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EXAMINING BARRIERS TO EXPANDING INNOVATIVE, VALUE-BASED CARE IN MEDICARE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

SEPTEMBER 13, 2018

Serial No. 115–166



Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
36–533 WASHINGTON : 2019

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EXAMINING BARRIERS TO EXPANDING INNOVATIVE, VALUE–BASED CARE IN MEDICARE

THURSDAY, SEPTEMBER 13, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 1:15 p.m., in room 2322 Rayburn House Office Building, Hon. Michael Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Guthrie, Shimkus, Latta, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Green, Matsui, Castor, Luján, Schrader, and Kennedy.

Staff present: Daniel Butler, Staff Assistant; Karen Christian, General Counsel; Jay Gulshen, Legislative Associate, Health; Brighton Haslett, Counsel, Oversight & Investigations; James Paluskiewicz, Professional Staff, Health; Brannon Rains, Staff Assistant; Jennifer Sherman, Press Secretary; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Una Lee, Minority Senior Health Counsel; Samantha Satchell, Minority Policy Analyst; and C.J. Young, Minority Press Secretary.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. We will go ahead and call the subcommittee to order, and thank you for your indulgence. We were waiting a few minutes because there was another hearing starting downstairs and some of our members may be joining us in progress.

But, for now, the hearing will come to order. I'll recognize myself 5 minutes for an opening statement.

And today, we are convening to discuss a topic that is of significant importance to the healthcare industry at large, and this is the ever-evolving transition to value-based care as well as new ways of assuming risk and the role technology can play in these efforts. Over the course of the last few years, our healthcare system has begun a shift toward rewarding physicians for the quality of care rather than the quantity, and building off these efforts, providers, doctors, health systems, and payers are willing to explore new value-based arrangements and open the door to providing new benefits for their beneficiaries. I am certain that many members of this subcommittee have taken meetings in their districts on this topic, especially in the past couple of years as the shift to value-based care has accelerated.

Notably, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 in the 114th Congress. For situational awareness, this is the 115th Congress, so that was 2 years ago. This was a critical step in the right direction as we helped begin to shift Medicare towards being a more value-based payment system. We have had other hearings about the Medicare Access and CHIP Reauthorization Act including the Merit-Based Incentive Payments Systems, conducting general oversight on the implementation of this crucial law.

A lot of the work that this subcommittee conducts is to oversee the influence in the healthcare industry as moving into coordination with the 21st century. The Medicare Access and CHIP Reauthorization Act provided a platform for this effort to do so, and this afternoon we are going to hear from a number of people on the front lines who are working to deliver better outcomes at lower costs. This hearing will provide us with a significant amount of information as we move forward in assessing value-based payments, where it holds the most promise, where there may be barriers that Congress might consider examining in the future to ensure its success. I think it goes without saying everything we can do to lower the burden on physicians, freeze them up to deliver more in-patient care and that is the general direction that I think it's good for us to go.

Value-based care models have been effective and have gained support throughout the country as they have proven to improve the quality of care and lower costs. This allows for positive outcomes for patients, physicians and insurers, as well as the overall healthcare system. As we have heard from witnesses at other hearings on this topic, taking these models on as a physician or healthcare system can be a difficult but still a rewarding task.

Promoting innovation and quality are essential to modernizing American healthcare and enabling our world-class physicians to focus on providing coordinated quality care to their patients.

Value-based models have evolved over time since their inception in the early 1990s, beginning with the efforts among private payers and state Medicaid programs to reward improvements in care with financial incentives. Models have grown broader and incentives more innovative as we have seen accountable care organizations and bundled payment programs, which address both quality and cost, take off across the country.

These newer and more advanced models have allowed for physicians and other professionals to voluntarily come together to provide more coordinated care for patients and rewarding physicians with bonuses for hitting certain quality measures and based payments on expected costs for specific episodes of care. These models are the future of healthcare and it is important that Congress hear from the industry about how the implementation of such models works on the ground, or to the extent it's not working it's important that we hear that as well.

Today, we have the chance to hear from witnesses about the models and ways that they are working to improve the quality of care or reducing cost. I suspect we will hear about the critical role that the laws we have worked on, including the Medicare Access and CHIP Reauthorization Act—the role that they have played in

expanding innovation, but that barriers to implementing potentially beneficial models still exist.

So I certainly look forward to hearing the thoughts of our expert panel of witnesses about the challenges and achievements in the world of value-based care. So I want to anticipate by thanking our witnesses for their willingness to testify today. We appreciate being able to have this important conversation and learn from your expertise.

Seeing that the ranking member of the subcommittee is not here, the chairman of the full committee is not here, and the ranking member of the full committee is not here, perhaps it would be prudent to proceed with witness statements and then we will allow those individuals—as they arrive from their other hearing we will interrupt and allow them to deliver their opening statements.

And I do want to remind members that all members' opening statements will be made a part of the record.

So thanks to your witnesses for being here today and taking time to testify before the subcommittee. Each witness will have the opportunity to give an opening statement followed then by questions from members.

Today, we are going to hear from Dr. Nishant Anand, the Chief Medical Officer for Adventist Health System; Ms. Mary Grealy, the President, Healthcare Leadership Council; Dr. Timothy Peck, CEO of Call9; Dr. Michael Weinstein, President, Digestive Health Physicians Association; Mr. Morgan Reed, President of the App Association; and Michael Robertson, Chief Medical Officer for Covenant Health Partners.

Again, we appreciate all of you being here today. Dr. Anand, you are now recognized for 5 minutes for the purpose of an opening statement, please.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Good afternoon. Today, we convene to discuss a topic that is of the utmost importance to the healthcare industry at large, the everevolving transition to value-based care as wells as new ways of assuming risk and the role technology can play in these efforts. Over the course of the last few years, our healthcare system has begun to shift towards rewarding physicians for the quality of care provided, rather than quantity. Building off these efforts, providers, health systems and payors are willing to explore new value-based arrangements that open the door to providing new benefits for beneficiaries. I am sure many of the members of this Subcommittee have taken numerous meetings regarding this topic, especially in the past several years as the shift to value-based care has accelerated.

