ROPES & GRAY

Health Care

Transcript

A View from Washington of President Trump's First 60 Days

Attorneys
Tom Bulleit
Adrianne Ortega

Tom Bulleit: Good afternoon and welcome to the first teleconference in Ropes & Gray's series on the transition to value-based health care. In the months ahead, our lawyers will be presenting a series of programs on this topic, including programs in April, presenting "Guidance for Providers and Medical Device Manufacturers," as well as a program in May focused on the impact of value-based care on digital health.

Today, we're kicking off the series with the view from Washington. It won't be a surprise to anyone that this is an appropriate starting point given last fall's election and the widely-reported changes that the new President and Congress have been talking about for the way health care's provided and paid for here in America.

I'm Tom Bulleit, and I head the health care practice in the firm's Washington, DC office. Joining me today is my colleague, Adrianne Ortega, a senior associate in the health care group who practices out of our Boston office. We hope you find the program worthwhile.

Before starting, we need to run through a few reminders. First, you should have already received the slides we'll be using. If you have not, please email RGEvents@ropesgray.com and someone will send them to you right away. Second, today's presentation's being recorded. Your phone line though is muted. Third, you will have an opportunity to ask questions during the presentation. If you'd like to do so, please email your question to RGEvents@ropesgray.com. We will try to weave your question into the presentation, or as time allows, answer it at the end of the program. Fourth, today's presentation is for educational, informational purposes only. Nothing we say, nor our slides, should be construed as legal advice or a legal opinion on any specific facts or circumstances. Today's presentation is not intended to create a lawyer-client relationship, and you are urged to consult with your own lawyer concerning your particular situation and any specific questions you may have. Finally, if you're interested in receiving CLE credit, please fill out the attorney affirmation form that was included in your confirmation email. At the end of the presentation, we'll give you the number code to add to the form so you can receive CLE credit. Once you get the code, please send the form to CLE.team@ropesgray.com.

Adrianne and I hope to provide some insight into how the advent of President Donald Trump and his team at the Department of Health and Human Services in collaboration with the Republican majorities in both houses of Congress will affect what up to now has been the health care industry's journey towards value-based health care. Got a spoiler alert: we think that journey is going to continue in largely the same direction as it has for the past decade, although there may be some more detours and yield signs along the way.

Those of you who are familiar with Ropes & Gray's health care group know that we have leading national practices in health care and the life sciences with lawyers on the ground in New York, Chicago and San Francisco, in addition to Boston and Washington. Our clients include some of the country's leading providers of health care services, including hospitals, academic medical centers and clinical laboratories,

makers of health care products like prescription drug and medical device manufacturers, and health care insurers. Our daily contact with this range of clients and their issues, gives us a unique perspective on the health care industry from all of its angles. We think those perspectives also give us a lot of insight into where the industry is going and how its development will affect our clients.

Among the trends that we've seen over the last decade has been the industry's transition to value-based health care. Moving from a world where providers were paid for how much health care they provided to one where their payment will be based on how good the health outcomes they provide. This is arguably the most disruptive change to the health care industry since the advent of the Medicare prospective payment system in the early 1980's; more disruptive than Obamacare, because it affects a much bigger slice of the market than just individual insurance. It affects providers by requiring them to consolidate, form networks and joint ventures to share in the risks and benefits of a system that bases pay on quality rather than quantity. It affects drug and device makers who may be asked to share in these risks and benefits by providing risk-based pricing for an increasingly diverse suite of consulting or management services to make sure that their products are used cost-effectively. And, of course, it affects payors who increasingly will be requiring providers to share these risks.

If you want to go to the slide that is titled "Agenda" that has the highlighted language "What Is Value-Based Health Care?," we'll talk about what we're going to talk about today. We're going to be discussing value-based health care generally, then we'll examine the Trump effect and will then discuss congressional activity, including the American Health Care Act, and then we'll return to review the effects of President Trump and Congress on value-based health care and discuss next steps for the health care industry. Although our focus today is going to be on the effect of a Trump administration on value-based health care, we should probably start by defining value-based health care and how it was affecting the industry when President Trump took office. If you will jump to the first slide titled "What Is Value-Based Health Care?," I will turn the mic over to Adrianne for that discussion.

