looking at a comparison of a -- we're looking at
21 domestic pricing for ASP, really just doing a straight
22 comparison internationally and just see can we buy drug,

1 see what that change would be, maybe for the same market
2 basket, if we looked at the top 100 or top 50 or top 250.
3 Is that data available or not available?

4 MS. NEUMAN: So the Department put out a study
5 where they looked at the prices in the U.S. versus other
6 countries and came up with estimates of what they thought
7 the differential is, so that's something we could come back
8 to you on with more information.

9 MR. THOMAS: And did they do that on a group of
10 drugs, on specific drugs?

11 MS. NEUMAN: Specific drugs, yeah, where they
12 thought they had good data, and it was Part B. It wasn't
13 D.

14 MR. THOMAS: Okay. And is it possible to look at
15 that for Part D as well? Because I think we get this --

16 DR. SCHMIDT: That gets more complicated.

17 MR. THOMAS: What's that?

18 DR. SCHMIDT: It's hard to observe the Part D
19 drugs directly without knowing the rebate information.

20 MR. THOMAS: I got it.

21 DR. CROSSON: Okay. Further questions?

22 Marge.

1 MS. MARJORIE GINSBURG: Warner brought up a topic
2 that I was interested in, and that is the comparison to
3 international, what other countries do, and of course,
4 we've always heard that those with universal or almost
5 universal health care have much better control of their
6 drug costs.

7 So my question is how much we know about what --
8 the specifics of what other countries do and whether they
9 apply certain processes like reference pricing or is it
10 simply a matter, they tell the drug company, "This is how
11 much we're going to pay. Take it or leave it." So do they
12 simply set a ceiling of what they're going to pay for
13 certain drugs, or do they actually utilize certain
14 mechanisms for making that determination?

15 MS. RAY: So that will vary from country to
16 country. In March, we were going to come back and just
17 give you a feel for a couple of countries, just to give you
18 several case studies. As I said, one we were planning on
19 coming back to you with is Germany.

20 DR. CROSSON: Warner.

21 MR. THOMAS: I just had another question, and I
22 think it's maybe building off of Karen's comment.

1 The idea of beneficiary out-of-pocket -- and,
2 once again, maybe we had this data and we've looked at it.
3 We've looked at a lot of data. So just the escalation of
4 beneficiary out-of-pocket in any of the programs, Part B,
5 Part D, over a period of time, do we have good information
6 around that, that sort of situation, about how that has
7 changed over the past three years, five years, et cetera,
8 as far as what they have to pay out of pocket?

9 DR. SCHMIDT: I can speak to D because we have
10 claims information, so we could come back with estimates.

11 But, generally, I think in D, so much of the
12 population has moved towards generic, so out-of-pocket for
13 many of those folks, zero, low co-pays. It's a pretty nice
14 deal. The problem is with the specialty drugs, the small
15 percentage of the D enrollees who are on those. That's
16 where they're facing co-insurance and on very, very high
17 prices. So that's where the burden lies for there.

18 DR. CROSSON: Karen and then Dana.

19 DR. DeSALVO: I had a reference pricing question.
20 You had mentioned somewhere of TRICARE as a model, and I
21 don't remember where that was in the list. But it made me
22 think about the VA. So is there a domestic reference

1 pricing opportunity or some reason why we're not able to
2 use VA as an example?

3 DR. SCHMIDT: Well, with VA, there's statutory
4 rebates, and they negotiate some additional rebates. They
5 have an ability with their prescribers to move market share
6 pretty strongly. There's more consensus among prescribing,
7 I would say. So those are two big reasons why they get
8 such good prices.

9 I think an objection that would come up to using
10 VA as a reference price is probably associated with the
11 statutory rebates. It's by law. That's not to say we
12 shouldn't go there. That's your decision, but that's an
13 objection that would arise. It's demanding by law, a
14 rebate. But other options we've brought to the table do
15 the same thing.

16 DR. CROSSON: Dana.

17 DR. SAFRAN: Yeah, two things.

18 One, back to the issue we were talking about a
19 little bit yesterday on cost-related non-adherence. I
20 don't have a clear understanding, so I just wanted to get
21 one, of whether there are direct data, meaning beneficiary-
22 reported data over time on cost-related non-adherence to

1 medications, or if not, hearing you talk about our ability
2 to use the claims data to get at some of the issues we've
3 been talking about so far did start me thinking about some
4 of the indirect ways that cost-related non-adherence has
5 been attempted. It's tricky with claims data, but that's
6 my first question: Do we have a way to measure what's
7 happening with respect to cost-related non-adherence as
8 we're moving around cost sharing and access?

9 DR. SCHMIDT: I'd have to think about whether --
10 on just beneficiary-reported adherence, whether there's
11 something that's reliable we could turn to there or some
12 other kind of clinical thing that would show up in data
13 that's readily accessible to us.

14 The other sorts of measures that are commonly
15 used for adherence, yes. That's, I think, possible to look
16 at those.

17 DR. SAFRAN: Because I think looking at that over
18 time would be extremely valuable for this issue that we're
19 immersed in and staying immersed in for the foreseeable
20 future.

21 The other thing, I just wanted to come back to
22 this international comparison in Part D because I heard

1 your answer to Warner's question about whether we could do
2 something like that for D and sort of the challenges of
3 doing that with rebate. It just seems like we should --
4 maybe this is a Round 2. It just seems like we shouldn't
5 be stopped, like we should make a best effort to see what
6 could be done there. That line of inquiry seems quite
7 important, and if that's the barrier, then I just wonder if
8 there's a way we can come at it.

9 DR. SCHMIDT: There were a couple of suggestions
10 yesterday for how to look at some brand-name drugs that
11 have been priced at a net level rather than inclusive
12 rebates. So it would be for a limited number of drugs, but
13 that's one way to get to it.

14 DR. CROSSON: Pat.

15 MS. WANG: The next time that we have this
16 conversation, would it be possible for you to do, sort of
17 in one place, a description of an evaluation of the
18 different types of statutory rebate programs that exist,
19 whether it's Medicaid, the VA, 340B, their similarity, and
20 just what the common themes are that perhaps we could
21 identify as being the most effective?

22 DR. SCHMIDT: [Nodding affirmatively.]

1 MS. WANG: Thank you.

2 DR. CROSSON: Okay. Seeing no further questions,
3 we're going to move on to the discussion.

4 I just want to make a couple of points. Number
5 one, maybe it's not been brought up explicitly. Much of
6 our work has focused on Part B and Part D. That doesn't
7 mean that in searching for solutions, we should ignore
8 another set of issues that Warner and other Commissioners
9 have brought up, and that's the impact of drug prices on
10 Part A and the impact that has on the ability of hospitals
11 to absorb cost increases over time. To the extent that we
12 address solutions here, we just need to keep in mind that
13 it's not simply Part D and Part B, but Part A is an
14 important consideration as well.

15 Second thing, just in terms of the conversation
16 here, you've done a wonderful job setting the table here.
17 This is a sumptuous buffet that we are facing here. I'm
18 probably going to mix metaphors here because I was going to
19 say something about boiling the ocean. But my experience
20 with buffets in the past is that sometimes overindulgence
21 is a risk.

22 I think what I'd like to do here and I think what

1 would be most helpful for the staff and for the Commission
2 in general is to try to focus your remarks, as best you
3 can, thinking about a few parameters. Relative
4 effectiveness, for example, what's most likely to work?
5 Even though we have some issues around quantitation, this
6 is as judgment issue. What do you think is going to be the
7 most likely approach or set of approaches to impact price
8 and to some degree, in some circumstances, the issue of
9 appropriate utilization of drugs as well?

10 What about feasibility? And I'm not so much
11 thinking about enactment here because I think that's very
12 difficult to predict in any environment, particularly at
13 the moment, but administrative feasibility, how this would
14 work out in the end.

15 The time to effect, how long would a particular
16 approach take to actually have an impact over what is
17 increasingly creating a sense of public concern, if not
18 alarm?

19 Then the question of unintended consequences,
20 downsides, impact on beneficiaries Karen brought up, but
21 there are other things as well.

22 That's a lot to absorb, but I would ask you to

1 try to be as focused along those lines as you can. And I'm
2 going to ask Kathy to begin the discussion.

3 MS. BUTO: Thanks, Jay, and I was going to sort
4 of start there.

5 DR. CROSSON: You were going to say what I was
6 going to say? Sorry about that.

7 MS. BUTO: No. Actually, what I started -- as I
8 looked at this document, which was comprehensive, one of
9 the things that occurred to me is it would be helpful to us
10 to try to sort those options so that we can focus the work
11 of all of us on those things that will have the biggest
12 impact. So that's why I asked the question about do we
13 know anything about magnitude of savings.

14 The other sorting that I thought about was new
15 drugs versus ongoing payment discipline or pricing issues
16 for existing drugs. So I actually think there's a lot of
17 concern about new drug pricing, and we ought to really look
18 at a constellation of things around that and also, then,
19 look at the ongoing maintenance pricing issue going
20 forward. So those are two sorts that I would try to do and
21 then, of course, the magnitude of savings.

22 The operational feasibility piece, I just offer

1 that it was my experience that the more you get into a
2 drug-by-drug kind of decision-making process the longer it
3 takes and the harder it is to make a systemic impact. So,
4 for example, one of your options is looking at the pass-
5 through policy for outpatients. That's not a drug-by-drug
6 approach. That is a systemic issue that definitely impacts
7 spending and pricing and everything else. So again, I
8 would try to figure out, not exclusively, but are there
9 areas where we know if a policy change happened it would be
10 pretty much an across-the-board, you know, improvement.

11 The other thing that is important, and this
12 probably comes from experience also, is the extent to which
13 a policy change can be implemented, not at the federal
14 level, because the federal level is very susceptible and
15 vulnerable to lobbying, congressional interference, et
16 cetera, statutory change that stops you from doing
17 something. So again, if we can think about, you know,
18 where are the pressure points that would make the change
19 actually happen, I think that's useful too.

20 And then I think we should consider whether the
21 policy options we're looking at would actually stimulate
22 higher launch prices. I think you alluded to some of

1 those, Rachel, in your setup. But there's some where we're
2 pretty sure that if we took that approach that it would
3 lead, initially, at least, to higher launch prices and then
4 maybe diminishing returns down the road. We don't know. I
5 think it's important to consider, also, the impact on
6 competition and innovation amongst drug categories and
7 individual drugs, so that's important.

8 One of the things that occurred to me -- and this
9 is just back to the point about new drugs versus existing -
10 - is in addition to policies designed to constrain, there
11 might be policies that could be used to constrain spending
12 for inappropriate uses that are really used more as a
13 carrot. So, for example, there might be a combination
14 policy where we want to delay the introduction or ability
15 of beneficiaries to get a wide range of indications off-
16 label, but the carrot could be if we believe that the
17 manufacturer wants to come in and talk about, you know,
18 more coverage with evidence development or some evidence
19 generation process, then they have an incentive to do that
20 and the program might benefit down the road.

21 So using the interest to stimulate something
22 else, even the issue of direct negotiation, which I know is

1 anathema to industry, might be appealing if it meant that
2 some breakthrough, as they define it, drug would get
3 earlier access in the program. So there might be a
4 willingness to negotiate in exchange for earlier access or
5 access in certain setting. In other words, I would try to
6 think of this as both carrots and sticks, constraints as
7 well as incentives, to try to induce the kind of generation
8 of information that we'd like to see. So not just ways to
9 stop prices from rising but also how can we get a better
10 value for the program.

11 And so I would just say, in the next go-around,
12 if we could have maybe a little bit of foundational
13 information about whether we think something is going to
14 have an impact of a greater magnitude, whether it's
15 operationally feasible in a relatively short period of time
16 and whether there is a mix of things that could be both
17 constraining but also stimulate, you know, better
18 information, longer-term registries, whatever it is we
19 think will provide better value to the program, I think it
20 would be good to have that sense.

21 DR. CROSSON: Thank you, Kathy. Very good.

22 Okay. So I think we're going to have a lot of

1 comments. I'll start with Paul and then Brian.

2 DR. PAUL GINSBURG: Thanks. I think you did an
3 excellent presentation and Kathy's comments were very wise.

4 I, too, kind of big-picture things that apply to
5 a lot of this. One is that as I was listening to the
6 different options I kept thinking about all different
7 aspects of price discrimination, and, you know, price
8 discrimination sometimes is a good thing, sometimes is a
9 bad thing, and that you might want to, when you come back
10 in March, do a few minutes' seminar for the Commission
11 about price discrimination, because it's going to come up
12 on a lot of the issues. And I think if we have a nuanced
13 perspective on it I think it will be very helpful, because,
14 really, some of these things make it easier to price
15 discriminate and some of them make it harder to, and, you
16 know, we need to go through that.

17 The other thing is that when we're in the Part B
18 space, a lot of times there's a tendency to say, well,
19 something won't work because of Medigap coverage. And, you
20 know, Medigap, to me, has been something that has driven
21 Medicare spending higher ever since the beginning of the
22 program, but I think there were some changes, some

1 restrictions on Medigap benefit design, and I know this
2 Commission has recommended it further, that we should
3 certainly, you know, resurrect some options. If all it
4 would take would be a change in Medigap benefit design, it
5 would make it a viable option. We shouldn't feel
6 constrained forever.

7 Getting back to the particular options, one that
8 was new to me is the one on coupons, about, you know, using
9 data on coupons to calculate ASP, because again, coupons
10 are really a price discrimination approach and I think
11 hurts the program, and I think hurts society, and we ought
12 to do that. And I'm also particularly interested in
13 various reference pricing approaches that we might be able
14 to come up with.

15 DR. CROSSON: Thank you, Paul. Brian.

16 DR. DeBUSK: First of all, thank you for a really
17 good chapter and I'm glad to see us jump into the middle of
18 drugs.

19 Jay, I agree with your assessment that it is a
20 buffet. I like that term and I was going to stick with
21 your analogy here. You know, if you talk about the
22 particularly attractive items on the buffet are things

1 we've identified before -- the DVP, for example, binding
2 arbitration, so the baseball-style arbitration, and the
3 restructuring of the reinsurance component of Part D.
4 But now I'm going to take your buffet one step further,
5 which is I think before any of these measures will be
6 effective we need to go revisit the rebate trap, because my
7 argument was that the rebate trap is the salmonella in the
8 whole buffet. And here's the issue.

9 DR. CROSSON: I think I see where this is all
10 going to go.

11 DR. DeBUSK: Well, there is an absolute necessity
12 for fees, discounts, and rebates. I mean, you guys
13 probably understand it as well or better than I do. There
14 is a place. You have to have that vehicle. But not all
15 fees, discounts, and rebates are created the same. Some
16 are used for legitimate purposes and some are used in very
17 predatory and punitive ways.

18 And, for example, if I'm buying -- I'll just get
19 specific -- if I'm buying \$10 million of something and
20 someone comes to me and says, "Hey, you're a great
21 customer. I want you to have a 25 percent rebate," well, I
22 may buy \$9 million next year, I may buy \$11 million the

1 next year, but I know I'm getting a proportional 25 percent
2 rebate on those purchase. That's very different than a
3 rebate -- when I'm buying \$10 million of something and
4 someone says the moment you shift one dollar away from that
5 \$10 million purchase I'm taking \$2.5 million away from you.

6 These disproportional rebates, these punitive
7 rebates are fundamentally different than legitimate fees,
8 discounts, and rebates that are proportional to the value
9 and volume of products sold. And I don't think it's our
10 place to go in and say, "Let's ban all these punitive
11 rebates." But they certainly shouldn't enjoy safe harbor
12 protection either. Right now all of these predatory
13 tactics enjoy safe harbor protection under the fees,
14 discounts, and rebates rule, and I do think it would be
15 within our purview to dig into the rebate, revisit the
16 rebate trap again, and try to identify these
17 disproportionate rebates, and try to put together good
18 policy on how to address them.