Notably, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) in the 114th Congress. This was a critical step in the right direction as we helped begin to shift Medicare toward being a more value-based payment system. We have held various other hearings about MACRA, including the Merit-Based Incentive Payments System, as we conduct oversight on the implementation of this crucial law.

Much of the work that this Subcommittee conducts is to oversee and influence the healthcare industry in moving care coordination into the 21st Century. MACRA provided the platform for this effort to do so, and today we will hear from people on the front lines who are working to deliver better outcomes and lower costs. This hearing will provide us with a wealth of information as we move forward in assessing the value-based payments space, where it holds the most promise, and where there may be barriers that Congress might consider examining in the future to ensure its success.

Value-based care models have been largely effective and have gained support throughout the country as they have proven to improve quality of care and lower

costs—boasting positive outcomes for patients, physicians, insurers, and the overall healthcare system. As we have heard from witnesses at other hearings on this topic, taking these models on as a physician or healthcare system can be a difficult, yet rewarding task.

As a physician and as a Congressman, I believe it is important for physicians and health systems to take on risk when it can lead to rewarding outcomes, both for them and for their patients. Promoting innovation and quality are essential to modernizing American healthcare and enabling our world-class physicians to focus on providing coordinated, quality care to their patients.

Value-based models have evolved over time since their inception in the early 1990s, beginning with the efforts among private payers and state Medicaid programs to reward improvements in care with financial incentives. Models have grown broader and incentives more innovative as we have seen accountable care organizations and bundled payment programs, which address both quality and cost, take off across the country.

These newer, more advanced models have allowed for physicians and other healthcare professionals to voluntarily come together to provide more coordinated care for patients, rewarded physicians with bonuses or reductions in payments for hitting certain quality measures, and based payments on expected costs for specific episodes of care. These models are the future of healthcare, and it is important that Congress hear from the industry about how the implementation of such models works on the ground.

Today, we have the chance to hear from witnesses about models that they are working on and how there are or could be effective ways of improving quality of care or reducing cost. I suspect that we will hear about the critical role that laws we worked on, including MACRA, have played in expanding innovation, but that barriers to implementing potentially beneficial models still exist.

I look forward to hearing the thoughts of our expert panel of witnesses about their challenges and achievements in the world of value-based healthcare. Thank you to our witnesses for their willingness to testify today. We appreciate being able to have this important conversation and to learn from your expertise.

STATEMENTS OF DR. NISHANT ANAND, CHIEF MEDICAL OFFICER, ADVENTIST HEALTH SYSTEM; MARY GREALY, PRESIDENT, HEALTHCARE LEADERSHIP COUNCIL; DR. TIMOTHY PECK, CEO, CALL9; DR. MICHAEL WEINSTEIN, PRESIDENT, DIGESTIVE HEALTH PHYSICIANS ASSOCIATION; MORGAN REED, PRESIDENT, THE APP ASSOCIATION; DR. MICHAEL ROBERTSON, CHIEF MEDICAL OFFICER, COVENANT HEALTH PARTNERS

STATEMENT OF DR. NISHANT ANAND

Dr. ANAND. Good afternoon, Chairman Burgess and members of the subcommittee. I am Dr. Nishant Anand and I serve at Adventist Health System as a Chief Medical Officer for Population Health Services and the Chief Transformation Officer.

We have 46 hospitals located in nine states serving 4 million people each year. This includes Florida Hospital Orlando, which is the largest single site Medicare provider and the second largest Medicaid provider in the nation.

We have accountable care organization arrangements in Kansas, North Carolina, and Florida. We serve more than 400,000 patients in our ACOs and we partner with several thousand physicians, two-thirds of which are independent physicians.

Additionally, we will participate in the BPCI advanced model and are successfully participating in the CJR program. Today, I speak to you as a board-certified emergency medicine physician and a healthcare professional who has led value transformations at Memorial Hermann Health System in Texas and at Banner Health Network, which was a pioneer ACO, in Arizona.

In value-based care delivery, I know firsthand the benefits this brings to patients and the barriers that block providers from realizing its full potential.

We can improve the health and wellbeing of our patients but we need policy changes. As healthcare providers, there are many innovations that we would like to undertake that will improve the health and wellbeing of Medicare and Medicaid beneficiaries.

First, we desire to build high value networks that enable healthcare providers to ensure high quality care and reduce variation in care. Second, we can expand shared technology services across that network. Third, we can develop common operational work flows to navigate patients across that complex network. Fourth, we can implement clinical pathways across the continuum of care—pathways that reward the triple aim rather than fragmented care.

These four focus areas will help us achieve higher quality and more cost effective healthcare. However, barriers impede progress.

These barriers are Stark Law, misaligned value-based model initiatives, and operational challenges.

Number one, Stark Law modernization—I am not an attorney and cannot speak to the complexity of the law. But as a physician, I experience the challenges of the Stark Law each and every day.

I believe that it causes barriers to doing the right thing for our patients. The Stark Law was developed in a reimbursement world that paid providers based on the volume of services.

In today's world, where ACO providers coordinate care in a highly effective manner, these regulations serve more as a barrier than a protection for our patients.

While HHS issues waivers for APMs, the problem is these waivers are not permanent. Number two, encourage providers to move to value. We are concerned that policies contained in CMS' proposed ACO rule would discourage providers from participating in value-based care.

The existing financial benchmark to specialty and lower cost markets make it financially prohibitive to transition to a two-sided risk model and will deter providers from participating in the program. If the benchmarks do not provide room for improvement, allowing providers to transition towards value-based care delivery over time, providers will not participate.