Adrianne Ortega: Thank you, Tom. Value-based payment rewards providers based on the quality of care delivered, rather than on the number of procedures performed. Value-based health care has been widely-perceived to be an effective method to reduce health care costs. CMS has announced a three-part aim of value-based health care. Better care for individuals, better health for populations and lower health care costs.

If we move to the next slide, "What Is Value-based Health Care", I will provide a brief overview of value-based health care programs in place at the federal level, starting with value-based health care programs that were promulgated under the Affordable Care Act.

The Affordable Care Act created the Center for Medicare and Medicaid Innovation, known as CMMI, to touch new, innovative health care payment and delivery models. These models include the Medicare Shared Savings Program, Accountable Care Organizations, known as ACOs, which reward ACOs that reduce the growth of their health care costs, while meeting certain performance standards related to quality of care and patient satisfaction.

The bundled payments for Comprehensive Care Improvement Initiative, known as BPCI, is a voluntary program that consists of four models which group payments for services related to a single episode of care. The comprehensive care for joint replacement initiative, known as CJR, has bundled payment and quality measures for episodes of care related to hip and knee replacements; and participating hospitals are

financially accountable for the cost and quality of the CJR episode of care, which encourages collaboration across health care providers. And CMS has implemented this model in 67 geographic areas across the country and this model is mandatory, meaning that hospitals selected by CMS are required to participate in the program.

The newest bundled payment initiatives for cardiac and orthopedic care include four new models: the acute myocardial infarction model, the coronary artery bypass graft model, the surgical hip and femur fracture treatment model and the cardiac rehabilitation incentive payment model. Of those models, other than the cardiac rehabilitation model, hospitals from selected geographic regions will be required to participate in retrospective bundled payments for services related to treatment and recovery, which are very similar to CJR. Under these models, all providers and suppliers will be reimbursed under the usual Medicare payment system rules. But for the episode based payment models at the end of the applicable performance year, hospitals may receive an additional payment from Medicare or repay Medicare for a portion of the episode spending exceeding the aggregate target price. For the cardiac rehabilitation model, hospitals will be eligible for an incentive payment depending on the utilization of cardiac rehabilitation services.

And finally, we have the Medicare Access and CHIP Reauthorization Act known as MACRA. And under MACRA's Quality Payment Program, clinicians may choose value-based adjustments on one of two payment tracks: the Merit-based Incentive Payment System or the Advanced Alternative Payment Model, known as the APM, and some CMMI programs may qualify as advanced APMs. Beginning in 2019, clinicians who participate in an advanced APM will receive annual 5% increase in Medicare Part B reimbursement.

So moving to the next slide, it's not only CMS that has begun moving to value-based payment as part of the Medicare program, but there are many players in the private sector that are also moving toward value-based payments. Under "private pay initiative" on the next slide, the number of Medicare and commercial ACOs has grown significantly since the creation of the Medicare Shared Savings Program. Examples of large ACO networks include The Blue Shield of California program and Advocate Health Care in Illinois.

Private payors have embraced the bundled payment programs as well. For example, UnitedHealth's prospective bundled payment program has scaled up from a smaller pilot program in 2015, to now covering over 40 hospitals and 2.2 million patients. Some payors have also established financial incentive to improve care coordination among providers. For example, Empire of Blue Cross Blue Shield has adopted the care coordination measure established by the Joint Commission, and provides financial incentives to its hospital networks to reach integrated care certification.

Another development is the increasing prevalence of patient-centered medical homes. Most medical home reimbursement models incorporate monthly care coordination payments, in addition to traditional fee for service reimbursement. These payments encourage increased collaboration across care providers. Here at Ropes, we've worked on a number of initiatives with our clients to prepare for the shift toward value-based health care. In working with our medical device clients, we've seen the adoption of increasingly broad bundled payment programs; the use of value-based pricing, where payment is contingent on outcomes; the expansion of their consulting and management capabilities; and increased activity in vertically integrating by owning providers. We've also developed models for value-based ventures including consulting and

management services, joint ventures and creative product offerings and advised on compliance with state and federal anti-kickback, antitrust, privacy and licensure laws in the context of proposed ventures.