19 DR. CROSSON: Thank you. Further comments? Amy.

20 DR. BRICKER: So there's so much here, and I
21 think it does warrant a lot of time for the Commission to
22 spend to really attempt to get this right. It's really

1 easy to grab one thread and pull it, but, of course, this
2 is very complicated.

3 I mentioned yesterday that I thought we'd seen
4 some success in Part D from a total spend -- the numbers
5 are still big and I'm not willing to debate whether or not
6 the number is a good number -- but we did see trend
7 flatten, year over year, '16 to '17. So in total spend,
8 that's a good sign. It's not escalating. But I do think
9 that it warrants us revisiting who is the winner and who is
10 the loser in the way that it's designed today -- whether or
11 not we've got the right incentives in place for plan
12 sponsors, whether or not we have the right protections in
13 place for beneficiaries.

14 In particular, you highlight around specialty
15 drugs. Absolutely in favor of us ensuring that the
16 beneficiary has a maximum out-of-pocket. That is, you
17 know, in line with a commercial market -- nothing more than
18 \$100, nothing more than -- you guys pick the numbers, but
19 something that would, you know, send a signal to plan
20 sponsors that we can't shift those high-cost benefits to
21 the beneficiaries.

22 I thought maybe I could just tick through some of

1 the things that you highlighted and just provide a
2 reaction. I'm interested in us exploring reference
3 pricing. It feels a little complicated but that's not a
4 reason not to do it. So I'm interested in that. I'm not a
5 fan of broader use of arbitration. For me, if we want to
6 give the tools to the Part D plan sponsors, or incent Part
7 B to actually be managed in a way similar to Part D, allow
8 those plan sponsors to exclude products, allow plan
9 sponsors to have leverage in a way that would essentially -
10 - you wouldn't need arbitration if you could actually
11 exclude products at launch. If you could demonstrate
12 increasing leverage over a manufacturer, you don't need a
13 binding arbitration. And furthermore, you're just
14 essentially -- and as I spoke about it when we went through
15 it last year or two years ago -- you're essentially
16 negotiating as a single entity. I don't know any other way
17 to see it. You're essentially negotiating, Medicare is
18 negotiating for drug benefit, or drug pricing, essentially.
19 So not a fan of that.

20 Otherwise, we talked a little bit about coupons,
21 and I think, picking up on what Paul mentioned, it has led
22 to increased pricing over time, and I appreciate the

1 estimate on the ASP but what if those coupon dollars would
2 also be required to show up as rebate in Part D? There you
3 would see a tremendous impact in overall cost. So
4 manufacturers could be required to report their coupon
5 dollars in the commercial market, and since Medicare
6 beneficiaries cannot receive those coupons, by statute,
7 then those dollars could go back to the plan sponsor, could
8 go back to the government as the payer. So one approach
9 for us to potentially consider.

10 Particular with LIS, because they don't have a
11 disincentive to use certain brand products because of the
12 way that the copay is structured, so again, just thinking
13 about the consequences of coupons and the overall impact,
14 not just it's to the, of course, Medicare benefit but what
15 also is happening in the commercial space I think might be
16 worth considering.

17 I'm a big fan of outcomes-based pricing, if we
18 can crack that nut. Historically, what's been the issue is
19 an anti-kickback, so if the drug becomes free then have you
20 crossed a line? And that's been my experience that
21 manufacturers fear that they don't want to enter into those
22 agreements because if they have to fully refund the product

1 then do they have a best price issue or are they in
2 violation of anti-kickbacks?
3 So things, I think, that we have to address if we're going
4 to recommend, and also I'm a fan of indication-based
5 pricing, because, and an example of that, I would like the
6 group to think about is cancer products, where a drug has
7 been approved for a certain cancer, it works really well,
8 we see that in evidence, it commands a high price. Off-
9 label an oncologist could use it for another type of
10 cancer. It doesn't work as well. Same price. So
11 manufacturers certainly, and today in the commercial world,
12 come to the table with I'll give you a different level of
13 pricing depending on the indication it's used.

14 With Kathy not in support of direct negotiation
15 by Medicare, and in favor of exclusive specialty pharmacy
16 networks, think about it this way. There isn't a specialty
17 pharmacy today where you walk up and you get the specialty
18 drug at the counter. All specialty pharmacies, be it, you
19 know, an independent or a very large pharmacy, those
20 products are delivered at your doorstep or at the
21 physician's office. So this isn't about reducing access.
22 It's about where is the best price, where can you get the

1 best price, and where can you get the best care?

2 So those two things, again, support of us
3 exploring that and moving certain drugs from B to D, again,
4 in support of. I would like to understand more about the
5 manufacturer rebates for wasted drugs.

6 All in all, I think what we've said is we can't
7 continue to just nibble at the edges of this problem that's
8 continuing to, you know, the volume is continuing to
9 increase. I think you have a group of folks here that want
10 to take on the issues in a large way, and it's complicated
11 but that shouldn't be the reason that we don't take it on.
12 And to spend the time to get folks, you know, educated on
13 what will work, what won't work, and the unintended
14 consequences of some of these actions, I think, is really
15 important.

16 So thank you and I appreciate all of the hard
17 work on this.

18 DR. CROSSON: Thank you, Amy. Jonathan.

19 DR. JAFFERY: Yeah, thank you. This is a great
20 array of topics.

21 I want to echo what Jay had said about not
22 forgetting Part A and thinking about actually not only the

1 impact on prices and costs for hospitals but thinking about
2 is there some beneficiary impact here. I'm thinking about
3 actually some of the things we've seen in the generic
4 world, which also is maybe not something that is deep in
5 the list of ideas yet, but there are a couple of egregious
6 examples of pricing increases in that space. But we're
7 starting to see some evidence of impact on beneficiaries.
8 There was a study out of the Cleveland Clinic recently that
9 looked at decreased utilization of nitroprusside, a drug
10 that launched in clinical use in 1928, so before any of us
11 here were born, and it rose over the course of a couple of
12 years. The average price rose from \$27 to almost \$900.
13 And now they're starting to see a decreased utilization of
14 a drug that has had a lot of clinical experience. So
15 that's one thing.

16 In terms of some of the other specifics, I will
17 just mention a few. I'm also really interested in
18 understanding more about reference pricing and the various
19 methods of being able to do that. I'm curious as to what
20 you would think about the impact on beneficiaries for
21 excluding new products at lunch, especially if there's not
22 a lot of other alternatives, and certainly regardless of

1 what we think that's going to be something that comes up
2 from advocacy groups and industry a lot.

3 And then the last thing I'll mention is on
4 outcome-based pricing. I guess I'm concerned that that may
5 not get to the issue, one big issue that's top-of-mind for
6 a lot of folks, which is just how expensive things are at
7 launch anyway. So, again, I want to understand more about
8 the mechanics of that. But now that we're seeing these
9 therapies that come out at half a million dollars or three-
10 quarters of a million dollars, if the manufacturers are in
11 a situation where they're being offered, or offering, or
12 are forced to offer that outcome-based approach, is that
13 going to -- what's the behavior there? Does that embolden
14 them to have prices that are going to be higher or just
15 come out with more of these really super high-priced drugs
16 at launch?

17 So just a couple of thoughts. Thanks.

18 DR. CROSSON: Sue.

19 MS. THOMPSON: First of all, Amy, I want to agree
20 with the comment you made about educating us. I mean, this
21 is a system that is complex by design and intention, it
22 seems, and the more we understand it, the better job we can

1 do. So I just want to underscore that comment.

2 And the second comment I want to underscore
3 before I labor on in commentary is the call out that Jay
4 did in his opening on round Part A and the impact this has
5 on Part A. On a newsfeed that came across this week or
6 last week, I read that hospitals are now stating they're
7 reducing labor, they're reducing nursing staff in order to
8 account for the increase in drug costs to hospitals. So
9 after -- I can't help but connect many of our chapters, and
10 after yesterday and the long deliberation around our update
11 to hospitals recognizing negative -- 11 percent negative
12 margins for hospitals in terms of Medicare margin, I mean,
13 these all connect. And I think it's important as
14 Commissioners for us to recognize that.

15 But in terms of the context for this chapter, in
16 addition to the complexity and all the technical details
17 that go into the formulas for pricing, we talk about the
18 effect to the beneficiary, and we reference out-of-pocket
19 spending, quite important. But there's a broader impact to
20 the beneficiary in the context of health care, and it has
21 to do with an assumption that drugs are good. And drugs do
22 a lot of good, but not all drugs are doing good things for

1 our beneficiaries. And there's a broader impact to this
2 system that I think just in terms of the context and the
3 urgency that this group of Commissioners feels around this
4 issue, it's important as we articulate our recommendations
5 that it's in a broad context of there's harm created to our
6 beneficiaries by the fact that we're not managing the
7 profiles of our beneficiaries. And we see patients coming
8 into our system, whether it's through the emergency
9 department after a fall or primary care clinics that are
10 overwhelmed and don't have time to reconcile the drug
11 lists, of patients that are on six, seven, eight, up to
12 twenty different prescriptions. And there's a consequence
13 to the system for this happening, and this is all one of
14 the unintended consequences of this assumption that drugs
15 are good and that a pill will fix things. And I just think
16 it's important for us to recognize there are costs well
17 beyond those that you have identified in this chapter that
18 go to the emergency department costs, the patient has an
19 inpatient stay, they end up going to skilled, and then all
20 the impact to the system and Medicare in that context. And
21 I think that's just important for us to pull these pieces
22 together and understand and tell our story and create that

1 urgency.

2 So just again, in terms of the context to the
3 discussion, there's a broader cost going on here to our
4 beneficiaries.

5 In terms of the recommendations, I am intrigued
6 with better understanding what's this coupon business about
7 and how does that weave together and what are the themes.
8 And, likewise, I'm interested more about the Medicaid
9 rebates and how that might have application in Medicare.

10 Thank you.

11 DR. CROSSON: Bruce.

12 MR. PYENSON: I want to second Brian's E. coli
13 reference -- sorry, it was Salmonella, on the importance of
14 the rebate trap that I don't think any of this -- any of
15 the other suggestions will work if that's not addressed.

16 But I'd like to set a goal of prices deflating as
17 a measure of success. Session after session, we're looking
18 at increasing prices on the various chapters that we
19 review, and in my mind, all of those represent failures for
20 our ultimate goal of the stability of the Medicare system.
21 A place to start is pharmaceuticals because they are
22 commodities that are manufactured. And manufactured goods

1 follow Moore's law or more or less that over time -- and
2 we've all witnessed this in our lives -- commodities become
3 less expensive, they get produced more efficiently, and
4 perhaps more profitably. So that should be our
5 expectation. I believe we should start with
6 pharmaceuticals, and if we don't get there, we haven't done
7 our job.

8 One particular area that I think deserves focus
9 is the failure in the United States of biosimilars.
10 Biosimilars have failed here. In a number of countries,
11 biosimilars are aggressively promoted by the national
12 systems and are in very wide use, and various obstacles
13 that we see in the U.S. have been resolved. Issues that
14 are not supported by science are repeatedly brought up in
15 the U.S., and there's a whole series -- you know, the
16 patent estate has become a patent thicket, and a series of
17 things that are outside our scope, but there's certainly
18 issues inside our realm that deal with the pricing and the
19 failure of biosimilars in Part D that we can address.

20 In particular, the failure of biosimilars in the
21 U.S. I think is going to destroy the potential of
22 personalized medicine because if we can't get efficient

1 production of biologic drugs on a mass scale and get that
2 through the system and into use, we'll never be able to do
3 that on an affordable basis for personalized medicine. So
4 this I think is really critical for future health care and
5 hope for solutions.

6 Finally, I really do like Kathy's concept of
7 carrot and stick. I think one of the real carrots that the
8 Medicare program has is its data. Actually, I'm not sure
9 if that's a carrot or a stick, but the ability of using
10 Medicare data, even claims data, as real-world data with
11 its vast scale and longitudinal capabilities could be put
12 to use to figure out what works and what doesn't work and
13 really indicate why. So I think that's potentially of
14 great value, and I suspect that innovators and
15 manufacturers would have a keen interest in using -- in
16 having access to that information.

17 DR. CROSSON: Jon.

18 DR. PERLIN: Let me thank the Commission for
19 really exceptionally thoughtful work on obviously a
20 critically important area.

21 I sit here thinking about the fact that our
22 discussion is frame within this is Part D, this is Part B.

1 You alluded to Part A. And it makes me think of two
2 things.

3 First, how might we think of this more
4 holistically, even though we have a buffet, it's still the
5 same meal? And, second, how would this be handled in other
6 settings? How would this be handled in the commercial
7 environment?

8 So just a couple thoughts that may offer some
9 opportunity in terms of unification and opportunity. When
10 we talk about the coverage with evidence determination and
11 comparative effectiveness, really we're talking about the
12 relative utility of certain products relative to each
13 other. And, you know, that leads to an implication that
14 some are, in fact, better. And the whole premise of
15 evidence-based medicine is that at any given moment there
16 is knowledge that suggests for a set of circumstances some
17 agent is better.

18 And I think that we're going to have to think
19 about -- and I liked Kathy's way of framing this -- how we
20 have incentives to offer beneficiaries best at any given
21 moment as opposed to, you know, the sort of traditional,
22 you know, wide open platter where, in fact, we know that

1 there are costs -- and I think we should quantify this --
2 of complications of inappropriate therapy. Goodness, we
3 talked at length about one category of that yesterday in
4 the area of opioids.

5 So I think we have found an obligation to think
6 about not only the coordination among programs in terms of
7 acquisition and supply of medications, but in terms of the
8 coordination between the different Medicare program
9 elements for the beneficiary herself.

10 I think this notion of data is undertapped. You
11 know, as someone who had the experience of caring
12 predominantly for older individuals in my clinical past, I
13 was always impressed with the number of obsolete
14 prescriptions that were still prescribed and the number of
15 times that those led to drug-drug interactions. One of the
16 costs that, you know, may offer some opportunity is the
17 cost of drug-drug interactions.

18 The medication reconciliation, while onerous at
19 one degree, is obligatory and, you know, has been
20 promulgated through the electronic health record, earlier
21 the meaningful use, and now performance improvement program
22 as well.

1 I would suspect, if we look systematically, that
2 we would find that there are medications that beneficiaries
3 are prescribed solely to treat the complications of other
4 medications, and that is a cost. And Dana mentioned an
5 incredibly important topic, which is the cost of non-
6 adherence. We know from our own internal work that when
7 heart failure patients return for readmission, oftentimes
8 it was lack of access to medications as an example. That's
9 why we're taking approaches to mitigate that. But, you
10 know, writ larger, when beneficiaries don't have a Part D
11 record in some window after, you know, certain categories
12 of hospitalization, I would argue that is a telltale data
13 trail of the cost of non-adherence leading to readmission
14 or potentially worse, and I hope we would actually look
15 into, you know, the relative rates of Part D encounters
16 following obviously admissions and their association with
17 readmission, if that health service research hasn't already
18 been done.

19 Then, finally, on this theme of using the data to
20 drive more ideal prescribing for efficiency and best
21 outcomes for beneficiaries, it's kind of interesting that
22 if any of us have an allergy to a medication, that is

1 recorded. But if something didn't work, it gets stopped,
2 and something else is tried, only to repeat the cycle
3 again. And while we know intellectually that at a genomic
4 level there's probably some molecular basis for that, the
5 problem is that that's not systematically recorded, and one
6 of the areas that would contribute tremendously to
7 understanding particularly in terms of tapping into
8 personalized medicine in the future is some systematic
9 recording of why a medication is stopped, short of an
10 allergy, and that would help to drive, you know, better
11 utilization as well as ultimately an understanding of the
12 genomics of pharmacotherapy.

13 So I appreciate those ideas. The short message
14 is that there are a number of utilization parameters that I
15 think we can follow that actually would allow progress even
16 as the table is set now. Second, the coordination amongst
17 programs would have a rationale not only in terms of
18 program management but in terms of the care and best care
19 of the individual beneficiary. And, third, in an election
20 world with the availability of data, there are data
21 elements that can help us drive this forward. And, fourth,
22 that the aggregate of those data drive us toward more

1 thoughtful prescribing practices that, as Kathy framed,
2 could be incentivized positively or other less desirable
3 prescribing practices discouraged.