Benchmarks must also be accurately risk adjusted. Lastly, the proposal to limit shared savings payments from 50 percent to 25 percent of the savings will create an unsustainable business model.

Number three, real-life operational challenges—to truly partner with private practice physicians, we want to share technology services such as clinical decisions support tools, telemedicine platforms, and referral solutions. I know these tools will help us make better decisions for patient care that will ultimately lead to better outcomes and lower costs. However, we need clarity that we can share these tools with our physicians to use with all patients. We need quick implementation of the 21st Century Cures Act.

As providers are investing in high value networks, we painstakingly work to ensure that our partnerships are with the best providers. As a result, we need to refer our patients more intentionally, making sure that they see the best clinicians, which is

sometimes at odds with the current Medicare conditions of participation.

In summary, I ask you to consider a deeper dive into value-based reforms that will accelerate our journey. We are ready to go faster but need additional help with payment reform, focusing on holistic care as well as regulatory reform.

We need to help ACOs achieve critical mass in order to hit the tipping point where value-based care is what we deliver. This will allow us to achieve the coordination abilities as a community that will better serve our Medicare and Medicaid beneficiaries.

I thank you for your time and interest and look forward to your questions.

[The prepared statement of Dr. Anand follows:]

Testimony for the Record

Submitted to the United States House Energy and Commerce Subcommittee on Health

For the Hearing Entitled

"Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

September 13, 2018

Nishant Anand, MD

Chief Medical Officer for Population Health Services,
Chief Transformation Officer for Adventist Health System and
Chairman of the Adventist Health System ACO

Good morning Chairman Burgess, Ranking member Green and members of the Subcommittee. My name is Dr. Nishant Anand. I serve at Adventist Health System as the Chief Medical Officer for Population Health Services and the Chief Transformation Officer. We have 46 hospital facilities located across nine states, serving four million people every year. Specific to Florida, where I am based, our largest hospital, Florida Hospital Orlando, is the largest single site Medicare provider and the second largest Medicaid provider in the nation. Our patients reflect the communities we serve in; diverse in age, race, ethnicity, income and payor. We treat everyone. Our Population Health Services Organization (PHSO) exists to guide and support our larger health system in its adoption of transformative, value-based integrative health care models. We have Accountable Care Organization (ACO) arrangements in Kansas, North Carolina, and most recently Florida, where we have 55,000 beneficiaries in our Medicare Shared Savings Program (MSSP) ACO. In all our ACOs and Clinical Integrated Networks (CINs) we serve more than 400,000 individuals. Additionally, we will participate in the Bundled Payment Care Improvement Advanced (BPCI-A) model later this fall and have been successfully participating in the Comprehensive Joint Replacement bundled payment model.

Today, I am speaking to you as a senior leader at Adventist Health System, an organization that is committed to our patients' health journey over their lifetime and the well-being of our communities at

large. We focus on the proactive, not just the reactive parts of health care with the goal of intervening before disease or illness occurs.

I also speak to you as a board-certified ER physician and as a health care professional who has led value transformations at other health systems. At Memorial Hermann Health System, in Houston, Texas, I ran their MSSP ACO, one of the highest performing ACOs in the country. At Banner Health Network, in Phoenix, Arizona, I helped transition the delivery system to a model supporting population health as a Pioneer ACO. Throughout my career, I have experienced not only the positive impact that a value-based system can have on patients' lives, but also the barriers that block providers from realizing the full potential of value-based care. I believe there are ways that we can change the delivery model that will enable us to reach more lives more effectively. We can improve the health and well-being of our seniors, but only together.

Across the nation, we are going through different stages of health care transformation. Starting with the Affordable Care Act, Medicare began the transition to a value-based payment system, through the development of ACOs and value-based quality payment programs. Now, as health care providers grapple with a post-MACRA world, and the evolving payment models, we are in a position and have begun focusing on redesigning the delivery of care to embrace value and focus where the opportunities lie. We know where to improve the health and well-being or our seniors. This can be done in four non-sequential steps.

First, we can build high functioning networks that enable health care providers to ensure high quality care and reduce variation in care.

Second, we can expand shared technology enablement services. To build a truly effective and high functioning network, providers must have a single, or multiple connected, Electronic Medical Records (EMRs). This will enable providers to know their patients and design pathways across physician

practices and hospitals. Moreover, providers need access to tools to help them do their job with greater ease and accuracy—telemedicine, clinical support tools, and referral solutions, for example.

Third, we can develop common operational workflows. As we continue our journey towards value, we have developed and honed new workflows that we believe are designed for effective care delivery. However, we can only implement these workflows with our beneficiaries within value-based models (e.g. ACOs). Knowing this is the best care we can deliver, we would like to extend these workflows to all Medicare and Medicaid beneficiaries, not just those connected to value-based models.

Fourth, we can implement clinical pathways across the continuum of care. With a focus on prevention, standard clinical pathways can lead to positive outcomes, and hopefully avoid unnecessary high-intensity, high-cost services.

I believe that these four opportunities will help us realize value-based health care. However, there are barriers that impede our ability to effectively redesign the delivery of care to embrace value. These barriers are as follows:

1. **The Stark Law needs modernization.** The Stark Law was developed in a reimbursement world that paid providers based on the volume of services. As CMS and Congress look to shift the financial risk of health care delivery into the provider community, as we collectively move toward value, the Stark Law is an impediment. I am not an attorney and cannot speak to the complexity of the law, but as a physician, I experience the shortcomings and challenges of Stark Law in real-life. ACOs come together, not with the intent to self-refer, but with the intent to coordinate care in a highly effective manner. Moreover, as I seek to transform our care delivery model, I work with our attorneys who continue to hit roadblocks as we work to develop high-performing networks.
2. **Payment incentives in value-based models, like ACOs, must be aligned with value.** The current structure of ACOs make it very difficult for providers to engage in value-based

arrangements. The model structure and financial incentives must enable and encourage provider participation, not stand in their way.