Tom Bulleit: Thanks, Adrianne, for that whirlwind introduction to what is really even a bigger array of health industry adaptations to the need to deliver quality health outcomes, rather than just quantity of health care products and services. Now to our main topic of the day—what will be the effect of the Trump Administration on those developments—if you will jump to the slide that is titled "The Trump Effect".

Adrianne Ortega: Thank you, Tom. Well let's start with what the President has said. He said he wants a full repeal and replacement of the Affordable Care Act, continued access to coverage for those with pre-existing conditions, increased incentives for health savings accounts, tax credits based on age to subsidize insurance premiums, tort reform to decrease malpractice costs for providers, protection for Medicare benefits, and flexibility for state governors to use their federal Medicaid funding. And the President has not really said anything that is specific to value-based health care. The closest he gets is in his reference to repealing the Affordable Care Act, which would have the effect of repealing CMMI and its value-based initiatives; but there is no indication from the President that that is a policy goal, and parenthetically, even without CMMI, CMS does have the ample authority to conduct demonstration programs that could advance the cause of value-based health care, so even a full repeal wouldn't necessarily take CMS out of the value-based health care business.

Moving to the next slide, let's review the new team at HHS titled "The Trump Effect – Key Appointments". Starting with Tom Price, the UN Secretary of Health and Human Services, he's an orthopedic surgeon and former Republican congressman from Georgia, who served as the chairman of the House Budget Committee and as a member of the Health Subcommittee of the House Committee on Ways and Means. Price has been a longstanding advocate for physicians, and in particular, he opposes what he perceives to be government interference in the doctor-patient relationship.

Price has also been a critic of the ACA and was one of the first Republicans to propose his own replacement plan, The Empowering Patients First Act, which is actually quite similar to the current Republican ACA replacement bill, with a focus on age-based tax credits for premiums and tort reform. And Price has been a vocal critic of CMMI on multiple occasions, and as a general matter, Price believes that CMMI models should be limited in size and scope and established through an open, transparent process with ample communications with physicians, patients and other stakeholders. So CMMI activity under Price will likely be limited and include increased involvement from providers.

Price has also been a vocal opponent of mandatory participation models—such as CJR—on the grounds that mandatory participation models are an over-reach of CMMI's authority to test payment models. We do know, however, that during his confirmation hearing, Secretary Price said that CMMI has great possibility and promise, and in prior written comments, he expressed support for ACOs as a tool for high-quality, low-cost care. He also expressed support for CMMI with respect to the testing of innovative health care financing and delivery models. So it appears likely that Price would probably seek to continue CMMI generally, including certain voluntary models like ACOs, but he may use his powers to fade out mandatory models like the CJR model.

Seema Verma, the CMS Administrator who was confirmed this week, is a Medicaid consultant with extensive experience obtaining state Medicaid waivers. Verma designed the Indiana, Ohio, Iowa and Kentucky Medicaid waiver applications, which emphasize personal responsibility in the Medicaid

program. For example, Indiana's Medicaid waiver increased reimbursement to providers, which in turn increased beneficiary provider access. But the state also required beneficiaries to contribute to health savings accounts and pay premiums, and beneficiaries above the poverty line to be locked out of the program for six months for missing a monthly premium payment.

Scott Gottlieb was recently nominated to be the Commissioner of the Food and Drug Administration, and Gottlieb has experience in the FDA as a former Deputy Commissioner for Medical and Scientific Affairs. He was a Resident Fellow at the American Enterprise Institute and has expressed support for the repeal of the ACA, the relaxation of the FDA's restriction on the promotion of off-label drug uses.

Moving to the next slide, now that we know the players, what does this mean for value-based health care? Now HHS under Price and Verma can affect those programs that were designed by CMMI. Those are created by rule and may be altered through the rule-making process. Therefore, without any legislation from Congress, HHS or CMS can reverse or scale back BPCI, CJR and the new bundled payment initiative.