4 And just a sort of asterisk on that, having had
5 the privilege of leading the VA system, it was the two-fold
6 -- it was not only the ability to structure the acquisition
7 of the medication, but also to couple that with work flow
8 that drove toward most optimal prescribing.

9 Thanks.

10 DR. CROSSON: Thank you Jon. Marge.

11 MS. MARJORIE GINSBURG: I just wanted to put out
12 a greater exploration in the whole area of cost-
13 effectiveness research. In part, I'd begin sort of
14 thinking about what are the primary principles that are
15 most important to us in trying to achieve lower prices.
16 And to me, the principle that stands out most of all is the
17 whole concept of clinical effectiveness and relative
18 clinical effectiveness.

19 I was a panel member for ICER for seven or eight
20 years, and even before it was ICER, when it was part of the
21 Blue Shield Foundation program. So I sort of grew up with
22 the program and, of course, anybody who is familiar with

1 it, you know, really came to respect it and enjoy it and
2 appreciate the incredible amount of work that goes into
3 being fair in determining what cost-effectiveness looks
4 like in terms of pricing of drugs.

5 So I hope we can give this its due. It's very
6 labor-intensive, and many people argue that we shouldn't be
7 using qualities as a measurement in any fashion. But I
8 just thought I wanted to speak from personal experience of
9 having been a panel member on ICER, that I really became a
10 true believer.

11 Thank you.

12 DR. CROSSON: Dana and then Warner.

13 DR. SAFRAN: This has been a great discussion.
14 Just one thing to add to it, which kind of picks up on
15 cost-effectiveness. I think I've mentioned this here
16 before, and so I don't know whether we've explored it, but
17 if we haven't, I think it would be good to.

18 Many other countries have a formal way that they
19 require when a new drug is coming to market that there be
20 cost-effectiveness data presented to them and that it be
21 used in determining coverage and price. And so I've
22 wondered, since we don't have an analogous mechanism to

1 something like NICE in the U.K., would it be possible to
2 require that all data and reports that had to be submitted
3 for approval of a therapy in other countries be reported in
4 the U.S., too? They don't have to do additional new,
5 different reporting, but at least to have that information
6 on hand as drugs are being looked at has always struck me
7 as information that could be helpful. So just an idea
8 about exploring that if we haven't already.

9 DR. CROSSON: On that point?

10 DR. PAUL GINSBURG: I just want to mention I'm
11 surprised that I have not heard yet in our discussion of
12 effectiveness the fact that we have legislation that
13 established an effectiveness agency. It's called PCORI.
14 Many people are -- from the beginning, it was prohibited to
15 looking at costs. I think many people have been
16 disappointed in what it's achieved, just looking at
17 effectiveness, and -- but in a sense -- so this is
18 something, revisiting a major policy that has been either
19 launched, or perhaps not launched because of the
20 restrictions on costs. And I'm not optimistic that we
21 could have a big impact in this area compared to some of
22 the other areas we've talked about.

1 DR. CROSSON: I lost track now. Warner.

2 MR. THOMAS: So I think all the comments have
3 been great. I think going back to Kathy's opening
4 comments, I do think -- and Karen's questions earlier, I do
5 think it would be helpful to -- whatever laundry list you
6 come up with, or the buffet as it has been referenced,
7 think about putting this on a 2x2 grid of, you know, from a
8 low to high positive impact to beneficiary from a cost
9 perspective, impact to the program, so we could understand
10 that we are -- you know, what we're targeting and making
11 sure that we're going down the road where at least from
12 your perspective we feel like we could have the most
13 impact. I think it would be helpful.

14 And I also like Jay's comment about what's
15 feasible. So let's look at the cost-effectiveness or the
16 cost impact and then the feasibility of actually what can
17 be, you know, put into place. I know all of those are
18 subjective, but at least we'd have a way to look at that.

19 You know, I think MedPAC has put a lot of ideas
20 out there and I think tried to be very creative about how
21 it approaches this situation. There hasn't been a lot of
22 uptake on many of those. There's been some but not a lot.

1 And I think we know that there's this pressure that we see
2 increasing drug prices and we hear the anecdotes in the
3 news, and, you know, there's an article in the Wall Street
4 Journal today about drug shortages, but also the fact that
5 we see costs increasing several hundred percent.

6 If we're sitting here talking about a several
7 hundred percent increase in home health pricing or hospital
8 pricing or any of the things we talked about yesterday,
9 we'd be like, "Are you kidding me?" I mean, how can this
10 be? But yet we've come to almost think that this is okay
11 or acceptable.

12 So I would really encourage us to be methodical
13 and thoughtful, but also take a hard line on this. And
14 although I don't think -- I hear the comments about direct
15 negotiation from a government perspective to the
16 manufacturers may not be the right way. I do think this
17 idea of taking the suggestion that was in Part B and maybe
18 extrapolating across all the programs, A, B, and D, of an
19 inflationary cap would at least put some downward pressure
20 on pricing and I think encourage manufacturers to get more
21 creative.

22 I think going to Bruce's comments around Moore's

1 law, I mean, many of these drugs that are so old, we should
2 see the pricing going down not up several hundred percent.
3 And, also, maybe we should talk about or there should be
4 some research done about how do we make it easier to get
5 into the world of manufacturing or are there other
6 opportunities there, because, you know, it's just not
7 sustainable, kind of what we're talking about.

8 So I would encourage us to look at the idea of a
9 cap across all the programs. I would also encourage us to
10 think about a cap around launch price. Now, you could have
11 a -- you could go to maybe binding arbitration if someone
12 wanted to go over that cap. But I think this idea -- I
13 mean, we started to hear this the other -- a couple
14 meetings ago about million-dollar drugs, you know, for a
15 dose, and it's just like obviously for that patient it's
16 extremely important, but is that really feasible to the
17 cost of health care and to our society to have million-
18 dollar drugs going forward or drugs that are several
19 hundred thousands dollars for treatments or for doses?

20 So I think we've got to start to put a cap on
21 these things and take a harder line. We can always have an
22 arbiter. It could be a binding arbitration, or you can

1 have an appeals process. But I would really encourage us
2 to take that as a hard line.

3 I also think it would be interesting to
4 understand -- we have somebody here who has a lot of
5 experience, Jonathan, in the VA. How has the VA done on
6 pricing? And how does that compare to what we're seeing in
7 our own government programs, which are actually larger, you
8 know, from a purchasing perspective? And just what are
9 those differentials?

10 I've got to be honest, I don't totally understand
11 the rebate area, and I think having more transparency
12 around that, it seems like it does create escalation in
13 pricing, and that there probably out to be some
14 modification of that program to create, number one, more
15 transparency, and for it not to be able to be used as a way
16 to drive pricing up. If it's a way to essentially rebate
17 so people get better deals or that beneficiaries have lower
18 out-of-pocket costs, great. But if it's, you know, just
19 used so we can drive the pricing up and kind of push it
20 back in a different fashion, I don't think that that makes
21 a lot of sense.

22 So I would just encourage us to take a much

1 harder line -- we can always back off from it, but I would
2 encourage us to take a much harder line around this idea of
3 escalation caps. We do this in all the other areas of the
4 program. Maybe in Part A we ought to -- and I actually
5 mentioned this to Jay before. Maybe we should index it to
6 whatever increase we put in for the inpatient increase for
7 hospitals. Maybe the drug escalation or price cap ought to
8 be whatever the inpatient rate increase is. That would be
9 a way to index it so that it's maybe more fair as far as
10 how we think about purchasing in the Part A program.

11 So those are some ideas that I'd like to see us
12 explore, and to not be scared by, you know, lack of R&D or
13 shortages -- because we have shortages today, and there's
14 virtually no control in pricing. So I think we've got to
15 do a better job putting some caps on this and forcing this
16 part of the industry to be a lot more creative in how they
17 look at costs and a lot more creative in how they come to
18 the table to be part of the solution.

19 DR. CROSSON: Karen, did you want to comment on
20 that?

21 DR. DeSALVO: [Speaking off microphone.]

22 DR. CROSSON: Okay. Jaewon first, then Karen and

1 Amy.

2 DR. RYU: I was just going to comment that it
3 seems like this topic, more than any other that we've
4 encountered, obviously very complex, but I'm noticing that
5 there are a lot of recommendations that we have previously
6 made that didn't gain traction. There are three whole
7 slides dedicated to it.

8 I wonder if it's got something to do with this
9 notion of it's a buffet. There's just too much, and you
10 don't even know where to start. So it's not even you're
11 overeating. You're not eating at all. You're just
12 confused and starving.

13 [Laughter.]

14 DR. RYU: So it would be helpful, at least to me,
15 when we revisit this in March, some notion of how do you
16 prioritize and where do we think is -- it's that notion of
17 feasibility, but it's what can be done quickly to just take
18 one step. If you extend the buffet, it's salad, start
19 here. Something like that would be good.

20 The ones I kind of gravitate towards, the
21 structural elements around the program and reinsurance and
22 catastrophic versus the capitated component, kind of what

1 we talked about yesterday, do those seem or feel at least
2 to have a little more immediacy to what can be done? But
3 I'm not sure about that.

4 If there's some way to say instead of this, let's
5 shrink the world and really look at this, I think that
6 might help to get traction. It seems like we've
7 recommended all the right things, and we could keep fine-
8 tuning, but where do we start?

9 DR. CROSSON: Karen.

10 DR. DeSALVO: First, just to underscore the
11 opportunity for us to do more education, I think that
12 MedPAC is uniquely situated to have a very evidence-based
13 frame and peel back the onion of the complexity in areas
14 like rebate and otherwise.

15 I want to offer three 3's as parameters for how
16 we can begin to determine which of the food has salmonella
17 and which doesn't. So the first of the three 3's would be
18 financial. The second would be impact on beneficiaries,
19 and the third would be execution.

20 The first, in financial, to look at overall
21 impact on cost, I'm thinking about Part A on price and on
22 spend, which I believe would be different kinds of notions.

1 The second area, impact on beneficiaries, we've
2 mentioned out-of-pocket, overall access, and then equity in
3 access.

4 Then the third, in execution and feasibility,
5 time to market, time to change.

6 I would just ask also about what's statutorily
7 allowable right now versus what would require congressional
8 action that will impact time and feasibility, but let us
9 know what's the near term. That's a suggestion for some
10 parameters that we might use to help sort and sift.

11 Thank you.

12 DR. CROSSON: Thank you, Karen.

13 I had Amy. Then I saw Marge and Kathy.

14 MS. BRICKER: Yeah. Just back on -- a couple of
15 Commissioners have mentioned the VA. It's just worth
16 noting that the VA is buying drug for each VA facility, and
17 the veterans have to use the VA to get access to those
18 drugs at those prices. So to suggest that we would use a
19 similar model would either mean that we're going to buy
20 drugs for every pharmacy in America and every hospital in
21 America or that we're going to suggest that Medicare is
22 going to have some sort of closed system, select

1 pharmacies, select hospitals, what have you.

2 Again, it sounds interesting, like why can't we
3 just do that. We just have to understand the model that
4 exists for deployment of those discounts, similar to a
5 Kaiser or something else.

6 A point to make again, I've heard the
7 international pricing and why has there been success in
8 other countries relative to this. This isn't because
9 manufacturers like those countries better. It's because,
10 again -- if you asked the question before -- it does depend
11 on the country, but for the majority, they just won't cover
12 the drug. The drug just is not available. So
13 manufacturers are forced to bring the price down to
14 something that -- they're forced to bring down the price,
15 period. We saw this in hep C, and they launched at a price
16 that was three times that in developing countries here in
17 the U.S. And it wasn't until competition that that price
18 actually now is less than in those other countries.

19 We simply have to allow the market, the free
20 market here in the U.S. If we're not going to go to a
21 socialized system, we have to allow the free market to
22 operate, and we get caught between fear that, oh, if we do

1 that, the manufacturers just will stop inventing drugs.
2 We've not seen that. That's what folks want us to believe
3 will be an outcome, but we have not seen that.

4 So, again, I'd just encourage us to think about
5 the handcuffs that are on this system today, as we've
6 designed it today, and take those off.

7 DR. CROSSON: Marge.

8 MS. MARJORIE GINSBURG: I personally wouldn't
9 mind a few limits on our free market system, myself, but
10 that's a different thing.

11 But as long as we're putting everything on the
12 table, it occurred to me -- and I'm a patient advocate --
13 that one possible way to bring down the use of more
14 expensive, less effective drugs is to charge patients
15 higher co-pays.

16 I don't know. Perhaps others have even
17 considered that in some fashion before, and I can't even
18 believe I'm actually saying it. But it's one of the few
19 things that is within our control. We talk about what's
20 feasible, and if we can't get the drug companies to lower
21 their prices, then we discourage take-up by telling
22 patients they have to pay more for a drug when it doesn't

1 work as well.

2 Downside to that is that people tend to equate
3 higher co-pays with higher quality. So we have that little
4 problem to deal with, but I just wanted to throw this out,
5 just to get it on the plate. Thank you. On the buffet
6 table.

7 DR. CROSSON: And just to note, Marge, that is a
8 mechanism in the commercial marketplace.

9 MS. MARJORIE GINSBURG: It is?

10 DR. CROSSON: Commercial drug coverage, yeah.

11 MS. MARJORIE GINSBURG: [Speaking off
12 microphone.]

13 DR. CROSSON: Me too.

14 Kathy.

15 MS. BUTO: And also, Marge, higher-cost drugs do
16 result in a higher co-insurance for beneficiaries. So I
17 think they are feeling that, unless they've got Medigap.

18 MS. MARJORIE GINSBURG: [Speaking off
19 microphone.]

20 MS. BUTO: Yeah. With more differential co-pays.

21 So I just wanted to add to Karen's three by three
22 or whatever it was by saying I think we need to have

1 something on unintended consequences, and one of the ones I
2 mentioned earlier was the potential to increase launch
3 prices. So if a policy is going to actually cause some
4 escalation in pricing, I think we want to be aware of that.
5 We might think it's worth pursuing anyway, but that's
6 something that we ought to consider.

7 Then I really hope that in the -- and this is
8 going to be hard because I think we're going to be sorting
9 through and identifying and prioritizing, but I think some
10 granularity around feasibility is going to be important
11 because there are these issues that I think Amy mentioned
12 of what if you allowed Part D plans to exclude drugs, or if
13 you want government at the federal level to do something,
14 how feasible is that? What process would they have to
15 follow? I think it's important for us to understand
16 because it affects timing, and it actually affects the
17 ability to turn around and make a revision, which I'm
18 always concerned about.

19 You can maybe do the first step, but then when
20 prices maybe go in a different direction or you want to
21 incorporate new competitors, how do you turn around and do
22 it again in a timely way?

1 So I think the feasibility is really important to
2 make these policies work.

3 DR. CROSSON: Okay. Thank you, Kathy.

4 And I think we're going to have to wrap up.

5 I want to make a couple concluding remarks,
6 basically building off of what Warner had to say a few
7 minutes ago.

8 Not to oversimplify -- or actually to
9 oversimplify, to paraphrase a former President, it's about
10 the price. That's really what we're dealing with, and I
11 think as we think our way through this -- and thank you
12 again to the staff for setting this up for us -- we're
13 going to have to think about, in addition to the parameters
14 that have been discussed, mechanisms to directly affect the
15 price, and then many of the other suggestions we have, do
16 that indirectly by changing the nature of the marketplace
17 or by various comparative effectiveness or comparative
18 pricing schemes and the like.

19 A lot of the public discussion right now is about
20 directly affecting the price through having Medicare
21 negotiate prices. I think we understand the reason behind
22 that. We also recognize the complexity that that would

1 require because it would fundamentally, in many ways,
2 change the relationship between hospitals and drug
3 manufacturers, change the structure of Part D.