3. **Real-life operational challenges that make it difficult for providers to participate in value-based arrangements must be addressed.** There are real challenges that we face regarding interoperability, sharing enabling technology with our physicians and navigating the care of our patients.

Only when we address these challenges head on will we empower and enable providers to successfully embrace value-based health care delivery. This document will expand on the four opportunities that I believe are before us, explore the barriers that impede a faster transition to value, and provide ideas on potential solutions.

Opportunities to Embrace Value

Developing High-Performing Networks

Developing and effectively managing high-performing networks is key to value-based care. A high-performing network is a highly coordinated, comprehensive model of care. This includes acute, post-acute, ambulatory and wellness services. This requires highly aligned physicians and may include the creation of CINs that align goals and incentives. Scale and size are needed to successfully engage physicians in providing wholistic care. However, it is very difficult for physicians to achieve the necessary size and scale, while only focusing on certain value-based arrangement beneficiaries. Often, physicians engaging in a single value-based payment model will struggle to have more than a handful of beneficiaries connected to the alternative payment model within their overall patient base. Moreover, taking care of patients wholistically requires additional time and efforts that are not rewarded in today's payment world. In fact, it is penalized. This can be addressed through a payment reform model that exists in some commercial payer arrangements.

As we build networks we need to be able to refer our patients to the quality providers that make up our network—in particular, to specialists. If we can refer patients into these high functioning networks, then we will see better outcomes, more coordinated and less duplicative care, lower cost and a better patient experience.

Shared Technology Enablement Services

As networks of providers are created through ACOs, providers must engage with their patients and one another more effectively and efficiently. Providers must have the ability to easily share patient information across and between different providers. Moreover, we need to be able to equip caregivers with technology that will enable them to do their job with more accuracy, efficiency and ease. This is especially true in small physician practices that may not be able to obtain these technologies or support their use by themselves.

Interoperability, a world in which information is shared and transferred seamlessly, will enable more consumer-centered care and provide new possibilities in clinical care delivery. This requires diverse EMRs that are seamlessly connected. At Adventist Health System, approximately two thirds of the physicians that we work with across our CIN and ACO are independent. That means we are simultaneously navigating over thirty different EMR platforms. This makes it increasingly difficult to share patient information between the providers that make up our network. The result is a consumer experience that is difficult and cumbersome, tests and treatments that are duplicated, and vital lifesaving information that is not always available.

Common Operation Workflows

We are encouraged that both Congress and the Administration share our goals to transform health care and continue to drive a value-based care agenda. To help us on this journey, we participate in the Premier Healthcare Alliance's Population Health Management Collaborative. As part of this collaborative, we can analyze and benchmark clinical and claims data with peers; receive clinical and

strategic support from national experts; as well as learn from and share insights and best practices with many other organizations participating in alternative payment models to improve performance.

This experience guides the development of operational workflows that help us care for and navigate our patients through their health journey. We are on the journey towards value-based care because we believe it is best for our patients. However, we are unable to utilize these operational workflows on patients that are not in our value-based arrangements. Physicians struggle to operationalize two workflows. To embrace value, we must be able to develop and implement common operation workflows with the patient in mind. If physicians have tools and technology at their disposal to navigate patients on their care journey, we want to help all our patients, not just those in a value-based delivery model.

From a providers' perspective, we believe that increased accountability for quality and cost is a critical component of the transformation that we are seeking in health care. Payment reform is a fundamental and essential component of change. There is, however, a delicate balance between pushing providers to risk and pushing them away from making needed changes. The movement to value involves significant changes in health care delivery in the opposite direction of the fee-for-service system's incentives that rewards care that is reactive, duplicative, and uncoordinated.

Clinical Pathways Across the Continuum of Care.

Clinical Pathways are medical best practices designed to reduce variation, improve quality of care and maximize the outcomes for our patients. While we have made great strides in developing standard Clinical Pathways in the medical field, I believe there is a real opportunity to develop Clinical Pathways that are rooted in preventative medicine. By doing so, we can provide our patients with the best chance of a positive outcome, and hopefully avoid unnecessary high-intensity, high-cost services. We must focus on prevention and not reaction. Only when we focus on preventing the disease from even starting and design a health care and payment delivery system that incentivizes providers to prevent disease, will we ever

truly realize value in health care. Historically, preventative care was not specifically reimbursed. The nation will need to be more attentive about creating prevention incentives if this important pathway to bend the cost curve is to succeed.

Regulatory Barriers that Impede Value

To realize value—through the creation of high-functioning networks, shared enabling technology, developing common workflows and standard clinical pathways—we need your help. There are existing barriers that impede our ability to provide a truly value-based delivery system.

Stark Law Modernization

For example, the Stark Law was enacted with the intent to regulate financial arrangements among physicians (or their immediate family members) and certain health care providers. The Stark Law is highly complex and has created a minefield for the health care industry due to its huge financial penalty risks and its unclear provisions. These risks result in health care providers avoiding value-based arrangements.

Congress recognized the challenges that Stark Law creates by authorizing the Secretary of HHS with the authority to issue regulatory waivers for new models of care, such as MSSP. The very existence of these waivers demonstrates that providers need relief from the Stark Law to participate in value-based payment models. The problem is that these waivers are issued program-by-program and are not permanent. Additionally, confusion between federal and state statutes continue to persist and providers need clarity to understand the limits of what can be done.

Adventist Health System has been part of the Healthcare Coalition for Stark Reform, and recently submitted comments to The Centers for Medicare and Medicaid Services in response to the Request for Information Regarding the Physician Self-Referral Law. Our comments provide much greater depth on

our position and thoughts on how we can modernize the Stark Law to enable more providers to engage in value-based delivery models.