However, the Medicare Shared Savings Program, ACOs and MACRA's value-based system cannot be reversed without repeal legislation since each was initially created through legislation, through the Affordable Care Act and MACRA, respectively. This doesn't mean that HHS or CMS can do anything contrary to existing regulations immediately. Rules made by CMS can't be undone except through more notice and comment rule making, and there's nothing immediate about that. So for example, absent legislation, the CJR rule requires notice and comment to repeal; and as an aside, CMS has just delayed the effective date of the final rule implementing the new mandatory bundling programs from February 18th to March 21st as part of the general regulatory freeze and review after the inauguration. HHS has publicly stated that the start date remains July 1, but it seems that if Secretary Price were really hostile to those programs, he could have used that rulemaking to postpone or even eliminate those programs.

Now in terms of predictions, we predict that BPCI will likely continue because it's voluntary and that ACOs and MACRA will likely continue because each have broad, bipartisan support. CJR may continue at least for the foreseeable future because the program is well underway and it is producing data, but in the future it may converted to a voluntary program. And with regard to the newer mandatory bundling programs, we do find it curious that this most recent rulemaking didn't already start to scale them back. So perhaps they will proceed as planned, but we would still guess that they will get scaled back or turn voluntary over the course of the next year. And on a going forward basis, it is unlikely that we will see any more mandatory programs out of CMMI and current mandatory programs may move to voluntary participation programs. Instead we may see more right-leaning experimentation, such as perhaps a pilot on Medicare premium support.

I will now turn it over to Tom to discuss the effects of current congressional activity on value-based health care. So if you move ahead to the next slide—the next agenda slide—with "Congressional Activity" highlighted. Tom—

Tom Bulleit: Thanks, Adrianne. So it's clear that the Trump HHS can do significant things to existing value-based health care programs coming out of CMMI without any help from Congress. But there's no indication that there will be an all-out war on value-based health care from the Trump HHS. Rather, more of a slow down. And there are indications that the private sector will step in. What we know that Congress intends to do is repeal and replace the Affordable Care Act, so what might the effect of repeal and replace be on the development of value-based health care?

Let's start by saying that the only thing that is 100% clear is that the Congress will pass, and President Trump will sign, a bill that will have the word "repeal" attached to it. There have been so many proposals floating around from so many members of Congress—and as of today, still nothing specific from the President—that it's anybody's guess exactly what even repeal will look like, let alone replace.

Although the House Republicans proposed the American Health Care Act on March 6, 2017 and the Ways and Means and Energy and Commerce Committees approved it on March 9th, and will be talking about it, there's not yet consensus on the bill and whether it will become law in its current form. At his address to Congress, President Trump spoke favorably about tax credits and health saving accounts—key elements of the House Leadership Proposal. But there is significant disagreement within the Republican caucus in the House and the Senate about even those tax credits, and as I do the math, sufficient disagreement to block a consensus effort; still, looking at the American Health Care Act as well as other Republican proposals, there were a few common threads that might help us answer a few questions, with some degree of certainty.

So if you'll go to the slide titled "Congressional Activity" that starts with "procedure of repeal and replace", let's review the bidding on how this gets accomplished procedurally. Generally, no legislation can pass through Congress without 60 votes in the Senate due to the filibuster. An important exception is the process of budget reconciliation, under which provisions that have an impact on the federal budget may pass with a simple majority. Since the Senate has 52 Republican members, reconciliation is a vehicle to repeal many of the provisions of the Affordable Care Act that Republicans particularly dislike, including the individual mandate, all the taxes, the pharma med device and Cadillac taxes, Medicaid expansion and the taxpayers subsidies for premium support and cost sharing. Before the inauguration both houses of Congress passed budget bills to set this up procedurally. So although generally 60 votes would be needed for most things, and at least 8 Democrats would have to be on board, Republicans hope to pass the American Health Care Act through the budget reconciliation process, thus eliminating the need to obtain 60 votes.

Now, budget reconciliation is subject to the so-called Byrd Rule, after former Senator Byrd, which requires that a reconciliation bill relate to the budget, meaning that some of the Affordable Care Act provisions can't be addressed via this process because they don't deal with federal tax or spending. It would be up to the Senate Parliamentarian to decide whether the legislation meets the Byrd Rule standards.