4 We have recommended changing the structure of
5 Part B, by the way.

6 In thinking about directly intervening on price,
7 I would like to say that the option that we chose in Part
8 B, which is to recommend in certain circumstances, binding
9 arbitration, particularly winner-take-all or baseball
10 arbitration, is one way to enforce the notion that Warner
11 brought up, which is to intervene in extreme circumstances,
12 either around launch prices or around inordinate escalation
13 of price over time, caps, enforcing caps in that way.

14 The notion of introducing arbitration is, I think
15 in the mind of man, a radical idea, and in the mind of
16 others, difficult to contemplate. But from my own
17 perspective, it's a little easier to understand how that
18 could be inserted into the existing programs that we have
19 and would fall well short of Medicare intervening and
20 directly negotiating prices.

21 As we go through this, among the other things
22 that we're going to discuss over the next year or so, I

1 think we are going to elaborate beyond our suggestion,
2 which by the way was introduced about 10 years ago by a
3 former Commissioner, Joe Newhouse from Harvard, of
4 expanding the idea of binding arbitration beyond our
5 recommendation in Part B to potentially include Part D and
6 also Part A.

7 How that would work is to be determined, but I
8 have some belief that in the end, that may turn out to be
9 more feasible in this country than the idea of excluding
10 new drugs from Medicare beneficiaries.

11 I mean, if we look at the experience over the
12 last years with coverage with evidence determination, which
13 is a much milder approach to exclusion, if you want to call
14 it that, that has just simply not been able to work
15 because, as has been mentioned, the pressure that's brought
16 by -- in some cases, legitimate pressure that's been
17 brought by interest groups for patients, for example.

18 So I do think we need to keep our eye on the ball
19 and make sure that in our prioritization process, we are
20 hitting at the core issue, which is price, both launch
21 prices and inappropriate escalation of price over time.

22 So, with that, thank you very much, and we'll

1 move on to the next presentation.

2 [Pause.]

3 DR. CROSSON: Okay. Let's move on to the final
4 presentation for the January meeting, and that's going to
5 be part of our continuing work on accountable care
6 organizations.

7 Today we're going to look at a set of analyses
8 with respect to the performance of the MSSP ACO program.

9 David, it looks like you're ready to go?

10 MR. GLASS: Yep. Ready to start.

11 So good morning. In this session, we'll be
12 discussing performance of the Medicare Shared Savings
13 Program, or MSSP, which is the largest Medicare accountable
14 care organization program in Medicare, and we're going to
15 look at it from several perspectives.

16 I would like to thank Emma Achola for her help
17 with this project and welcome Luis Serna. He's going to
18 answer all of your difficult questions.

19 [Laughter.]

20 MR. GLASS: I'll begin today by giving some brief
21 background on Medicare's ACOs and the MSSP. I'll then
22 discuss differing estimates of MSSP performance on cost.

1 And we're just talking MSSP, and we're not doing quality
2 this time, just costs.

3 We will look at performance from three
4 perspectives. First, relative to the cost targets or
5 benchmarks CMS sets for the program; then estimates from
6 the research literature on savings relative to
7 counterfactuals, that is, what spending would have been in
8 the absence of MSSP ACOs. And, finally, Jeff will present
9 the results of our new analysis of the relationship between
10 changes in spending and assignment to ACOs. He will then
11 present some implications and turn it over to you for
12 discussion.

13 As you know, ACOs are groups of health care
14 providers who have agreed to be held accountable for the
15 cost and quality of care for a group of beneficiaries.

16 The goals of Medicare's ACO programs are to
17 increase quality of care and patient experience, lower the
18 growth in health care costs, and achieve care coordination
19 at a lower administrative cost than MA plans. And ACOs
20 that are successful are rewarded with shared savings.

21 There are three key concepts for ACOs that will
22 come up throughout our discussion today. The first is

1 assignment. Beneficiaries have to be eligible, which means
2 they must be in fee-for-service, not MA, and have at least
3 one visit with an ACO physician.

4 The basis for assignment is the plurality of
5 primary care services, although some of those services
6 could be provided by specialists.

7 Timing can differ. Assignment can be
8 prospective; that is, beneficiaries are assigned on claims
9 from the prior year, thus the ACO knows which beneficiaries
10 are assigned at the start of the year. Or assignment can
11 be retrospective, and the ACO does not know final
12 assignment until the end of the year, because assignment is
13 based on claims in the current year. This distinction
14 between prospective and retrospective assignment will be
15 important in our discussions of findings from our analyses
16 and their implications.

17 ACO models at one-sided risk have shared savings
18 but no shared losses, and two-sided risk models have shared
19 savings and losses.

20 So to create incentives for ACOs to control cost,
21 CMS creates benchmarks. The benchmark is a function of
22 historical and regional spending, although for the period

1 of analysis in this briefing, primarily historical
2 spending.

3 MSSP has three tracks that differ on several
4 parameters. The important thing to note is that Track 1 is
5 a one-sided risk model with retrospective attribution. By
6 the way, these tracks will all change mid 2019 according to
7 the recent final rule, so don't get too attached to them.

8 First, the number of MSSP ACOs has steadily
9 increased over the years and in 2018 reached over 500 ACOs,
10 with over 10 million assigned beneficiaries. As I said,
11 please note that the vast majority of ACOs are in Track 1,
12 the green bar.

13 Remember, Track 1 is a one-sided risk model, with
14 no shared losses, only shared savings.

15 Track 2 and track 3 ACOs are two-sided risk
16 models, the blue and yellow bars. The first Track 2 ACOs
17 began in 2013, and Track 3 began in 2016.

18 We are going to be discussing MSSP as a whole in
19 this briefing, and for the period of our analysis, almost
20 all the ACOs were in Track 1, with one-sided risk and
21 retrospective assignment.

22 There are two basic methods to estimate MSSP

1 performance. The first is performance relative to
2 benchmarks. The benchmarks or spending targets are set in
3 advance by CMS and are designed to approximate expected
4 spending on the beneficiaries assigned to the ACO while
5 creating incentives for the ACOs and to further policy
6 objectives.

7 For example, they might be designed to encourage
8 ACOs to participate or further equity within or across
9 markets. They are forward-looking, based on past
10 experience and set in advance. Benchmarks are the
11 pertinent estimate from the ACO's perspective because it
12 determines if they are eligible for shared savings.

13 The second method is performance relative to a
14 counterfactual. These estimates are determined after the
15 fact. They compare the spending of the ACO beneficiaries to
16 the actual spending for a comparison group. The intent is
17 to determine what spending on the ACO beneficiaries would
18 have been if the ACO program had not existed, hence the
19 term "counterfactual."

20 Figuring out who is in the ACO group and who is
21 in the comparison group is clearly important.

22 This approach is used in the research literature

1 to assess performance of the program as a whole rather than
2 to determine which ACOs won or lost.

3 So we will first look at performance relative to
4 benchmarks and then at two examples of estimates relative
5 to counterfactuals.

6 Let us start by looking at CMS estimate of
7 savings relative to the CMS-computed benchmarks. As I
8 mentioned, this is the most pertinent estimate from the
9 ACO's perspective because it determines if they are
10 eligible for shared savings.

11 Actual spending on ACO beneficiaries was about
12 1.2 percent below their ACOs' benchmarks in 2017.

13 Shared savings payments, that is, what CMS paid
14 ACOs over and above claims, were about 0.8 percent of
15 benchmarks. Thus, net savings in 2017, after accounting
16 for shared savings payments and doing some rounding, was
17 about 0.3 percent of benchmarks.

18 2017 was the first year with net savings for the
19 MSSP. There were no net savings found in earlier years;
20 that is, aggregate shared savings payments exceeded
21 relative savings in those years.

22 Dobson DeVanzo and Associates did a study for

1 NAACOS, which is the National Association of ACOs, on
2 savings in the MSSP. Their analysis compared the growth in
3 spending on beneficiaries assigned to ACOs to growth in
4 spending for other beneficiaries in the market using an as-
5 treated difference-in-difference study design. It adjusted
6 spending for changes in risk scores and found gross savings
7 of 1.1 to 1.2 percent of Medicare spending from 2013 to
8 2015. That is equivalent to net savings of 0.3 percent
9 after taking into account shared savings payments through
10 2015.

11 Michael McWilliams and colleagues have been
12 estimating MSSP performance for a number of years. In
13 2018, they published their findings of MSSP performance
14 after three years. They used an intent-to-treat
15 difference-in-difference study design. It aligns tax IDs
16 with an ACO, and even if that ACO drops out of the program,
17 it continues to consider that tax ID's patients as ACO
18 patients.

19 In addition, they assigned beneficiaries to ACOs
20 on a plurality of primary care office visits with a primary
21 care physician, and that differs from CMS in that it
22 excludes specialty visits and visits in SNFs.

1 The analysis found savings relative to the
2 counterfactual. It found higher savings for physician-only
3 ACOs than hospital ACOs; that is, ACOs with hospitals as
4 participants. It found higher savings for older ACOs than
5 newer ACOs and net savings in 2015 relative to the
6 counterfactual for physician ACOs and no net savings for
7 hospital ACOs.

8 However, they suggest additional savings may come
9 from spillover; that is, savings from treating patients in
10 Medicare fee-for-service who are not assigned to ACOs, the
11 same way as those who are assigned to the ACO.

12 In sum, from each of the perspectives I have
13 discussed, MSSP ACOs seem to be saving a few percent at
14 best of their benchmark or expected spending, with net
15 savings below 1 percent overall.

16 I have just discussed three estimates of MSSP
17 performance, one relative to benchmarks and two relative to
18 counterfactuals. We were interested in constructing our
19 own counterfactual, which would be less dependent on risk
20 adjustment, because we were concerned about the effect of
21 coding.

22 So Jeff will now explain what we have found along

1 the way to doing that.

2 DR. STENSLAND: All right. So the studies David
3 just talked about, the researchers compared spending for a
4 cohort of beneficiaries in years prior to the ACOs forming
5 to spending for a different cohort of beneficiaries in
6 years after the ACOs were formed. And to adjust for
7 changes in the makeup of the pre-ACO and post-ACO cohorts
8 of beneficiaries, the studies risk-adjusted spending.

9 To complement the analysis David just talked
10 about and to reduce the reliance on risk adjustment, we
11 took a different approach. We chose to track a consistent
12 cohort of individuals over time. The goal is to see how
13 changes in spending over time are associated with changes
14 in assignment into or out of an ACO.

15 We tracked specific patients who were alive from
16 2012 to 2016 and eligible for ACO assignment in every year.
17 We examined how moving in and moving out of ACOs is
18 associated with changes in spending. We compare spending
19 growth for individuals consistently in ACOs, to those never
20 in ACOs, and to beneficiaries who switched in and out of
21 ACOs.

22 Next, I will show you some preliminary

1 descriptive statistics. These are only designed to look at
2 the effect of moving in or out of the ACO. We will come
3 back in April and discuss the implications for overall ACO
4 savings with a propensity-matched system.

5 The following three tables examine the percentage
6 point change in spending from 2012 to 2016. A negative
7 number will be mean spending that is slower than average in
8 the market, implying savings.

9 The first row looks at beneficiaries continually
10 assigned to an ACO from 2013 to 2015. On average, those
11 beneficiaries' spending growth was 2.3 percentage points
12 lower than the average in their market.

13 The second row looks at beneficiaries continually
14 assigned to an physician-only ACO -- the first row was
15 hospitals -- from 2013 through 2015 had spending growth
16 that was 5.6 percent lower than the average in their
17 market. This finding of slower growth for physician-only
18 ACOs relative to hospital-only ACOs is consistent with the
19 work by McWilliams. In your paper, we described how this
20 appears to be partially due to the nature of physician-only
21 ACOs, but also partially due to those physician ACOs
22 tending to form in higher-spending markets, where spending

1 reductions are easier.

2 Next, look at the third row. These are
3 beneficiaries who were never in an ACO. We see their
4 spending growth on average was 1.3 percent lower than the
5 average for their market. So, so far, we're in Lake
6 Wobegon where everyone's spending is slower than average.
7 So which beneficiaries are growing faster than average?

8 Now look at the bottom row. These are
9 beneficiaries that switched in or out of an ACO. They had
10 spending that was 3.1 percentage points above the average
11 in their market, and we call these the "switchers."

12 Next, we will look at the higher cost for these
13 2.2 million beneficiaries that switched in or out of and
14 ACO in a little more detail.

15 So this slide decomposes the last row of the
16 previous slide, the switchers, into three groups, all of
17 which had higher growth than their market average.

18 The first row is those who switched in or out of
19 an ACO during 2013 to 2015, and they had slightly higher
20 than average spending growth through 2016.

21 The second row are beneficiaries who were
22 assigned to a new ACO in 2016 after having never been

1 assigned to an ACO in prior years. They also had slightly
2 higher growth than average.

3 Let's focus on the third row. These are
4 beneficiaries who did not primarily use an ACO doctor in
5 their market for the prior three years, even though ACOs
6 were operating in their market. Then in 2016, they started
7 to use an ACO doctor. One possibility is that their health
8 status changed, and that triggered a change in doctors. We
9 see a large jump up in their health spending, and the
10 result is spending growth that was 16 percentage points
11 above the average growth from 2012 to 2016.

12 For these MSSP beneficiaries, assignment is
13 largely retrospective. That means that when a beneficiary
14 switches to an ACO physician in 2016, the ACO is
15 responsible for all of that 2016 spending, even if part of
16 that spending occurred before an ACO doctor ever saw the
17 patient.

18 Now we can also decompose the rows in the first
19 slide that included beneficiaries assigned to the ACO in
20 2013, '14, and '15 according to what happened to that
21 beneficiary in 2016.

22 Those who stayed in the same ACO from 2013 to

1 2016 had much lower spending growth than their market
2 average, 10 percentage points less on average, 10
3 percentage points less. These may disproportionately be
4 beneficiaries without a change in health status.

5 In contrast, the row in yellow shows
6 beneficiaries who lost assignment to an ACO in 2016. These
7 beneficiaries had spending growth that was 13.8 percentage
8 points higher than average in their market. These
9 beneficiaries had the benefit of care coordination the ACO
10 provided during 2013, 2014, and 2015, but something
11 happened in 2016. Most likely, they changed physicians
12 they saw, possibly due to a change in health status.

13 We see a big jump in spending in 2016, after
14 having slow growth in spending through '12 through '15.
15 This tells us there is an association between changes in
16 assignment and changes in spending; for example, a
17 beneficiary may fall ill and start to use a new set of
18 physicians. The effect of the changes in health status
19 appear to outweigh the benefits of the care coordination
20 provided by ACO physicians in the prior three years.

21 In summary, two groups of beneficiaries had very
22 high spending growth compared to their market averages,

1 those who lost assignment to their ACO in 2016 and those
2 who gained assignment to an existing ACO in 2016. Other
3 switchers had higher than average growth as well, but those
4 were smaller differences.

5 Because the spending growth is so much higher
6 than average for these two groups, it is important whether
7 they are assigned to the ACO when determining their shared
8 savings. Whether they are assigned to the ACO in the
9 switcher year will hinge on whether the ACO has prospective
10 or retrospective assignment. So let's review those two
11 concepts.

12 To review retrospective and prospective
13 assignment, let's look at a hypothetical example of a
14 Medicare beneficiary who first sees an ACO physician in
15 2016. In this hypothetical example, the ACO beneficiary
16 has \$20,000 of spending in 2016 and \$30,000 of spending in
17 2017.

18 The ACO provided a plurality of care in 2016, and
19 the beneficiary will be assigned to that ACO. But the
20 question is, Are they assigned to that ACO for 2016
21 spending or for 2017 spending?