Align Payment Model Incentives

As Alternative Payment Models are developed, it is critical that we ensure that the incentives of each model are aligned with value-based care delivery. We are concerned that policies contained in CMS's recently released proposed redesign of the MSSP, if finalized, would discourage organizations from participating in value-based care. As we describe below, we are most concerned with the current benchmark standards, the lack of risk adjustment, and the 25% limit to shared savings payments.

First, the existing financial benchmarks make it financially prohibitive to transition to a two-sided risk model and will deter providers from participating in the program. If a provider is in an efficient market, the benchmarks are set much more aggressively. If the benchmarks do not provide room for improvement, allowing providers to transition towards value-based care delivery over time, providers will not participate. We must find a way to adjust for the regional variations across the country.

Second, benchmarks must take into consideration risk adjustment for social determinants of health to ensure that the financial expenditure benchmarks more accurately reflect the underlying health status of the ACO's population.

Third, CMS is also proposing to limit shared savings payments to 25% percent of the total, down from the current 50%. Shared savings payments are critical as part of the transformation toward value-based care and are necessary for our Adventist Health System ACO to continue to make the infrastructure investments needed to transform our processes and care delivery. A lower shared savings rate means we will have less to reinvest into population management and care coordination. Coupled with the aggressive progression to risk, this low savings rate provides little incentive for ACOs to join the MSSP and does not support a sound business plan for organizations to stay in the model. It would be unfortunate to slow the

movement to value by establishing an ACO model where the business model fails to offer a sufficient return to cover the investment costs.

Fourth, the proposed timeline to spur providers into two-sided risk does not take into consideration the reality of many providers. The journey towards accountable care is long, requiring organizations to fundamentally change their operations through new legal structures, alter staffing, adopt new technologies, engage in more robust data analytics, and alter structures with an emphasis on ambulatory care rather than inpatient care. Providers must also address the opportunity costs associated with seeking to reduce inpatient admissions and shift care to lower paying sites of service. These changes have not happened overnight, and organizations need time to make them before taking on significant financial risk.

Lastly, we are uncertain where these shared savings programs will end up. By design, the targets get more difficult to hit each year. If we can design a path to Medicare Advantage or an analogous program, that would give us a destination to work towards and make investments for.

Operational Challenges

As providers build high-functioning, high-performing networks, challenges remain in operationalizing care delivery models.

Interoperability

I believe that efforts to achieve interoperability should be centered on the patient. As patients navigate throughout the continuum of care—through physician offices, hospitals, same-day surgery centers, or community clinics—their records should be easily transferrable between all organizations. In an ideal state of interoperability, patients would not be placed under the burden of having to seek their medical records from different providers.

One of the greatest challenges to achieve this level of interoperability is the lack of a single patient identifier that can move from system to system and ensure records can be passed between disparate entities without fail. The lack of a national patient identifier makes it difficult for data to be exchanged seamlessly between organizations. Regardless of the electronic system, there will always be variability in the registration and data entry processes at each organization. This will prevent the health care industry from achieving full positive identity matching.

Moreover, EHR systems are expensive and there is a lack of competition with, what are essentially, monolithic EHR systems. We believe that the federal government has an important role to play in addressing these issues and advancing reforms that will improve the interoperability of EHR data by taking the following steps:

- The Office of the National Coordinator for Health IT (ONC) should designate an open Application Programming Interface (API) standard(s) for EHRs (i.e., FHIR; CDS hooks) to ensure that APIs are implemented consistently and to ensure fair market adoption and implementation across EHR platforms.
- Providers must be able to connect any third-party application (conformant to the recognized standard API and successor standards) of their choosing to their EHR.
- Providers must be able to use third party applications (conformant to the recognized standard API and successor standards) without obtaining "permission" from or pre-registering the application with their EHR vendor.
- APIs should support bulk data extract and real-time data update/exchange.
- EHR vendors should not put limits on the data extracted or the frequency of data requests.
- Certified EHR vendors should be required to disclose all known material limitations (such as fees or costs) associated with their API's functionality and app integration services and capabilities.

By taking these steps, ONC will facilitate the development of applications that can provide clinical decision support and other tools that providers can use to improve the quality and cost effectiveness of care. It will also enable the exchange of data between different EHR systems.

Enabling Provider Technology to Physicians in Independent Practice

To truly partner with our employed, as well as private practice, physicians, we want to share technology enabled services. As the volume of data and information becomes available, clinical support tools help physicians sort through enormous amounts of digital data to suggest evidence-based next steps for treatment. As technology advances, telemedicine can help skilled specialists connect with rural patients who otherwise have very limited access. Technology enabled services can bolster our physicians to embrace value-based delivery principles and models. For example, we are piloting a physician referral system at a sub-set of our hospitals. With a CIN or ACO, I believe I can implement this referral system to help our clinicians guide our patients to the right setting of care at the right price to meet their needs. I know this tool will help us make better decisions for patient care that will ultimately lead to better outcomes and lower cost. However, we are not confident that we can share this tool with physicians outside of our CIN and ACO, even though we believe it will help them deliver better care. Even if we are not taking risk, we want to do the right things for our patients and there is not clarity on whether or not we can.

Care Navigation

Value-based models have specific waivers (i.e. anti-referral) to enable physicians to engage differently with their patients. These waivers are very important to physicians. However, waivers only apply to Medicare beneficiaries attributed to us in our given ACO. The reality is that not all patients in a physician's panel are part of a single, or any, value-based payment model. If, for example, a physician has a panel of 1000 and only 10 patients are part of a value-based model, it is very difficult to regularly

identify and engage with the 10 patients differently than all the other patients. When it comes to the ACO waivers, it is difficult for a physician to know who is covered and who is not. It is critically important that waivers be extended to all Medicare and Medicaid beneficiaries treated by a physician so that when a patient comes into one of our facilities or office practices, we can coordinate and navigate their care across our network. Physicians find it difficult to operationalize treating patients differently. By attributing value-based delivery to the provider and not the patient, we can ensure that providers focus on what should be their primary focus—their patients.