Despite all the bluster related to repeal of the Affordable Care Act, there may be real consequences politically to the replacement of the ACA with a bill that does not provide sufficient health insurance coverage. The reconciliation bill that Congress passed last year, HR 3762, knowing it would be vetoed—so it really didn't matter what was in it—repealed all of the budgetary provisions, especially the mandate, the taxes, the subsidies and Medicaid expansion.

But now that the Republicans will own the repeal. The prospect of just repealing insurance subsidies for some 20 million Americans is scary. As a result, there is disagreement in the Republican caucus between, let us call them the true believer conservatives—those who think the federal government shouldn't be in the business of expanding federal welfare programs to help people buy health insurance with taxpayer money—and moderates and pragmatists who recognize that a large number of Trump voters were blue collar people who might very well need assistance to afford health insurance. For example, Senator

Alexander of Tennessee and Senator Hatch have expressed hesitancy about repeal and replace and have suggested that repair of the Affordable Care Act may be a more pragmatic approach.

At least four Republicans, Rob Portman, Shelley Moore Capito, Cory Gardner and Lisa Murkowski have expressed rejection to Senator McConnell regarding the House Republicans treatment of the Medicaid expansion and federal Medicaid funding in the replacement bill. Also, people could not have missed that the Congressional Budget Office released its report on the Affordable Care Act this week, finding that the legislation would reduce the federal deficit by $337 billion between 2017 and 2026, but it would significantly reduce the number of people who were insured. 14 million more people would be uninsured by 2018 and that number jumps to 24 million by 2026. The CBO estimates that the legislation would increase average premiums in the non-group market prior to 2020, but lower them after that compared to the current law. So it seems the dynamic here is, in a way, pretty simple – the federal government would spend less because the subsidies would go down and Medicaid expansion will wind down and without a mandate and fewer people would be insured.

If you want to go to the slide called "Congressional Activity", with "American Health Care Act" right underneath it—the AHCA was proposed on March the 6th, the Committees approved it on March the 9th. The bill is moving steadily through the House with strong support from Speaker Ryan and the White House. Note that the AHCA does not contain any explicit reference to repeal of CMMI. In addition, certain factions of Republican members of Congress feel differently about how to approach repeal and replace. And some of those differences are important enough that they could derail the effort.

So if you go to the next slide, which starts with "Contested Issues among Congressional Republicans"…On the Obamacare taxes, some Republicans including Senator Cassidy of Louisiana, Senator Sessions of Texas, think we have to keep the taxes for a while, until Congress gets some other funding sources. Some think the taxes have to go right away including Senator Hatch and Representative Kevin Brady. This is a really important issue because Obamacare's funding of Medicaid expansion and the ACA subsidies to the individual insurance market are funded by these taxes. If they go away, Congress will need another funding source. The AHCA accounts for its tax credits by converting federal Medicaid contributions to per capita amounts and removing the tax break for some portion of employer provided health insurance in 2025. This approach may not easily command a majority even in the House.

On Medicaid expansion, the American Health Care Act would allow the federal increase match to continue for a while, then freeze Medicaid enrollment for the expansion population in 2020. In addition, the AHCA would provide additional provider reimbursement funding to the states that didn't expand Medicaid under Obama and these states may choose to expand before the expansion enrollment freeze in 2020.

On credits and deductions, the most contentious issue has been which way to go. The AHCA includes its advanceable and refundable credits which the conservatives call, not without some reason, just another subsidy or entitlement program. The key difference from Obamacare is that the credits would be age-banded so that older people would get more, rather than means tested. So these credits could be used to pay premiums because they would be available up front and any excess not used to pay premiums could go into a health savings account. But the change would take money currently targeted at the poor and aim it at the elderly. The Republican Study Group, one of the larger conservative sub-caucuses in the House, proposal calls for a standard health insurance premium deduction, and certain enhancements to HSA

contributions that would be tax deductible—and that really benefits only higher income people who pay taxes.