22 Under retrospective assignment, the patient is

1 assigned to the ACO in 2016. CMS retrospectively looks
2 back at 2016 claims and then definitively determines the
3 beneficiary should have been assigned to that ACO for 2016.
4 The ACO would then be responsible for \$20,000 of 2016
5 spending. The 2016 spending would be adjusted for the
6 beneficiary's 2016 risk score, which was actually based on
7 diagnosis through 2015. So, under retrospective
8 assignment, the ACO will not know for sure which patient is
9 assigned to it until 2017.

10 In contrast, under prospective assignment, the
11 patient will see an ACO physician in 2016 and then have
12 that patient assigned to them in 2017. They will be
13 responsible for the \$30,000 of spending in 2017, but that
14 spending will be risk adjusted for diagnosis recorded by
15 the ACO physician during the patient's 2016 visits.

16 A key point is that under prospective assignment,
17 an ACO physician always has seen a patient prior to that
18 ACO being responsible for any of that patient's spending.

19 So the data has the following implications. The
20 relationship between assignment and changes in spending
21 makes assignment algorithms important. It can result in
22 favorable or unfavorable selection for the ACO.

1 ACOs may achieve favorable selection if the ACO
2 can retain healthy beneficiaries and shift out those with
3 declining health status.

4 In contrast, ACOs can face adverse selection if
5 beneficiaries see an ACO clinician for the first time when
6 their health status is declining.

7 In part, the risk to the CMS stems from allowing
8 retrospective assignment. Under retrospective assignment,
9 the ACO can see a partial-year spending data before
10 deciding whether to take actions to try and retain
11 assignment of a beneficiary.

12 In contrast, under prospective assignment, ACOs
13 take responsibility for the beneficiary first and then
14 become accountable for spending going forward.

15 CMS has less risk under prospective assignment,
16 and ACOs have more opportunity to manage care. ACOs may be
17 willing to accept prospective assignment, despite losing
18 some ability to influence who is assigned to them.

19 The two key benefits of prospective assignment
20 for ACOs are, first, ACO doctors will have seen the
21 beneficiary before the ACO is responsible for the
22 beneficiary's spending; and second, the ACO will know who

1 they are responsible for at the start of the year.

2 For example, think about a patient who had
3 significant medical spending in the first half of 2016,
4 then saw an ACO physician in the second half of 2016.
5 Under retrospective assignment, the ACO is responsible for
6 all 2016 spending, even if most of that spending occurred
7 before the patient ever saw an ACO physician.

8 In contrast, under prospective assignment, the
9 ACO is never responsible for seeing a patient prior to an
10 ACO physician having seen them.

11 So I want to stress here that all of this data
12 we've talked about is only through 2016, and assignment
13 rules changed, benchmarking rules changed, and provider
14 behavior will have changed since then also, and these
15 regulatory changes we've talked about have implications.

16 The key changes are as follows. First, CMS is
17 moving toward two-sided risk, and second, CMS is moving
18 toward having 50 percent of the benchmark based on regional
19 spending. This means ACOs that have historically been low
20 spenders in their region will do better and ACOs that have
21 historically been high spending in their region will do
22 worse.

1 CMS is also allowing up to a 3 percent increase
2 in HCC scores. ACOs we have talked about plan to put more
3 effort into coding, so we expect ACOs to report increased
4 HCC scores that will result in greater payments to the
5 ACOs.

6 ACOs are also allowed to choose retrospective or
7 prospective alignment, and you change that decision yearly.
8 In our 2018 comment letter, we stated all ACOs should all
9 use prospective attribution.

10 In 2019, ACOs can encourage specific
11 beneficiaries to come in for wellness visits by paying them
12 a \$20 fee to come in for the visit. In 2016, about 18
13 percent of traditional fee-for-service patients received
14 wellness visits compared to 33 percent of MSSP ACO
15 patients. This difference, we expect it to grow in 2019,
16 as ACOs try to improve their patient selection.

17 The net result is that the Medicare program's
18 payments to ACOs could be influenced by changes in coding
19 patterns and efforts by ACOs to improve their patient
20 selection, and generating savings for the Medicare program
21 may be more difficult.

22 Therefore, the current savings we see by looking

1 at this -- or the past savings we see looking at 2016 data,
2 may not be indicative of what the savings will be like in
3 2019.

4 So this brings us to some potential discussion
5 topics. First, you might want to talk about the
6 ramifications of the relationships between assignment
7 changes and changes in health status that we illustrated.
8 You could also discuss issues regarding prospective and
9 retrospective assignment, and you could talk about next
10 steps. We plan to do further analysis after creating a
11 more closely matched comparison group. We will look at
12 wellness visits and the effect on spending, and examine the
13 relationship between major health events and changes in
14 attribution further.

15 And now we turn it over to Jon to start the
16 discussion.

17 DR. CHRISTIANSON: [Presiding.] Well, I think
18 all of this has been perfectly clear to all of us, but just
19 in case it hasn't been, we could start with questions of
20 clarification. Dana.

21 DR. SAFRAN: Thanks. You've done a great job,
22 both in the chapter and in this presentation, in dealing

1 with a really complex topic, and I'll have some ideas to
2 share in the comment round. But a couple of questions
3 first.

4 So first question is, did you do any work -- when
5 you looked at those who I'll call switchers, did you do any
6 work to look at whether they were switching within or
7 between markets?

8 DR. STENSLAND: No. We didn't do that, but we
9 could look at that. They were just switching out of one
10 ACO into another, or in or out of ACOS.

11 DR. SAFRAN: Yeah.

12 DR. STENSLAND: So we could look at -- I'm
13 guessing we'll probably end up with more extreme results if
14 we take out those who moved.

15 DR. SAFRAN: I think it's important, because in
16 work that I led before my tenure at Blue Cross, where we
17 had, among other things, an eight-year longitudinal study
18 of Medicare beneficiaries and we were looking to understand
19 performance differences between Medicare Advantage and fee-
20 for-service Medicare, we had to confront -- and our
21 outcomes were on functional status, not so much on cost.
22 But nonetheless, I think that all the methods that we had

1 to grapple with are very relevant to what you're dealing
2 with here. And we absolutely saw evidence that when people
3 get sick, especially with something big and important, they
4 often change system, not because they're dissatisfied, not
5 because the, in this case, ACO is failing them, but because
6 the care they need is somewhere else.

7 That's a different matter from a beneficiary who
8 relocated. And so I think you'd want to tease those things
9 out in what you're doing. So that was my first question.

10 Do you have evidence, or have you looked at what
11 kind of health events seem to be triggering switching? I
12 saw, both in the presentation and the chapter, this sort of
13 hypothesis that there could be some health events going on
14 here, and, you know, as I'm sharing from my own work in
15 this area, I think you're right. So I'm just trying to
16 understand whether you've explicitly looked to understand
17 how health events seem to be triggering switch or whether
18 it's just a hypothesis that you're putting out there.

19 MR. GLASS: We haven't looked in detail yet.

20 DR. SAFRAN: Okay.

21 MR. GLASS: Are we going to do that?

22 DR. SAFRAN: Okay.

1 DR. STENSLAND: We could look at new diagnoses,
2 and certainly we can look at who was admitted and who
3 wasn't admitted --

4 DR. SAFRAN: Yeah.

5 DR. STENSLAND: -- you know, that type of thing.

6 DR. SAFRAN: Yeah. And I think you're going to
7 want to look at, you know, patients who had such a new
8 diagnosis and stayed versus those who had a new diagnosis
9 and switched, to really start to tease apart some of the
10 hypotheses I think you have.

11 And then just one other question having to do
12 with assignments, because I'll come back to it in the
13 comment round, some of the important distinctions you're
14 making between prospective and retrospective. This is just
15 ignorance on my part with respect to how the program works
16 when it's retrospective. I understand that with
17 retrospective that the settlement on who your population
18 was doesn't happen until the end of the year and claims
19 reveal who that was. Is there any notification along the
20 way, in the programs that use retrospective, which would
21 make it more what I would call concurrent assignment?

22 MR. GLASS: Yeah. They -- I will try to get this

1 right. There is a special name for it. It's provisionally
2 prospectively assigned with retrospective --

3 DR. SAFRAN: Yeah.

4 MR. GLASS: -- final attribution.

5 DR. SAFRAN: Yeah. Okay.

6 MR. GLASS: So, yes.

7 DR. SAFRAN: So it's not -- you know, because any
8 layperson who think about this for a minute would say,
9 "That's unfair. How can you manage a population if you
10 don't know who you are?" But in retrospective assignment
11 it's not that it's a black box. The participants are
12 getting information along the way, but who, at the end of
13 the day, they're accountable for gets settled up at the
14 very end of the year, with who's still with you.

15 MR. GLASS: And they're told quarterly, I think,
16 who is on the list.

17 DR. SAFRAN: Yeah, okay. Thanks for clarifying
18 that.

19 DR. STENSLAND: They will know the ones who --
20 especially if they had them last year, they'll be on their
21 prospective list for this year. But they probably won't
22 know they're switchers until a couple of quarters after.

1 So the people that just started using them.

2 DR. SAFRAN: Yeah. Thank you.

3 DR. CHRISTIANSON: Bruce, I saw you --

4 MR. PYENSON: This is really wonderful work. I
5 want to compliment the team on that. I noticed you
6 excluded people who died during the time, and mortality is
7 maybe 4 percent or something in the Medicare population. I
8 wonder if you could explain what you think that meant or
9 why you did that.

10 DR. STENSLAND: We did that purely for
11 simplicity. We have another dataset sitting there with all
12 the people who died, and we wanted to separate the people
13 who died from the people who didn't die, and we'll be going
14 through the people who died to see if we see anything
15 different. Preliminary results indicate that the relatives
16 don't seem that much different. Of course, you see a huge
17 growth in spending for the people who died, you know,
18 monthly spending in their last years of life. But in terms
19 of the effective switchers, non-switchers, we haven't seen.

20 [Pause.]

21 DR. CROSSON: [Presiding.] Sue.

22 MS. THOMPSON: Thank you. What do we know about

1 their savings? Do we know anything about how they achieve
2 savings?

3 DR. STENSLAND: I think we're going to come back
4 to you in April with that, in a couple of ways. One is
5 we're going to try to have a more closely matched
6 comparison group, and then we'll break down things a little
7 bit more to you in terms of, you know, how much of this is
8 post-acute care, how much of this is acute, and that kind
9 of thing.

10 MS. THOMPSON: And in our work in ACOs, have we
11 done anything in terms of understanding the investment in
12 infrastructure that's being made by the actual ACO?

13 MR. GLASS: We did delve into that some years
14 ago, you know, in round numbers and million dollars a year,
15 but, you know, that various, obviously, by ACO. We haven't
16 tried to get into it in real detail.

17 MS. THOMPSON: Okay.

18 DR. STENSLAND: We talked in our last ACO
19 chapter, we mentioned a percent, I think, something in the
20 neighborhood of 1 percent, something like this, maybe 1 to
21 2, depending on what you do. And I think we don't have
22 firm data on this, so what we have is we've gone out and

1 talked to people. And you guys were on these ACOs. You
2 maybe have better firm data. But when we talked to people
3 we tend to have more confidence in the little, small ACOs,
4 where they have a separate group of people that you manage
5 the ACO and you're in a little box and that's all you do
6 with the ACO.

7 For some of the big systems we have, they have
8 some people that are doing ACOs sometimes and they're doing
9 other stuff, and it's hard for them sometimes to tease out
10 what's the exact cost of this because they have people
11 doing ACO and non-ACO.

12 MS. THOMPSON: One more question. In the
13 breakdown of physician ACOs versus hospital-based ACOs,
14 let's call them, do we know, by low, medium, and high use,
15 how that breaks out?

16 DR. STENSLAND: We have a slide. We can -- yeah,
17 if you click there's a -- I should go all the way down.

18 But, no, we don't have the numbers there. We
19 have looked at that and the hospital ACOs, in general, tend
20 to be more likely in the lower-spending markets, and the
21 physician ACOs tend to be more in the higher-spending
22 markets. And this would imply either that the physicians

1 are not as interested in setting up an ACO where they think
2 they're not going to be able to make any money, or maybe if
3 they're in a high-spending market, you know, if you're in
4 Miami or someplace like this where you think you can save
5 money as an ACO, you may be less interested in teaming with
6 the hospital and maybe just want to do it on your own.

7 MS. THOMPSON: Thank you.

8 DR. CROSSON: Paul, David, okay, Pat, Jaewon,
9 Brian, Jon.

10 DR. PAUL GINSBURG: Yeah. I would appreciate if
11 you could go through in a little more detail which
12 physician the patient, the beneficiary, is assigned to and
13 which ACO they were in. You know, so think of a
14 hypothetical beneficiary that just has primary care, and
15 then they have a heart attack or cancer, and they start
16 having a lot of visits with a cardiologist or an
17 oncologist. Could you just take us through, you know,
18 which ACO they get assigned to, based on their physician
19 use?

20 MR. GLASS: So, actually, Kate Bloniarz has
21 worked on this, and if I misspeak she will correct me, I'm
22 sure.

1 The first thing that has to happen is the
2 beneficiary has to have a primary care service from an ACO
3 physician, and if they don't they are not eligible for
4 assignment.

5 DR. PAUL GINSBURG: And do you find the primary
6 care service as an office visit?

7 MR. GLASS: They have a list of them --

8 DR. PAUL GINSBURG: Okay.

9 MR. GLASS: -- and we have that list, if you want
10 it. But it's mainly E&M visits. And then after that, if
11 you have more primary care services from ACO primary care
12 clinicians, and clinicians here includes physicians and
13 nurse practitioners and PAs, so if you have more of those
14 services from ACO clinicians, primary care clinicians, than
15 any other ACO, or any other single taxpayer identifier
16 number, then you're assigned to the ACO. Now if you don't
17 meet that qualification but you do have a primary care
18 service with a primary care clinician, then you're not
19 assigned to the ACO. If none of those things happen, and
20 you have more primary care services from ACO specialist
21 than any other ACO or any other single TIN, then you're
22 also assigned to the ACO.

1 So it's kind of complicated. What it means is if
2 you're not assigned on your primary care services right
3 away then you can be assigned on specialist service. They
4 call it Step 2. And there are some weird things about, you
5 know, I guess we discussed yesterday nurse practitioners,
6 PAs, they're all counted as primary care people, even
7 though they may be working in the office of an orthopedist,
8 and that can lead to some odd things happening.

9 And also the other super-detail on this was that
10 the visits, in SNFs, were counted in the years we're
11 talking about. So if a beneficiary went to the hospital,
12 was discharged to a SNF, then saw a SNF physician many
13 times while they were there, they would probably get
14 assigned to that physician, if that physician were in an
15 ACO. So it gets very detailed.

16 DR. PAUL GINSBURG: Yeah, I appreciate you going
17 through it because I think the implication is that ACO
18 assignment is sensitive to whether the person is sick or
19 not, and that's really, you know, a flaw and a weakness of
20 the whole system, which your research is bringing out.

21 DR. GRABOWSKI: Great. I'm glad I get to ask
22 this question right after Paul's because it very much

1 builds on Paul's question. I was trying to think through
2 this myself and, David, you described this population as
3 very complicated. Another way of describing them is that
4 they're very selected. They're very different here.
5 They've had a change in health status which has led to an
6 interaction with a physician or a SNF, which ultimately
7 changes their enrollment in the ACO.

8 I worry a little bit -- so I think,
9 descriptively, I really like what you're doing in
10 documenting this group. I worry a lot about trying to
11 examine this group and look at the effect they might have
12 on program spending, just because it's so hard to construct
13 a counterfactual for them. You mentioned propensity score
14 matching. I would love to learn more about what you're
15 thinking there because I don't think -- this group is so
16 selective that I just worry, are you actually going to be
17 able to find a comparable group to actually do this in a
18 credible way.

19 DR. STENSLAND: Yeah, I think -- you know, what
20 we're thinking about doing, and you should send us a nice
21 email later if you have any great ideas -- is --

22 DR. GRABOWSKI: I like that you used the word

1 "nice" there.