In a value-based delivery model, all health providers are centered on the shared goal of positive patient outcomes. This requires access to high-quality providers. In our ACO and CINs we partner with 2684[1] independent physicians to collectively serve our patients. We diligently work to ensure that we partner with the best providers in our region, regardless of whether they are in independent private practice or in an employment arrangement. Knowing that our providers are the best chance for our patients' success, we want to refer patients within these high functioning networks. We believe we will see better outcomes and lower cost.

A patient's choice of provider may result in a patient choosing a low-quality provider, such as one that has higher rates of readmission or infection. In a value-based world, providers are at risk for patient outcomes and total cost of the care provided. This risk goes beyond the hospital walls and across the post-acute setting. Therefore, care management plays an increasingly important role; helping guide a patient across this continuum of providers, ensuring that our patients receive the best care in the best and least expensive setting. To do that in a meaningful way, we need to direct our patients more intentionally to the right providers. When health systems are investing in high-performing provider networks to be successful at value-based delivery models, we are painstakingly working to ensure that our partnerships are with the highest-preforming providers.

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[1] As of July 2018

Conclusion

In health care and payment delivery reform, we can focus on short-term, medium-term or long-term efforts. Today, we often focus on short-term improvement. That is, a concentration on complex patients with multiple chronic conditions. Yes, this will lead to better outcomes for this specific population group and lower cost in the immediate time, but what if we looked to medium-term efforts? Focusing on chronic conditions, such as diabetes, that may take 10 years to materialize. I believe we would see a longer return in both patient outcomes and lower costs. But if we were to focus on prevention, I believe that would be a game changer. This requires more work up front from clinicians and more testing to get to the root cause of the problem. But the downstream effects are dramatic.

In summary, I would ask your indulgence to consider a deeper dive into value-based reforms that will accelerate this journey that we are on. To build high performing networks, we must be able to assist physicians who are in solo or small practices make the investment in tools and technologies. To share technology enablement services with providers, we must overcome the barriers to interoperability. To develop common operation workflow, ACOs must be operationalized to enable physicians to focus on patient care, not on administration. And if we are to implement clinical pathways rooted in prevention, we must redesign our reimbursement system to reward providers for preventing disease, not just treating it. To achieve this, we must modernize the regulatory environment that currently slows providers down on their journey towards value-based health care delivery.

We in the health care delivery industry are ready to go faster but need additional help with payment reform focusing on wholistic case as well regulatory reform. We need to help ACOs achieve critical mass in order to hit the tipping point where value-based care is what we deliver. This will allow us to achieve the coordination abilities as a community that will better serve our Medicare beneficiaries. I thank you for your time and interest.

Mr. BURGESS. Thank you, Dr. Anand.
Ms. Grealy, you're recognized for 5 minutes, please.

STATEMENT OF MARY GREALY

Ms. GREALY. Good afternoon, Chairman Burgess and members of the subcommittee, and thank you for the opportunity to testify today on what I believe to be one of the most important topics in American healthcare.

As our healthcare system evolves from a long-standing fee-for-serve orientation to a patient-centered value-based approach to care, I am proud that the members of my organization, the Healthcare Leadership Council, are not only supportive of this transformation but have led it.

Our members are innovative systems such as Adventist health plans, drug and device manufacturers, distributors, academic health centers, health information technology firms, and all are driving change within and across virtually every healthcare sector.

We appreciate your effort today to shine a light on some of the barriers that are preventing an optimal transformation and transition to value-based care that will result in better outcomes for patients and improve sustainability for the Medicare program.

Today, I would like to focus on several areas that warrant significant attention of this committee. I will begin by saying a word about the legal barriers that are keeping healthcare innovators from accelerating toward value-based care.

Let me be clear. We believe it is essential to keep consumer and program protections in place while, at the same time, working in both the legislative and regulatory spheres to create an open unobstructed pathway for these value-focused activities that benefit both patients and the system as a whole.

The Stark Physician Self-Referral Law and the Anti-Kickback Statute were created to prevent overutilization and inappropriate influence in a fee-for-service environment in which healthcare sectors and entities operated in their own individual silos.

Today, however, in order to make the transformation to value-based care we need greater integration of services, improved coordination of care with cross-sector collaborations, and payment that is linked to outcomes rather than volume.

Adopting these new delivery and payment models becomes difficult when faced with outdated fraud and abuse laws and potential penalties of considerable severity. For example, it is desired for healthcare providers to achieve optimal health outcomes through coordinated care, meeting high quality and performance metrics, and saving money through the avoidance of unnecessary hospital admissions and office visits.

And yet, there are obstacles to incentivizing this level of performance. If a hospital wishes to provide performance-based compensation, it can run afoul of the current fraud and abuse framework. In fact, in terms of maintaining good patient health, the legal status quo does not even allow physicians to provide patients with a blood pressure cuff or a scale to monitor their healthy weight at home.

To achieve meaningful progress toward a value-based healthcare system, it is also necessary to address how to foster further success

in alternative payment models such as accountable care organizations. We know that better care coordination results in better outcomes for patients, which is the goal of accountable care organizations. But we must address the flaws in the current ACO structure.

Medicare beneficiaries today do not choose to enroll in a particular ACO. Rather, they are assigned to one based on the physician they choose to see. So the accountable care organization is charged with the responsibility of managing the patient's care even though the patient is likely unaware they are even under that umbrella.

Medicare beneficiaries may also not be aware of the benefits of this approach. Patients should be proactively informed of the benefits of coordinating care among providers. They should also be encouraged to remain in ACOs and other care delivery models that focus on coordination, information flow, and value. Doing so will enable these models to better achieve quality outcomes while controlling costs, and also to optimize the effectiveness of ACOs more progress needs to be made in data sharing and data interoperability so that entities have real-time knowledge of work flows, care coordination, and progress toward quality measures.