So if you'll go to the next slide, which is titled "Less Consensus among Congressional Republicans", there's also less consensus on some other issues. And we may see some activity related to these issues at the fringes. Policies that vary across reform proposals include: expanded tax benefits to encourage health savings accounts. The AHCA would increase the annual contribution limit to $6,000 from about $3,400, or double that for families, and expand the definition of qualified medical expenses to include over the counter medicines and expenses incurred up to 60 days prior to the date of an HSA opening. And it would also decrease the tax penalties for withdrawals for non qualified expenses from 20% to 10%.

Other Republican proposals would have increased access to HSA's in slightly different ways, for example, Representative Price's bill had a lower maximum HSA contribution – 5,000 and 10,000 – but would have expanded eligibility for HSA's to veterans and tri-care and Indian health care service beneficiaries. The Republican Study Group's proposal would have expanded qualified health care expenses to include certain fitness program, nutritional and dietary supplements and periodic fees for direct practice primary care practitioners, and included a new type of HSA – the Deferred Use Child HSA – to allow parents to create an HSA which could be transferred to their child when he or she obtains self coverage independent of the parents.

Another policy that has had dispute is what to do about pre existing conditions. As probably everybody remembers, the Affordable Care Act for the first time created a new, broadly applicable rule that insurers could not discriminate on the basis of pre existing conditions. Could not deny coverage and could not underwrite based on the health risks associated with those conditions. The American Health Care Act and Representative Price's bill would protect the pre existing condition coverage in the ACA if the individual has had continuous coverage, but imposed penalties for gaps in coverage. Under the AHCA insurers could charge individuals with pre existing conditions who had a 63 day gap in coverage over the prior 12-months 30% higher premiums for a year, while Price's bill contained even harsher penalties for coverage gaps allowing insurers to charge 50% higher premiums for two years and excluding certain qualified pre existing conditions from coverage for about 18 months. Both the Mark Sanford/Rand Paul bill and the Republican Study Group's proposal would have repealed entirely the ACA's protections with those for pre existing conditions.

And then there is another contested issue around high risk pools, which are an alternative to coverage when you don't have the opportunity to have pre existing condition coverage guaranteed, the American Health Care Act would provide innovation and stability program grants to states to fund high risk pools. The state and federal funding for high risk pools intended to provided options to cover the sickest patients who can't afford even this insurance. In contrast, the more conservative republican proposals, like Sanford/Paul and the Republican Study Group, would offer funding for high risk pools as the sole avenue for protecting those with pre existing conditions.

Policies excluded from the AHCA but that may be still on the table for subsequent legislation include sale of coverage across state lines. The American Health Care Act did not include a provision to permit this, but it was included in the Sanford bill, in Tom Price's earlier bill and in the Republican Study Group proposal. Probably that's because this is not something that could be handled in budget reconciliation. Senators Collins of Maine and Cassidy of Louisiana proposed a replacement bill that would allow states to

choose between keeping the ACA and adopting expanded health savings account measures, keeping the same federal money available to the ACA. Although this sounds like something that might peel off some democratic votes, no democrats have embraced it so far and Senator Schumer, who is probably the leader of the no compromise movement, has already objected.

So what comes next? The bill will move through the House Budget and Rules Committees. The bill has to pass the House. Speaker Ryan hopes to schedule a full floor vote the week of March the 20th. Then the bill has to pass the Senate, either through budget reconciliation, which we discussed has only 50 votes, or the senate could do a significant rewrite of the bill setting up a possible conference committee process between the House and the Senate and then the bill would go to the President's desk for signature.

As we talked about above, we think there is still significant disagreement among Republicans based on key issues in the bill and the March 13th CBO report does not help matters for the republicans who claim that the bill would create more access to insurance for Americans. Bottom line, the form and political feasibility of passing an ACA replacement bill is largely uncertain.

Adrianne Ortega: Well thank you, Tom. Well … so the question now is what does all of this mean for value-based health care? So if you move to the next slide—the "agenda" slide with "Effects on Value-Based Health Care" highlighted, and then the following slide: "Effects on Value-Based Health care – The Future of Value-Based Programs", let's talk about what will be the likely effect of all of this on health and life sciences companies.