2 DR. STENSLAND: Yeah. I'm just trying to keep
3 things polite. We're planning to do the propensity
4 matching, but the propensity matching all has to do with
5 stuff that happened before our time period. And then we
6 have some of these unforeseen things that are happening
7 that are moving you around. So we're thinking about, when
8 we're going to looking at what the changes are for these
9 propensity-matched groups, to look at it in different ways
10 and then try to describe what we think the bias is in the
11 different ways. I think, in some ways, you might
12 overestimate savings and in some ways you might
13 underestimate savings, and we can talk about that in the
14 future. Maybe we'll have some more ideas on that.

15 DR. GRABOWSKI: As a follow-up, so why doesn't
16 the intent-to-treat framework address this issue with the
17 switchers. You're defining them at baseline. Isn't that
18 just a simpler way to do this than to try to kind of take
19 account of all the switchers over time?

20 DR. STENSLAND: We could look at like people that
21 were initially in an ACO in 2013, and then just follow them
22 all the way through, kind of more an intent-to-treat model.

1 And I think McWilliams' intent-to-treat model is fine too,
2 and I think this kind of following them all through will be
3 one of our assortment, our buffet of different outcomes
4 that we'll have. And I think it will complement some of
5 the intent-to-treat stuff that McWilliams did.

6 MS. WANG: Thank you. This was really
7 interesting work.

8 This is just a question about, I guess,
9 attribution to an ACO. Is an ACO permitted to change the
10 physicians in the ACO throughout the course of the year,
11 and if not, you know, throughout the course of the year,
12 year by year? What are the rules around that?

13 MR. GLASS: Okay. I'm trying to recall this from
14 memory. We can get back to you on it. But I think, in the
15 MSSP program, they allow quarterly changes in your
16 physician list, or your participant list.

17 MS. WANG: I'm sorry. I missed the --

18 MR. GLASS: Quarterly changes.

19 MS. WANG: Quarterly changes. That's really
20 interesting.

21 MR. GLASS: Yeah. And then you raise another
22 question of, oh, does that mean you have to change the

1 benchmark because now you have a different set of people?

2 MS. WANG: That actually wasn't -- but I think
3 that is a good question. I was more wondering about, you
4 know, susceptibility to managing your panel, to keep your
5 healthier members --

6 MR. GLASS: Well, it's interesting you bring that
7 up because there was a --

8 MS. WANG: -- on a managed care plan.

9 MR. GLASS: Yeah. There was a recent RAND-AMA
10 study, and they did find that some organizations were
11 realizing this and moving some of the physicians from one
12 TIN to another, in and out of the ACO.

13 MS. WANG: Yeah. It's something to bear in mind,
14 obviously.

15 The related question is whether or not, in your
16 switchers, you have any information on differences in
17 frequency or incident as between physician-led ACOs versus
18 hospital ACOs. And I'm not suggesting any kind of
19 pernicious behavior there. But one of the things that I
20 think happens when somebody gets sick is they may have a
21 primary care doc, you know, that they've been seeing for
22 years and years. They develop a serious health condition.

1 They go a medical center and the medical center suggests
2 "why don't you switch our PCP over here, because we can
3 take care of you better." And I just wonder whether that's
4 anything that you can pick up from the information you've
5 looked at.

6 MR. GLASS: Well, anecdotally, we've been told by
7 some ACOs that that is the case, and that they're losing
8 beneficiary attribution over to a hospital-based ACO. So
9 we've been told that. We don't have -- we haven't noticed
10 it in the data but we haven't been, you know, searching.

11 DR. STENSLAND: We ran those numbers but we can
12 put them in a footnote in your next chapter.

13 MS. WANG: I was just interested in the
14 switchers, in particular, with the hypothesis that it might
15 have been triggered by a health event, whether there's a
16 closer look that can be made there. Again, it has
17 implications for the evaluation of the performance of one
18 type of ACO versus another type of ACO.

19 DR. CROSSON: I just want to clarify one thing
20 myself now. So if the physician that the patient saw and
21 as a consequence became part of that ACO retrospectively
22 leaves the ACO, the ACO still has that patient. Correct?

1 DR. STENSLAND: Not if the patient moves with
2 their physician. So if you were treating somebody and the
3 ACO decided -- we would hope they wouldn't be doing this,
4 but let's say they said, oh, this is Jay and he takes a
5 long time with all his patients, people send him all their
6 expensive patients and he's in our ACO, next year they
7 could have you start billing under a different TIN, and
8 then all your patients would leave the ACO.

9 DR. CROSSON: Next year, but not --

10 DR. STENSLAND: Next year.

11 DR. CROSSON: Not in the reference year.

12 DR. STENSLAND: Well, it depends. You know, it
13 depends if you're the retrospective or prospective --

14 DR. CROSSON: We're talking about retrospective.

15 DR. STENSLAND: Yeah, so if it's retrospective
16 and you are in the -- you sign up to be in the ACO for that
17 year and they're seeing you that year, then they're
18 responsible for the cost.

19 DR. CROSSON: Whether you leave or not.

20 DR. STENSLAND: Whether you leave or not during
21 that year, unless you left in the middle of the year and
22 started billing under a different TIN and they saw you more

1 often under that other TIN than they did under the prior
2 TIN, then the patient would leave with you.

3 DR. CROSSON: Okay. Jonathan, you looked like
4 you wanted to comment on that?

5 DR. JAFFERY: Well, that was -- the final point
6 was the point I was going to make, because it's based on
7 the plurality of --

8 DR. CROSSON: The plurality, so the -- okay. All
9 right.

10 DR. JAFFERY: So if you left in September, you
11 probably wouldn't --

12 DR. CROSSON: Got it, got it.

13 DR. JAFFERY: And then I guess one other point of
14 clarification about this, and we were just -- I think we're
15 recalling that for adding or subtracting MSSP physicians,
16 you can only add annually, I think, not quarterly, and you
17 can drop any time, which becomes, obviously, important
18 because people leave organizations.

19 DR. CROSSON: Okay.

20 MS. THOMPSON: And when a provider drops, the
21 beneficiaries attributed to that provider go out of the
22 ACO?

1 DR. CROSSON: Go what, Sue?

2 MS. THOMPSON: Out of the ACO.

3 DR. CROSSON: Out of the ACO.

4 MS. THOMPSON: So if the ACO loses a provider,
5 they lose the lives that were attributed to that TIN.

6 MR. GLASS: I'm sorry. If an individual provider
7 leaves or if that TIN leaves?

8 MS. THOMPSON: I'm sorry. If an individual
9 provider leaves with an individual TIN.

10 MR. GLASS: With an individual TIN, yeah. So in
11 MSSP this is all done on the TIN level, which can range
12 from one provider to an entire health care system. So
13 that's another complication. It's not done at the TIN NPI
14 level.

15 DR. CROSSON: Got it. Thanks very much. That
16 helps. Jaewon.

17 DR. RYU: Yeah, on the shared savings payments,
18 how does that get treated in terms of rebasing the
19 benchmark and also in terms of how it impacts the MA
20 benchmark? Is that treated as spending?

21 DR. STENSLAND: Yes. So there's a little bit of
22 a multiplier effect here. Let's say the ACO is generating

1 savings and it's generating savings larger than the shared
2 savings payment, so on net, the system is benefitting.
3 That will lower MA benchmarks in the market, and the system
4 will have a little bit of a secondary benefit by having
5 lower MA benchmarks and lower MA spending. But it can go
6 the other way, too. If, let's say, the ACOs actually just
7 broke even but the shared savings payments were larger so
8 on net the system was losing, well, then, on net that would
9 increase the MA benchmarks.

10 DR. RYU: So if you add \$100 of savings and then
11 you had to pay back \$75 of it as part of the shared savings
12 payments, would the \$75 of payment count towards the MA
13 benchmark and towards the rebasing of the --

14 DR. STENSLAND: Yes.

15 DR. RYU: Okay.

16 DR. CROSSON: Brian.

17 DR. DeBUSK: First of all, thanks for a great
18 chapter. I really enjoyed the analysis. I'm really
19 looking forward to this matching that you're doing, too. I
20 think there's some real novelty there.

21 What I was going to ask about, retrospective
22 attribution has always been one of those serious flaws with

1 the ACO program, and it seems like prospective attribution
2 solves a lot of those problems. Just sort of your initial
3 impression -- and I know you're not done with the analysis.
4 Are you left with the impression that prospective analysis
5 -- or prospective attribution fixes or addresses this
6 issue, at least in a reasonably complete way? Or is this
7 just a way point or a stepping stone to maybe even a more
8 sophisticated enrollment type mechanism?

9 MR. GLASS: Prospective assignment would not
10 solve all of these issues.

11 DR. DeBUSK: So --

12 MR. GLASS: But it would be better and --

13 DR. DeBUSK: Okay, so we should look at this as
14 clearly an improving direction. I think there is no doubt
15 this is an improving direction. But this is a way point to
16 maybe even something better in terms of attribution.

17 DR. STENSLAND: Yeah, like I said, I'm not sure
18 if this is like this is an improvement and good enough or
19 an improvement and we've got to make another step to make
20 things even better. But I'm not sure what that other
21 better step would be.

22 DR. DeBUSK: Okay. I was just trying to get a

1 feel for how complete prospective assignment is.

2 The other thing I was going to ask, have you guys
3 looked at any ways to engage the beneficiary in
4 attribution? Everything right now, I mean, some of these
5 people have no idea they're even in ACOs.

6 MR. GLASS: I would say most of the people don't
7 have any idea --

8 DR. DeBUSK: Yeah, I was going to be nice because
9 Jeff likes nice.

10 MR. GLASS: Some of the physicians don't even
11 know they're in ACOs. But, I mean, you know, this
12 particular analysis, we didn't look at that at all.
13 Recently, you know, they've introduced -- you can have
14 voluntary assignment where if a beneficiary goes into
15 Physician Compare, or wherever it is, and says this is my
16 main doctor or primary physician, then they're assigned to
17 that physician's ACO. So there is that. And under the new
18 rules, they can also offer people money to show up, and
19 that could increase attachment.

20 DR. DeBUSK: Well, thank you. I was just trying
21 to get a feel for how close to settling this issue we are,
22 and it sounds like this is sort of the second inning of a

1 long game.

2 DR. STENSLAND: And I think we should emphasize
3 that we're talking about the MSSP, and we have a couple
4 people here who are Next Gen, and they've already kind of
5 moved into the second inning. You know, they have
6 prospective assignment. They have assignment based not
7 just on the TINs but also the NPIs. So it's not like we
8 have to start from scratch here.

9 DR. CROSSON: Okay. I've got one of those people
10 lined up. That's Jonathan, and then Warner and Pat.

11 DR. JAFFERY: Yeah. So thanks. First of all, I
12 really appreciate this creative look. As we've
13 acknowledged, this is now about -- we've got Medicare
14 beneficiaries basically in three programs in about thirds:
15 regular fee-for-service, MA, and now this. And I think you
16 could argue that in terms of changing provider behavior,
17 the ACOs is doing more than MA has in many ways. Clearly,
18 there's lots of other changes that have happened, but
19 providers are doing things, even if many of them aren't
20 aware they're in ACOs, which I think is true.

21 A couple things. First of all, to follow up on
22 some things others have said. So, Dana, you had asked

1 about the retrospective attribution and the number of
2 people, and so the way that I think typically worked is
3 you'd end up with your initial prospective assignment being
4 very, very large and then every quarter it just gets
5 smaller until you're left with a significantly smaller
6 number.

7 I think the cost issue about ACO costs, I think
8 that is tricky. Certainly in my organization, we do sort
9 of try and assign some of the cost to the ACO, but it's not
10 very self-contained.

11 A couple specific questions. Let me go to Slide
12 14. This is a pretty quick question. You've got the
13 assigned to the same ACO, the bottom, and then left in
14 2016. Are those folks who are assigned to the same ACO for
15 those three years and then left to another ACO, to not be
16 in a new ACO, or a combination?

17 DR. STENSLAND: Combination.

18 DR. JAFFERY: Okay. And then I had one other
19 question, but I forgot it, so sorry.

20 [Laughter.]

21 DR. CROSSON: Warner. You can always sneak it
22 into Round 2. Warner.

1 MR. THOMAS: Has there been discussion or have
2 you guys looked at just the whole concept just going
3 primary care assignment for traditional Medicare? And what
4 do you see as the -- it's obviously not being done. What
5 has been the discussion on that? And where do you see the
6 challenges with that?

7 MR. GLASS: Well, the history of this is that
8 people didn't want to leave specialists out of ACOs. They
9 wanted to get them involved. It was felt that there were a
10 lot of beneficiaries who maybe they see their cardiologist
11 as their primary doctor, and we don't want to leave them
12 out. And I think so all of that kind of militated for some
13 way to get the specialist into it, and they ended up with
14 this second stage assignment sort of thing.

15 Now, why they shifted to the two-stage, I'm not
16 sure, but they did have the two steps, and I think part of
17 it is kind of the way the statute's written. It talks
18 about primary care physicians.

19 MR. THOMAS: Do you think going to that model,
20 even if you identified your cardiologist as your primary
21 care doctor, do you think that would solve some of this
22 problem? I mean, even just having the beneficiaries go

1 through the thought of like who is my direct caregiver and
2 that they know that they're in this program, do you think
3 that would help in any of these scenarios?

4 DR. STENSLAND: I think it would make a cleaner
5 comparison between you and the other groups, and this is
6 actually -- when McWilliams did his evaluation, he only --
7 he did his own assignment based only on primary care,
8 because he thought that provided a better comparison
9 between the ACO and the non-ACO. So I think for
10 evaluation, that might make sense. The only -- the
11 downside we have here is if we go to only primary care
12 visits, you're going to end up with fewer people assigned
13 to the ACO, because you've got about maybe 12 percent of
14 the people that only end up seeing specialists in the year.
15 So, you know, you have all these people in Medicare. About
16 10 or 12 percent don't see anybody. Another 12 percent
17 only see primary care -- or only see specialists, so you're
18 going to have a smaller group. And you're going to have to
19 end up then trying to get bigger ACOs, because we already
20 have a problem with some of these small ACOs which have
21 5,000 or 10,000 people having lots of random variation.
22 Whenever it gets smaller, you have more random variation.

1 So I think to me this is a trade-off between better
2 attribution versus smaller sample size in the random
3 variation you have there.

4 MR. THOMAS: Has there been any studies done or
5 have you guys talked to beneficiaries about how they would
6 feel about the fact that they're in this organization, that
7 the idea is to have better coordination? I mean, because I
8 think there's always this view that, oh, well, we don't
9 want to go to primary care assignment because it's limiting
10 choice and beneficiaries are going to feel bad about it.
11 And I just wonder if it was really explained to them as,
12 you know, you're entering a system of care, we want to
13 identify someone who's your go-to person, you know, that it
14 probably would be much better accepted versus it being this
15 kind of covert sort of thing. So has there been any
16 dialogue or any studies around that?

17 MR. GLASS: When they started ACOs, there was a
18 letter that went out to the beneficiaries saying,
19 "Congratulations. You're now in an ACO. This means your
20 data is going to get shared." And the reaction was
21 incredibly negative. You know, "I don't want the
22 government to know what doctor I'm going to." And beyond

1 that, it became -- it really caused a lot of trouble for
2 the physicians' offices because they were getting all these
3 calls, you know: "What does this mean? Why are you doing
4 this to me?" And so they quit sending out the letters
5 because it did not help.

6 MR. THOMAS: That kind of gets back to my point
7 of, you know, perhaps there should be some study or some
8 work done to understand from beneficiaries -- number one,
9 to explain to them and have them understand like what are
10 we really talking about. This isn't just like -- number
11 one, the government can look at all your data anyway
12 because they look at all the claims information. But,
13 anyway --

14 DR. PAUL GINSBURG: They're paying the bills [off
15 microphone].

16 MR. THOMAS: Exactly, they're paying the bills.
17 But more importantly, you know, especially you want to have
18 coordination and you want to have folks that are kind of
19 focused on being preventative. I just wonder if we had a
20 better way and approach to explain this, I think we'd get
21 much, much better acceptance. I honestly think -- so I
22 don't know -- I just know that there's been studies on

1 that, or maybe that's something we should think about
2 doing.