Mr. Chairman, I also need to mention the importance of technology and the movement toward value-based care. Specifically, the expanded use of telemedicine is essential to more efficient utilization of healthcare resources, expanding the reach of healthcare providers.

So we urge Congress and the administration to address Medicare's restrictions on reimbursement for telemedicine services and there's also considerable value to be found in making digital health applications more accessible for beneficiaries.

And, finally, as we talk about coordinated care, we must focus on how we can gain the greatest patient and population health benefits from our healthcare workforce.

All healthcare professionals must be empowered and rewarded to perform to the full extent of their professional license and to be valued members of healthcare teams.

Thank you again for the opportunity to testify and I look forward to your questions.

[The prepared statement of Ms. Grealy follows:]



Testimony of

Mary R. Grealy, President
Healthcare Leadership Council

Before the
House Energy and Commerce Committee
Subcommittee on Health

Examining Barriers to Expanding Innovative, Value-Based Care in Medicare

September 13, 2018

Good afternoon. Chairman Burgess, Ranking Member Green, members of the subcommittee, thank you for the opportunity to testify today on what I believe to be one of the most important topics in American healthcare.

As our healthcare system evolves from a long-standing fee-for-service orientation to a patient-centered, value-based approach to care, I'm proud that the members of my organization, the Healthcare Leadership Council (HLC), are not only supportive of this transformation, but have led it. Our members are innovative hospitals, health plans, drug and device manufacturers, distributors, academic health centers, health information technology firms, and in fact are driving change within and across virtually every healthcare sector.

We appreciate your effort today to shine a light on some of the barriers that are preventing an optimal transition to value-based care that will result in better outcomes for patients and improved sustainability for the Medicare program. There are areas that warrant significant attention from the committee.

Legal barriers that exist are keeping healthcare innovators from accelerating toward value-based care. We believe it is essential to keep consumer protections in place while, at the same time, working in both the legislative and regulatory spheres to create an open, unobstructed pathway for value-focused activities that benefit both patients and the system as a whole.

The Stark Physician Self-Referral Law and the Anti-Kickback Statute were created to prevent overutilization and inappropriate influence in a fee-for-service environment in which healthcare sectors and entities operated in their own individual silos. Today,

however – in order to make the transformation to value-based care – we need greater integration of services, improved coordination of care with cross-sector collaborations, and payment that is linked to outcomes rather than volume. Adopting these new delivery and payment models becomes difficult when faced with outdated fraud and abuse laws and potential penalties of considerable severity.

For example, it is desirable for healthcare providers to achieve optimal health outcomes through coordinated care, meeting high quality and performance metrics, and saving money through the avoidance of unnecessary hospital admissions and office visits. And yet, there are obstacles to incentivizing this level of performance. If a hospital wishes to provide performance-based compensation, it can run afoul of the current fraud and abuse framework. In fact, in terms of maintaining good patient health, the legal status quo does not even allow physicians to provide patients with a blood pressure cuff or a scale to monitor healthy weight at home.

To achieve meaningful progress toward a value-based healthcare system, it is also necessary to address how to foster further success in alternative payment models, such as Accountable Care Organizations (ACO). We know that better care coordination results in better outcomes for patients, which is the goal of Accountable Care Organizations, but we must address flaws in the ACO structure. Currently, Medicare beneficiaries do not choose to enroll in a particular ACO. Rather they are assigned to one based on the physician they choose to see. Thus, the ACO is charged with the responsibility of managing this patient's care even though the patient is likely unaware they are under that umbrella.

Also, many Medicare beneficiaries may not be aware of the benefits of this approach. Proactively informing patients about the benefits of coordinating care among their providers and creating tangible incentives to encourage patients to remain in ACOs and other care delivery models that focus on coordination, information flow, and value will allow these models to better achieve quality outcomes while controlling costs.

Also, to optimize the effectiveness of ACOs, more progress needs to be made in data sharing and data interoperability, so that entities have real-time knowledge of workflows, care coordination, and progress toward quality measures.

Mr. Chairman, I need to also mention the importance of technology in the movement toward value-based care. Specifically, the expanded use of telemedicine is essential in more efficient utilization of healthcare resources and expanding the reach of health providers. We urge Congress and the administration to further address Medicare's

restrictions on reimbursement for telemedicine services. There is also considerable value to be found in making digital health applications more accessible for beneficiaries.

And, finally, as we talk about coordinated care, we must focus as well on how to gain the greatest patient and population health benefits from our healthcare workforce. All healthcare professionals must be empowered and rewarded to perform to the top of their professional license and to be valued members of care teams.

With this testimony, I am providing a copy of the HLC Red Tape Reforms, developed with input from our members earlier this year to identify areas that pose barriers to value-based care, as well as: an HLC white paper of potential regulatory and legislative modifications to the Anti-Kickback Statute and Physician Self-Referral Law to better support innovative and integrated care delivery and payment models; a selection of value-based examples; and examples of patient and program protection provisions that should remain in place, in relation to modernizing the Anti-Kickback Statute and Physician Self-Referral Law.

I thank you again for this opportunity to testify and look forward to responding to your questions.

Mr. BURGESS. Thank you, Ms. Grealy. Thank you for participating with us today.

Next, we'll hear from Dr. Timothy Peck. You're recognized for 5 minutes, please.

STATEMENT OF DR. TIMOTHY PECK

Dr. PECK. Thank you, Chairman Burgess, and please extend my gratitude to Ranking Member Green and members of the subcommittee for the honor to speak to you today.

I am here to share how I've seen firsthand how the lack of value-based care in Medicare fee-for-service system has led to wasted dollars on patient care.

My name is Timothy Peck. I am an emergency physician and I am also an entrepreneur. I went to residency and did my chief here at Harvard Medical School and Beth Israel Deaconess and stayed on as faculty there.