Let's start with the most obvious – what about the current bundled payment programs? Well we observed above, earlier in this program, that some of these programs will continue because they are voluntary. And even though some may get scaled back, the movement toward requiring providers to shoulder some of the risk for better outcomes and their costs has support in the private sector and is likely to continue.

For providers, this is generally a less favorable environment than pure fee for service, but it does provide opportunities for providers who put together a strong network and develop treatment protocols and care pathways in a way of sharing risks, savings and incentives that engage the entire episode of care. The pressure will be on to sign up the best post-acute providers, so the trend toward consolidation will likely continue. For example, in July, two large west coast health systems—Providence Health and St. Joseph Health—merged, creating a combined health system of 50 hospitals and 829 physician clinics across the north and southwest.

And for payors, they're likely to continue to work on doing deals with large health systems to transfer this risk. There has been an increase in recent years in health systems purchasing or entering into joint ventures with payors to further integrate health planning and care for enrollees to address value-based care trends. For example, in 2015, Ascension Health purchased U.S. Health and Life to strengthen its physician-led, clinically integrated network that offers plans in a small employer market. Anthem has also entered into two joint ventures with health care systems since 2014.

Tom Bulleit: So the effect of these trends on product makers—drug and device makers—may be less obvious. Medical device makers, for a number of years, have been working on changing from pure product makers to providers of solutions for their provider customers. Many have acquired consulting companies or built internal consulting capacity to help hospitals, in particular, do the procedures in which their products are used cost effectively. And increasingly they're offering these services beyond their own

product lines. Examples include Stryker, whose Performance Solutions division is the next generation of the acquisition of Marshall Steel several years ago, which includes an online portal to manage the entire episode of care for joint replacement. Medtronic's product, Beacon, which provides care management services for high risk heart failure patients, and J&J's new product, CareAdvantage, which will help hospital clients track patient behaviors and outcomes in orthopedics, surgical oncology and cardiovascular treatment.

Medical device makers are also headed towards vertical integration—managing or even owning health care providers. A prominent example is Medtronic, which has been acquiring companies such as Cardiocom, with technology for wireless device monitoring to increase its product offerings to provide products and services to assist providers throughout an entire episode of care. Medtronic is also launching professional development programs this year in Europe, the Middle East and Africa to promote value-based health care initiatives. And that program will include online and in person education for health care professionals. Medtronic CEO, Omar Ishrak, noted on a 2013 earnings call that the U.S. is wisely moving to a fee per value approach which incentivizes value over volume and outcomes over inputs.

And then pharma companies, who have been better at avoiding the effect of value-based health care until recently, may be looking at some changes because the effect of some very prominent price increases during the 2016 presidential campaign and the vocal insistence by President Trump that drug prices are too high, is leading to a lot of voluntary effort to control prices. Trump, in a news conference just in January, stated that drug makers were getting away with murder and promised to start a bidding process over drug pricing that would save the government billions of dollars. In response, AbbVie CEO, Richard Gonzalez, said that AbbVie would only raise prices once in 2017 and that percentage increases would not exceed single digits. Other drug companies have also pledged only single digit increases.

And while pharma dodged the bullet of the CMMI Medicare Part B Bundle Payment Program, which CMS withdrew that in December, some drug companies are already partnering with private payors to offer rebates based on the outcomes of their products. For example, in February of 2016, Novartis entered into value-based contracts with Aetna and Cigna for its heart drug, Entresto; and Amgen and Harvard Pilgrim Health care entered into a deal where Amgen must provide rebates to Harvard Pilgrim if members using a cholesterol lowering drug, Repatha, did not see levels reduced to what was observed during the clinical trials.

So if you want to move to the slide called "Effects on Value-Based Health Care Legislation Rulemaking and Lawyering", just thinking about how all this is going to affect the role of lawyers. Choosing a legal structure for provider consolidations and networks requires some careful thinking. Should it all be contractual? Should there be joint ventures? Should there be actual acquisitions? And those decisions will be driven in significant part by the antitrust laws and the fraud and abuse laws.