3 DR. STENSLAND: We do focus groups every year,
4 and we ask them things like, "Are you in an ACO?" And
5 almost no one knows if they're in an ACO or not. And
6 sometimes we try to explain what an ACO is, which I think
7 for a lot of these people is extremely difficult. Like we
8 have people that don't know if they're in an MA plan or in
9 fee-for-service in these focus groups and what's the
10 difference between a Medigap plan and an MA plan. A lot of
11 them don't know that.

12 So if we tried to explain to them the difference
13 between an ACO and an MA plan and traditional fee-for-
14 service, I think the share that we would get that would
15 really understand what's going on would be smaller than the
16 share that would just be scared.

17 And then there's the -- but the thing that you
18 touched on that might work that they can do is they can get
19 on and say, "Who is your primary care doctor?" I think
20 that's much more easy for them to understand, "This is my
21 doctor," as opposed to "This is my ACO."

22 MR. GLASS: That route is open. Not many have

1 used it yet, but that's a matter of education, and I think
2 people certainly in commercial plans are willing to say,
3 "This is my primary care physician" and would certainly --
4 I mean, we could entertain the idea of asking that when
5 people first join Medicare.

6 DR. CROSSON: Okay. I've got Pat and then Kathy,
7 and we're still in Round 1, sort of.

8 [Laughter.]

9 DR. CROSSON: I think Round 2 is going to be kind
10 of like what are the implications of these findings, and I
11 think we're already doing that. But just for formality's
12 purposes --

13 MS. WANG: These are actually questions. Do the
14 changes in spending growth include Part D?

15 DR. STENSLAND: [Nodding affirmatively.]

16 MS. WANG: Okay. have you thought about looking
17 at that?

18 DR. STENSLAND: Yes, and it's hard.

19 MS. BUTO: Jeff, Part D is not managed by the
20 ACO, correct?

21 MS. WANG: It's true, but sometimes, you know,
22 changes in spending in one area can -- decreases in one

1 area can result in increases in the other, and I think it's
2 something that one would want to know about, the total
3 package of care that's --

4 MR. GLASS: So you could conceivably look at it
5 for the subset of ACO beneficiaries who are also in a Part
6 D plan for which we have the data.

7 MS. WANG: Thanks. The second question is: Can
8 you summarize the reasons in the comment letter on the new
9 MSSP rule that you disagreed with the notion of both
10 prospective and retrospective assignment?

11 MR. GLASS: Right. So in the comment letter, the
12 Commission opined that allowing ACOs to switch between
13 retrospective and prospective assignment was a bad idea,
14 allowing them to switch annually between, because it opens
15 up large possibilities of gaming, you know: I'm in
16 retrospective this year. I noticed my -- I did really
17 well. I think I'll switch to prospective. They'll give me
18 the same set of beneficiaries I had last year. The
19 simplest.

20 But it also introduces terrible administrative
21 complexity for CMS because they have to compute a different
22 benchmark. It's a different set of beneficiaries, and it's

1 a different lookback period, so they have to do a different
2 benchmark if an ACO switches between one -- from
3 prospective to retrospective or vice versa. And we didn't
4 agree that it was necessary to do any of this. They
5 implied that statute which was really changed to allow
6 Track 1 and Track 2 to use prospective, therefore implied
7 that going forward they should always be allowed to switch
8 between the two. And since Track 1 and Track 2 no longer
9 exist, we think that the problem went away.

10 DR. CROSSON: Jonathan, on this point?

11 DR. JAFFERY: Yeah.

12 DR. CROSSON: Okay. Go ahead.

13 DR. JAFFERY: Do you know in your focus groups if
14 there are people who are interested in switching? Or most
15 people I think are more interested in the prospective for
16 some of the reasons we've said. So have you heard, gotten
17 feedback from groups that like the retrospective?

18 MR. GLASS: I'm sorry, focus groups with ACOs?

19 DR. JAFFERY: Yeah, yeah.

20 MR. GLASS: Discussions with ACOs?

21 DR. JAFFERY: Yeah.

22 MR. GLASS: It seemed early on there were people

1 who did like the retrospective, but, yeah, I'm not sure.
2 We haven't talked recently, being allowed to switch back
3 and forth, whether people like that or not.

4 DR. CROSSON: Kathy

5 MS. BUTO: I'm going to hold off until Round 2.

6 DR. CROSSON: Okay. So Round 2 starts now, sort
7 of, and we're going to engage in comments about the
8 implications of the findings, and I think Paul has offered
9 to begin the discussion.

10 DR. PAUL GINSBURG: Thanks.

11 Anyway, I think you've done a great job pursuing
12 this research, and it has a lot of implications. The first
13 implications were that Medicare's -- or CMS's decisions
14 about rewarding ACOs or penalizing ACOs are subject to a
15 lot of error because of the changes in the patient
16 switching into or out of different ACOs. It also means
17 that a lot of the research is subject to perhaps more error
18 than we might have thought.

19 We probably wouldn't care so much with the latter
20 if the ACOs were more successful than they've been, but
21 since we're talking about 1 percent gains or losses, it
22 suddenly becomes a big deal whether we think we're making

1 progress or not. If we had 5 percent gains, we probably
2 would say all the different approaches, we don't even have
3 to worry about those because the gains are clear, full
4 steam ahead.

5 But the other implications, which came out a lot
6 in our Round 1, is that the model can be improved, and I
7 think someone asked a great question, is going in a
8 perspective going to change it, and clearly that would be
9 an improvement. But it's not getting at the underlying
10 problem, which is the attribution, because I think the
11 whole concept behind the ACO is that all beneficiaries
12 would be assigned to their primary care physician, no
13 matter what happens. We have these situations. some are
14 clearly getting assigned to specialists, only when they get
15 sick. To me, that's a really big problem for the ACOs as
16 well as for the program, and I think it's really worth our
17 time to perhaps come up with ideas to, in a sense, really
18 turbocharge the process, pay the beneficiaries if they'll
19 go in and identify their primary care physician, to really
20 reduce this issue of people who don't have primary care
21 physicians or have them, but wind up being assigned to a
22 specialist when they get sick.

1 DR. CROSSON: Thank you, Paul.

2 Dana first, Bruce, Jonathan, Kathy, David, Brian.

3 DR. SAFRAN: So thanks for tackling this really
4 important work.

5 Where I want to start is you made the distinction
6 at the beginning that I think is a critical one for us to
7 keep our eye on throughout this line of analysis of the
8 evaluation against a benchmark evaluation, where we're
9 trying to create the counterfactual.

10 I think you may not have said it exactly this
11 way, but you did make the point that the benchmark matters
12 to organizations because it drives whether or not they're
13 succeeding in getting paid.

14 The counterfactual matters for all of us to
15 figure out is the program succeeding.

16 So I think that the number one point I wanted to
17 make is that the distinctions that you're making and the
18 demonstration you did on one of the last slides of the
19 difference that prospective versus retrospective assignment
20 makes to the answer to both questions, whether the
21 organization wins and whether we appear to have a program
22 that's succeeding is a really important point.

1 I will make the point that I hear a lot of folks
2 saying it's just so obvious, prospective is better. I will
3 tell you that I don't share that point of view. That in
4 the work that I led at Blue Cross, we used what we called
5 "concurrent assignment," and that's why I asked the
6 question I did about how it works for the programs for CMS
7 because how that worked was you know all through the year
8 who we think is attributed to you, but at the end of the
9 year, we settle up on who actually manifests as your
10 patient, because of all the switching that happens.

11 I'm not going to try to settle that here. I'm
12 just flagging the fact that I think for the first purpose,
13 how do we set the benchmarks, how do we settle the program,
14 the policy questions -- or maybe we'll call them the
15 "programmatic questions," I think this modeling of the
16 difference that it makes, the prospective and
17 retrospective, is it does a really important service, and
18 so I would encourage you to continue that line.

19 The other comment I want to really underscore, I
20 think I teed up a little bit with some of my questions,
21 which is this issue that you're on to, which I think has
22 been skipped over in both the academic evaluations and in

1 the CMS's own actuarial evaluations of switching is
2 extremely, extremely important. You show the numbers are
3 significant.

4 But it is -- I'll call it a closed course for
5 professional drivers. I mean, like the modeling that you
6 have to do in order to understand, just some of the basic
7 questions I was asking you of like did this person have a
8 health event that motivated the switch and how do you know
9 that it was because of that, and what happened to the
10 people that had the same health event that didn't switch,
11 that sort of gets a little bit at the propensity matching
12 you're wanting to do.

13 So I guess I just want to say I really encourage
14 this line of analysis for the second category, which is
15 establishing the right counterfactual so we can know more
16 accurately how well this program is succeeding.

17 But I want to encourage you to engage a
18 methodologist who has been driving on this course. I have
19 at least one to recommend to you, so I'll do that after the
20 meeting. But I think it's really important to address
21 these issues of moving around.

22 Thank you.

1 DR. CROSSON: Thank you, Dana.

2 Bruce.

3 DR. PYENSON: Again, I continue to be just really
4 impressed by the longitudinal study that you did as really
5 adding a lot of knowledge.

6 Paul's comment that if ACOs were much more
7 successful, we wouldn't be fussing over a lot of this and
8 Dana's cautionary note that prospective is not necessarily
9 the right way to go, I agree with.

10 But I did want to say, to me, this work
11 identifies one of the prevailing myths of population health
12 that I think many people have hoped would be realized with
13 the ACO movement, and that is, that if somehow we simply
14 engaged physicians and engaged patients better and got them
15 into the system consistently, we would be able to bring the
16 magic of better care to them, and they'd be healthier and
17 less expensive.

18 It's not quite a perfect analogy to Jay's comment
19 that "It's the price, dummy," but there's the issue of what
20 spending is actually malleable.

21 There's often the attempt to blame the patient,
22 "Oh, if the patients were only compliant" or only if they

1 were indentured servants and didn't move around, but the
2 reality is it's not the patient that decides unnecessary
3 surgery and admissions and excessive stays in SNF and
4 things of that sort.

5 So, ultimately, I think what we're up against
6 here is the failure to take the kinds of steps that are, in
7 fact, short term and effective in the short term at saving
8 money, and of course, the incentives are not aligned to
9 make that happen. So, hence, we're in this awkward
10 situation of a program that seems so promising but is
11 disappointing.

12 The fluctuation in the churn of 30 percent or so
13 that's been reported actually is not perhaps such a huge
14 problem. That's existed for generations in the insurance
15 industry. It's a little less now because there's so many
16 fewer insurers, but it's risk. And there's certainly ways
17 to manage it. Given that it's the reality of this
18 population, I think that emphasizes the importance of
19 short-term actions to make the care more efficient.

20 So this is my interpretation of the data that's
21 coming out of this that it actually points in a different
22 direction of what ACOs need to do to be effective than many

1 of the underlying assumptions that I hear very frequently
2 because I think, certainly, within the context and the
3 examples of MA plans, there's certainly potential
4 effectiveness.

5 So potential things to change here, less
6 concerned about attribution and that sort of issue, but the
7 ability to direct care more strongly, I think would be a
8 very important tool to get at some of the underlying
9 potential savings in the short term.

10 DR. CROSSON: So, Bruce, just let me ask you to
11 expand a little bit on that because I think the ability to
12 direct care in this context would be -- correct me if I'm
13 wrong -- the management of the ACO with respect to the, for
14 example, individual physicians.

15 Now, to me, that brings into play, perhaps, a
16 piece of this that we haven't spent much time on, which is
17 how the individual physicians are paid, what the incentives
18 are at the level of the individual physicians. Is that
19 where you're going or somewhere else?

20 DR. PYENSON: More on a referral policy and
21 ability to, if you will, some of the techniques that are
22 routinely used in Medicare Advantage, for example,

1 utilization management.

2 DR. CROSSON: Okay.

3 DR. PYENSON: So the challenge with an ACO doing
4 that is that it would be a loss for them to do that
5 relative to the shared savings and especially given the
6 churn. When you look at an organization, they're better
7 off not decreasing admissions, not decreasing ER, and
8 getting the revenue on that side rather than the relatively
9 small shared savings.

10 DR. CROSSON: Because of the disproportionate
11 shared savings. All right. Okay. Thanks very much.

12 Jonathan.

13 DR. JAFFERY: Yeah. Thanks, and thanks again for
14 this. I do wish maybe we had had this conversation before
15 I started at an ACO at a center. I'll have to think about
16 that. Yeah. So I have, as you can imagine, a lot of
17 thoughts, but I'll try and really limit it to implications
18 of this report, things like that.

19 So I think the switcher idea is super
20 interesting, and I would echo what others have said about
21 thinking about additional -- digging deeper into the
22 switches. I think the propensity-matching idea is

1 intriguing, important, and I want to acknowledge the
2 potential issues that David and Paul brought up but think
3 that that's important.

4 I'm trying to think about some other
5 characteristics of the switches, some things that others
6 have brought up about what does it mean around their health
7 needs and changes in health needs, and then also maybe a
8 little bit more about where they go. Are they going to
9 ACOs with hospitals? Are they going to academic medical
10 centers? Some things that intuitively might be driving
11 some of the other differences we see, but I'd like to
12 understand more about that.

13 And then a couple other things that I think the
14 report reinforced that we've heard, that we've seen in to
15 her reports, or people have observed that I think are
16 really key to success of the program long term -- so one
17 thing that you talked about in the report and today is the
18 longer you're in an ACO, the more likely -- the longer the
19 ACO exists, the more likely it is to achieve shared
20 savings, at least relative to the benchmark. So I think
21 that's something we need to think about that's important,
22 especially in light of the 2019 rule, which is going to get

1 people -- moving people towards risk faster. If they have
2 to be in risk in two years, but it takes on an average four
3 years to get to the point where your processes are in place
4 to make savings, it's just another hurdle for
5 participation, which of course is voluntary at this point.

6 Then the last thing that keeps coming out -- and,
7 again, you showed it today -- is that the best predictor of
8 shared savings is to be in a high-use area, high cost of
9 baseline, and none of these things really are getting at
10 that. The long-term sustainability of the program that is
11 asking organizations to make investments and then
12 continually just beat their own success. So, hopefully, we
13 can weave those things into further analysis too as we
14 think about opportunities for recommendations about program
15 design going forward.

16 MR. GLASS: Well, they are putting in regional
17 spending into the benchmark, which will -- depending on
18 whether you're high or low to begin with.

19 DR. JAFFERY: Right. I think I mentioned
20 yesterday, depending on your market, that may make
21 absolutely no difference.

22 DR. CROSSON: Okay. I've got Kathy, David,

1 Brian, Pat, Warner, Karen.

2 MS. BUTO: And Sue.

3 DR. CROSSON: Okay.

4 MS. BUTO: So I thought this work was really
5 interesting, and I really want to commend you for doing it
6 and actually taking a very innovative approach to looking
7 at what is underneath the spending growth and particularly
8 for switchers.

9 Like other people, I think it's important to
10 really understand what's going on there. It raised for me
11 two kind of issues that are not necessarily going in the
12 same direction, if you will.

13 One of them was I think the point that Warner was
14 getting at earlier, which is part of the ACO -- I guess our
15 aspiration for ACOs was not just about moderating spending
16 growth, but increasing management of care. So I think the
17 bonding or the connection with primary care physician is
18 something that if we understand better what's going on with
19 switching, we might be able to tease apart in a way that we
20 understand better how to increase the incentives or the
21 elements of the program that would stabilize that
22 relationship in a better way.

1 The ability to offer \$20 to beneficiaries and
2 have that make a difference in their showing up tells me
3 that there are other opportunities there that for
4 increasing connectivity and sort of engagement on the part
5 of beneficiaries to the ACO, and I hope that at some point,
6 we'll get more into that aspect of it.

7 On the other side, I guess the thing that I'm
8 aware of is there may be really good reasons why people are
9 switching, and yes, it leaves the spending growth, but
10 would we want them not to switch, in a sense, in this
11 construct? Yes, if they're in an MA plan, but this
12 approach was designed to allow for greater flexibility. So
13 that's why I think it's important to better understand why
14 they're going out or why they're migrating outside the ACO,
15 and it may be for very good reasons. Maybe they should be
16 in a medical center if they're got a complex medical
17 condition, and both the primary care and specialty care can
18 be better managed together. So I think that's why it's
19 important to go the next level.

20 MR. GLASS: I don't think we said switching leads
21 to spending growth. I think people switch for a reason, as
22 you just said.

1 MS. BUTO: Right.

2 MR. GLASS: And they get sick. They start seeing
3 other doctors.

4 MS. BUTO: That growth won't occur.

5 MR. GLASS: I know from my own experience --

6 MS. BUTO: Wherever, yeah.

7 MR. GLASS: -- changes in health status are
8 usually not good. It's going to cost you money, and it's
9 going to be seeing a lot of doctors. And so the switching
10 causes --

11 MS. BUTO: You're saying the spending growth
12 would occur --

13 MR. GLASS: Exactly. Right.

14 MS. BUTO: -- wherever they are.

15 I'm just saying that the switching itself might
16 be a very rational thing and driven by the right clinical
17 consideration.

18 DR. CROSSON: Okay. So we are running out of our
19 allotted time. I've got David, Brian, Pat, Warner, Karen,
20 and Sue, and I think that will be the end of the
21 discussion.

22 David.

1 DR. GRABOWSKI: Thanks again for this work.

2 On page 1, you write this paper examines the
3 effect of the MSSP on Medicare program spending, and you
4 have these three sections in the report, the first looking
5 at performance relative to the benchmarks; the second,
6 performance relative to counterfactuals, seeing some of the
7 work from the literature, and then the third, this
8 descriptive examination of switches.

9 I would argue based on that goal of wanting to
10 look at the effect on Medicare program spending that only
11 that second section is really meeting that overall
12 objective, and Dana has already made this point, but I'll
13 make it again. Benchmarks don't equal counterfactuals, and
14 I don't know that that section belongs in here. I think it
15 just confuses. The benchmarks are really important to the
16 participating organizations, but they're not important to
17 Medicare program spending.

18 I'll quickly note my colleague Michael McWilliams
19 actually had bumper stickers printed up that said
20 "Benchmarks do not equal counterfactuals." I'm going to
21 get one for Jeff, and, Jeff, we're going to put in on your
22 car at the next meeting. We'll go out and --

1 [Laughter.]

2 DR. STENSLAND: If that's not going to elevate my
3 cool status, I don't know what will.

4 DR. GRABOWSKI: I don't know what will. That's
5 right. That's right. I think it would look great on your
6 car, though, Jeff.

7 DR. CROSSON: Let me just point out you've got a
8 great football team over there. I think that makes much
9 more sense.

10 DR. GRABOWSKI: That's right. Right, right.

11 DR. DeSALVO: It's going to be great until the
12 Saints crush them.

13 [Laughter.]

14 DR. SAFRAN: I just want to mention that I have
15 that bumper sticker.

16 DR. GRABOWSKI: There you go.

17 [Laughter.]

18 DR. GRABOWSKI: Is it on your car, though, Dana?

19 DR. CROSSON: All right.

20 DR. GRABOWSKI: The other point I wanted to make,
21 quickly -- I'll come back -- I touched on this in Round 1,
22 but the switchers are not random. They're a highly

1 selected group and I just worry that we have this change in
2 health status which leads to this change in provider which
3 ultimately leads to this change in assignment. There's
4 something very different about these individuals. So I
5 think Dana framed that nicely. It's a really challenging
6 course and we want an expert driver. But I worry, even
7 with an expert driver, that we're not going to be able to
8 navigate it. It's really hard to kind of do this with
9 propensity-matching and actually come up with a good
10 counterfactual.

11 So I'll say I remain skeptical about whether we
12 can actually do that. So thanks.

13 DR. CROSSON: Brian.

14 DR. DeBUSK: Thanks again on a really insightful
15 chapter. I really enjoyed the analysis. And like so many
16 others have said, I think studying and understanding the
17 switchers is obviously a huge component of this.

18 I'll tell you the prospective assignment feels
19 like progress. It does clearly seem like it's a step
20 forward. But we're in a pretty awkward situation here
21 because, you know, as we've talked about now, this clearly
22 isn't an endpoint. This is a way point, at best.

1 And so I think we're going to be tasked with
2 trying to push forward on even better ways to do this
3 attribution in this assignment, and what I was going to
4 encourage here is really two-fold. Number one, you know,
5 from what we've learned from the switchers, I don't know
6 that we can conveniently put someone in this box or in that
7 box and say this is the person that's responsible. We may
8 have to take more of a hybrid approach, where we do bring
9 some retrospective ideas and some prospective ideas
10 together, and maybe even do some cross-attribution or some
11 mixed attribution. And, I mean, we can follow up with
12 emails with that.

13 But I think having something that's more
14 continuous, where someone doesn't have to leap from one ACO
15 to the other may, at least, for analytic purposes, help us
16 understand the nature of these transitions, because I could
17 see someone being attributed to one ACO, getting sick,
18 racking up claims in this new ACO, triggering their
19 basically cross, or their reattribution, and then once they
20 resolve going right back to their original ACO.
21 So let's think about, you know, are there more continuous
22 ways to do, again, some type of cross-assignment or a more

1 continuous type of assignment, even that could be claims-
2 based.

3 The other thing I was going to mention, too, is I
4 think the analytics are only going to get us so far, and I
5 think Kathy briefly alluded to the idea of beneficiary
6 engagement, you know, if you were focusing on the \$20
7 payment for a healthy visit. I still ultimately think
8 we're going to have to do something to engage
9 beneficiaries, and sort of, to me, the obvious mechanism
10 would be some type, ultimately -- I'm probably going to get
11 thrown out of here for this -- but ultimately some type of
12 surcharge for people who insist on unmanaged care. If I
13 don't want to identify a primary care physician, I don't
14 want to participate in an ACO, and I don't want to enroll
15 in MA, ultimately, we're going to have to capture that
16 cost. Is it a \$12, is it an \$18 surcharge on your Part B
17 premium? I don't know.

18 But at some point we need to recognize the fact
19 that people who insist on not participating in any of the
20 choices in front of them are costing the system extra
21 money, and I think that may be the beneficiary engagement
22 mechanism that we need to also address some of these

1 attribution issues with ACOs.

2 DR. CROSSON: Great. Pat.

3 MS. WANG: Thanks. Again, I commend you on the
4 work and I think it's really important, and I think, just
5 for the record, to state clearly, I think that the work is
6 important to keep evolving the ACO program and to keep
7 getting better and better and better at this.

8 The discussion around switchers is really
9 important and people have raised all of the relevant
10 points. Attribution models, even in managed care plans,
11 are phenomenally difficult because we may think that
12 somebody should recognize their PCP as, you know, the
13 person in charge of coordinating everything, but human
14 behavior often is not like that. And people will say,
15 "You're my PCP but I go get my care someplace else," and
16 you just have to recognize that as human behavior.

17 But the thing that is raises to me -- and I think
18 the work is important and needs to keep going -- but what
19 it raises to me is that ACOs are still such a partial and
20 segmented solution, and that that is one of the reasons
21 that we're spending a lot of time talking about why are
22 people switching, you know, et cetera, et cetera. And it's

1 good, what are the characteristics of switchers; it's fine.
2 But the goal, ultimately, is that those people who switch
3 because they develop a serious health condition, or move to
4 a different part of town, are still in an organized care
5 delivery system that does the best job possible for them.
6 Their health outcome may change because they might be
7 gravely ill, so at that point they're really in an acute
8 situation. You just want the care to be good.

9 And so, you know, I would just observe that over
10 time, hopefully, this archipelago of ACOs will be connected
11 into some sort of continent. Like ideally, you'd think
12 about there's a regional ACO, because there are switchers.
13 People are always going to switch for some reasons. You
14 just want to make sure that they're moving from one
15 organized delivery system into another organized delivery
16 system. So we have a ways to go there.

17 One of the reasons that I asked about change or
18 evaluation of Part D spending, and I understand that it's
19 not part of the ACO's responsibility. I do think it's
20 important to look at, because if you look at total program
21 spending it's a big part of total program spending. And
22 part of the reason to try to understand whether there are

1 any changes there is precisely because the ACO is not
2 responsible for it. I think that we would want to know
3 whether there are changes in care patterns that are
4 producing, you know, changes in spending growth, up or
5 down, that may be related to parts of the benefit package
6 that are not the responsibility of the group that is
7 charged with managing that population. Substitute medical
8 care with increased prescribing would not be a good thing,
9 but you kind of want to know that.

10 Over time -- and I don't know how to do this --
11 but it would be great for ACO members, who are, by
12 definition, enrolled in freestanding PDPs, that don't
13 really have quality metrics that are tied to health
14 outcomes, to somehow align to what the ACOs are trying to
15 do. Jonathan, you know, I think really vividly described
16 yesterday the consequence of non-adherence to medications
17 when somebody shows up in the hospital and it creates all
18 kinds of problems for them. It would be great if, at some
19 point, ACOs, who are managing those kinds of outcomes,
20 could have aligned incentives and data-sharing with PDPs
21 who right now have no -- there's no star measure for a PDP
22 for med adherence, for example. You know, to somehow, over

1 time, examine how those linkages might be made so that at
2 some point they're connected, because it's hard to imagine
3 an ACO managing a Part D benefit but there might be
4 something in between.

5 I'm not in favor of kind of pushing ACOs down the
6 road of do your own utilization management. It's an
7 incredibly costly enterprise. It has a lot involved in it.
8 It's not just, you know, decide what you think should be
9 approved, not approved. It will never go -- it's a
10 different model than insurance and a capitated model, so it
11 will never take that final step. But I think that, to me,
12 the goal and the drive of ACOs is to create a more
13 coordinated, connected delivery system that can fit into a
14 better fee-for-service system, a better MA system, and,
15 ultimately, those should be the two pathways for
16 beneficiaries.

17 DR. CROSSON: So, pat, this question you raise
18 about integration between ACOs and Part D is on our work
19 plan.

20 Warner.

21 MR. THOMAS: I'll be brief, given the timing.

22 First of all, I was actually pleased with the result, and I

1 think given the short time period that ACOs have been in
2 existence, I think we are seeing results. So I hope that
3 people feel like we're heading in the right direction here.

4 I'm also not surprised with the fact that for
5 folks that stay with the same ACO or stay with the same
6 physician that they see better results. And it's one of
7 the reasons I really think we should look at primary care
8 assignment or physician assignment. If we need to broaden
9 it, I think that's fine, but I do think having people --
10 we're seeing this with our own employees. You know, once
11 we went to primary care assignment they identify with that
12 person, they create more of a system, they understand that
13 they are part of a system. So I think the better we can
14 explain that and help people understand that I think the
15 better off we will be.

16 So I would just -- hopefully we can take away
17 from this a positive view of what's happening here, and
18 what's going to, I think, continue to push people down the
19 road of more risk and more downside exposure so that there
20 is more innovation around changing care, and I think we'll
21 continue to see positive results. But I'd really like to
22 see us take on the idea of educating beneficiaries, being

1 able to interact with beneficiaries in a much, much more
2 direct way, and also this idea of primary care or physician
3 assignment.

4 DR. CROSSON: Thank you, Warner.

5 Karen, a brief Drew Brees kind of factual would
6 be allowed.

7 DR. DeSALVO: Like where he's best throwing
8 passes -- short.

9 I want to just maybe underline some themes, that
10 it seems that the program, as designed originally, or
11 conceived, was to get people into better care management,
12 and it's really, in some ways, maybe we're seeing some
13 claims avoidance behavior. And so that care management
14 piece, I feel like when the beneficiaries switch or for
15 whatever reason are no longer part of the ACO, it's almost
16 like they're being released into the fee-for-service wild,
17 and that's the time when they may need the most care
18 coordination, because they're having a lot of complexity.
19 So the implication is along the lines of what Pat just
20 shared, and Warner, that we really need to think about a
21 world in which this is not a side business but there is
22 accountability entity responsible for total health and

1 total cost of every Medicare beneficiary, so that they have
2 a quarterback to help manage their care.

3 I want to just make two other points. One is
4 that some of the physician results make me think about
5 aligned incentives also, in that there's some writing from
6 that world of physician ACOs that more proximate
7 incentives, proximate understanding about quality and
8 outcomes and also alignment really does change some of the
9 practice behavior on the front lines, a little bit of what
10 came up in this conversation with Bruce. So it's maybe not
11 a comment but a question I'd love to tease out a little bit
12 of. Is there something about that importance of aligning
13 the incentives for the physicians? It's not just having an
14 accountable entity.

15 And the final point is about selection, which is
16 there are lots of ways. It seems that there's claims
17 avoidance and selection happening. I just want to put on
18 your radar the world in which big data is allowing plans to
19 not just look back at who was in the hospital and was
20 expensive but look forward and do that using retail data
21 and social data. And it's turning into an entire industry
22 that -- and most of its conception is about claims

1 avoidance, how to not allow people into your plan, but in
2 its best format could be a real opportunity for care
3 management to help identify people who are going to be in
4 trouble, and wrap your arms around them and help them into
5 the future.

6 Thank you.

7 DR. CROSSON: Thank you, Karen. And Sue.

8 MS. THOMPSON: I will also be brief. But thank
9 you again for this chapter. And, David, I think it was you
10 who said in the beginning of your remarks that this is data
11 from 2015 and '16, and there are a lot of changes coming in
12 '19, that I just think it's important for us to put in
13 context here. What we are looking at here in '15 and '16
14 are primarily, predominantly ACOs that were upside only,
15 and in '19 -- and I think it's important in terms of sort
16 of the pace and the urgency, those of us who are in ACOs
17 are feeling about the impact that the changes in '19 are
18 going to make on continued enthusiasm for remaining in
19 ACOs. I mean, basically the risk coding and the quality
20 becomes just baseline expectation. We're rebasing. So
21 there's going to be a lot of industry sort of, "Oh, my god,
22 do I want to stay here or not?"

1 So I agree with Warner. This is probably the
2 most enthusiastic I have felt the Commissioners about ACOs,
3 despite the fact, you know, the results are still in
4 question. But I would remind everyone, what we're looking
5 at here is upside only ACOs. So just to keep that in
6 perspective.

7 A couple of points I want to make. On page 5 you
8 did reference the Pioneer ACO, predominantly urban. I am
9 fairly familiar with one that was quite rural and quite
10 small, so don't forget those organizations out there that
11 are cost-based, that are rural, that probably have
12 specialists providing primary care, that are probably
13 messing up the whole specialist attribution model. Because
14 I don't want to lose that portion of our country in staying
15 engaged in this work, thinking that they're somehow going
16 to be outside and exempted from. Just a call-out for the
17 old rural Pioneer ACO. Thanks.

18 DR. CROSSON: Thank you, Sue, and thank you,
19 Jeff, for this breakthrough research, and David and Luis
20 for the presentation, and thanks to the Commissioners for
21 this discussion, the pathway to value-based payment leading
22 to better care and less expense for beneficiaries in the

1 program. Part of that lies through ACOs, and I think the
2 work here, continuing work to get that improved, is
3 something that we will dedicate ourselves to.

4 We have now finished the discussion and we have
5 the opportunity for public comment. If there are any of
6 our guests who would like to come up and make a comment,
7 please come to the microphone so we can identify you.

8 [No response.]

9 DR. CROSSON: Seeing no one at the microphone we
10 are adjourned until our meeting in March. Thanks very
11 much. Safe travels, everyone.

12 [Whereupon, at 11:45 a.m., the meeting was
13 adjourned.]

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