Likewise, the relationship of product makers to their customers raise fraud and abuse concerns of free product or service to induce the purchase of other product or service. The Medicare Shared Savings ACO program has specific waivers and Senator Hatch has spoken favorably about creating similar waivers under MACRA. But a lot of those programs won't have that benefit.

So there will be a considerable role for lawyers in advising clients and in lobbying HHS for rules or Congress for legislation, and just last week it was announced that in response to its annual solicitation for proposals for new safe harbors, the OIG had received letters from pharma and AdvaMed, and some device

and pharma companies suggesting changes to the Anti-Kickback Statute safe harbors to expand their availability for value-based type programs. At the moment the political reality is there's not much oxygen left in the room for these kinds of niceties, but I would anticipate that some of them will move forward over the course of the next year.

So if you want to move to the next slide, which we call "Next Steps For Companies in the Health Care Industry", are there any useful take away messages that would allow companies in the industry to take steps now to prepare themselves to deal with the future of value-based health care? Adrianne—you're going to talk about providers, right?

Adrianne: Yes, so next steps for companies in the health care industry: providers – so for providers, first next steps are to continue with consolidation and network building; despite Secretary Price's skepticism toward mandatory payment programs when he was Congress, there are good indications that the movement toward value-based health care will continue. And providers will still need to be thinking about cost consolidation whether in strong, clinically integrated networks or otherwise in a way that would allow them to accept and spread risk to maximum their health care reimbursement.

In fact, if the last few months are any indication, there may be more rapid movement in the private sector to bring about these initiatives. And this also includes expanding information technology capabilities to be able to meet reporting requirements related to value-based payment models. Providers also need to prepare for gain-sharing and risk-sharing proposals. Not only payors, but medical device and pharmaceutical companies will increasingly be approaching hospitals, physicians and other providers with proposals that look unorthodox and that correspondingly will require outside-the-box thinking by business principals and their lawyers. And finally, engaging with trade associations and DC offices; although getting the attention of Congress for value-based health care issues will be difficult over the next few months, preparing a strategy for legislative action, especially on waivers for anti trust and fraud and abuse matters is something that may ultimately yield dividends.

And if you want to go to the next slide where we considered the same issue for drug and device makers—the message is really quite similar: probably you should continue your transition to becoming a solutions provider. The idea that continued innovation to produce better and better products but that don't show any substantial improvement in long term patient outcomes will continue to lead to increased profits has to be seen with more and more limitations. If customers are asked to bear the risk for cost and outcomes, so you will be asked to share their pain and increase your value proposition by helping them reduce costs and improve outcomes. This is probably especially true for the device maker, whose customers are often institutional providers, but drug companies too will have to consider ways of contributing to patient outcomes.

Another thing is probably to develop better gain sharing and risk sharing arrangements. In a way, the flip side of the coin, providers will be expecting this and you and your business owners and lawyers will have to be testing new models that don't just contemplate growth in product sale revenues. And then likewise, engaging with trade associations in DC offices—I mentioned AdvaMed and pharma were already advocating for more flexibility in value-based health care type arrangements. And this is a case where the drug and device makers interests and that of the customers have significant alignment. While larger provider systems with more buying power may put pressure on product pricing, the quid pro quo may be

that your developing expertise and consulting management and risk sharing will justify a fresh look at the fraud and abuse laws that were developed in, obviously, an age of fee for service medicine.

So if you want to jump to the final slide in our presentation today, given all the interests and activity in this growing area, Ropes & Gray will be hosting additional webinars on value-based health care which we encourage you to attend starting off with our Guidance for Providers on April 4th, Recommendations for Medical Device Manufacturers on April 27th, The Impact of Digital Health on May 10th and What it Means for Pharmaceutical Companies on June 7th and What Payors Need to Know on June 19th. We haven't received any questions to answer, so at this time we'd like to note that if you're interested in CLE credit, please enter CLE code 2901 on the affirmation form and send it to CLE.team@ropesgray.com.

This concludes our program. Thank you all for joining us. If you'd like further information on this topic please feel free to contact Adrianne or myself. Our contact information is on the last slide and we hope that you can join us again soon.

This concludes today's conference call. Thank you for your participation.