I left my career in early 2015 to be an entrepreneur and solve a problem—a problem that, in the emergency department, I lived every day. Nineteen percent of the patients who arrive in an ambulance to the emergency department come from SNFs—from skilled nursing facilities. One out of five patients I saw every day from an ambulance came from a SNF.

Nursing home patients and patients over 65 in general don't receive great care in the emergency department. Hospitals are not a great place to get well for those over 65. Our own data on patients in nursing homes shows that 43 percent of patients in SNFs have dementia and almost all become delirious from moving them from a familiar place to the bright lights of the emergency department.

In emergency departments we order every test under the rainbow. We put them in the hallway. They get renal failure and bed sores. We then admit them to the hospital that exposes them to infections and they often experience post-hospital syndrome condition in which most patients leave the hospital worse off than when they came in.

Although I knew this about emergency departments and hospitals because I worked there, I didn't know anything about nursing homes. I went to medical school. I went to residency, and I had never once stepped foot into a nursing home. I needed to understand these patients better and why they were coming to me, and so I went and lived in a nursing home for 3 months myself.

CMS says two-thirds of the transfers are avoidable and 45 percent of the hospitalizations to the hospitals are avoidable for an estimated cost of about $20 billion per year. I needed to understand why this was happening. Right now, as of this moment, the only way to get paid for this care is to go by what the fee-for-service system says, and that is to put those patients in an endless loop of expensive care in which they're treated in the nursing home at a cost, they're put in an ambulance at a cost, and admitted to the hospital at a cost, to go right back into the SNF again.

I needed to break this loop and, based on my research from living in the nursing home, I created a model in which we embed a first responder in the nursing home 24/7 who connects to an emergency physician by telehealth, who is home, remote, 24/7 whenever there's any type of acute change in condition of that patient. The

emergency physician who's home directs the care of that patient and decreases hospitalizations by upwards of 50 percent, saving $8 million per 200-bed nursing home.

In our first nursing home we've served, Central Island Healthcare in New York, according to CMS' own nursing home compare website, the percentage of Medicare residents who are re-hospitalized after admission to Central Island is 11.1 percent. The national average is 22.4 percent. Because of their success on this measure, Central Island received the highest possible quality score under the new SNF value-based payment program. One of our most recent SNFs, Terence Cardinal Cooke in Manhattan, has been able to lower its rehospitalization to single digits after full activation of the Call9 model.

There are 15,600 nursing homes in the U.S. and there are billions of dollars and millions of lives to improve. I, myself, had no way of getting paid for the fee-for-service—from the fee-for-service system for this type of program, and so we treated 3,500 Medicare patients, losing money on every single one, to be able to give you the data on—that I just quoted.

It's not just us. I know a lot of health systems, providers, and entrepreneurs who have amazing ideas. But they are in no way incentivized to execute them.

The only existing option for testing models is CMMI. When CMMI is able to succeed, it brings innovation to our patients, which they need. However, in the startups world we had a saying that in order to learn you need to be flexible and fail fast, fail smartly, fail safely, but also fail inexpensively. When CMMI doesn't work, it's far from inexpensive.

The other way we can bring innovations to the Medicare program is by lifting 1834(m) of the Social Security Act. The issue is that the fee-for-service schedule does not create value and lifting 1834(m) would not protect us from those fees. Changing fee-for-service is the way that we need to move forward.

Representatives Griffith, Luján, Smith, Black, and Crowley have already championed a new approach, the RUSH Act of 2018. What this does is allows Medicare to avoid the $20 billion being spent on unnecessary hospitalizations and a novel approach in which providers can have value-based contracting instead of following the fee-for-service schedule. RUSH Act is the tip of the spear creating value-based contracting by supporting a program that has shown to increase quality and decrease costs.

The bill is set up in a way that when savings happen, providers, nursing homes, and Medicare share in the potential savings. It's also set up in a way that providers get kicked out of the program if they don't save money or increase quality, which is how value-based care should be set up.

You can be the change agent. You can be the reason why we saved Medicare program, not only for the $20 billion being spent on nursing home patients, the billions being spent on unnecessary services every year.

The faster this happens, the less lives are lost and the more money that is saved.

Thank you to the committee and Congressmen Griffith and Luján for introducing the RUSH Act. It's the first step to bringing value to Medicare.

[The prepared statement of Dr. Peck follows:]

Call9

Testimony of Timothy C. Peck, MD
Co-founder and CEO, Call9

House Committee on Energy and Commerce
Subcommittee on Health
Hearing on Examining Barriers to Expanding Innovative, Value-Based Care in Medicare
September 13, 2018

Thank you, Chairman Burgess, Ranking Member Greene, and members of the Subcommittee for the opportunity to speak to you today. I am speaking to you from the unique perspective of being both a physician who cares for Medicare patients and an entrepreneur challenging the status quo to actively deliver better care to patients. My testimony will focus on a new approach to incorporating innovation into the Medicare program that will both save taxpayers money and, most importantly, improve patient care. This is a model that provides a mechanism for Medicare to support value for the patient, their families and the system.

My story begins as a young attending Emergency Physician at Beth Israel Deaconess and Harvard Medical School who became frustrated that there was no mechanism – operationally or financially – to be with patients at their most vulnerable moments - the time of their emergencies. At this same time, telehealth was becoming more and more common as a way to help patients and physicians manage chronic conditions and members of this Subcommittee were forming work groups to champion telehealth policy. I thought – what if I could use technology in a different way - to be with patients at the time of their emergencies?

As I researched where the majority of emergencies happen, I found that 19 percent of transfers to the emergency department are from skilled nursing facilities (SNFs).[1] I then set out to develop an approach that paired emergency clinical skills with technology to scale a model that could replace 911 in nursing homes to treat Medicare's most vulnerable patient population: nursing home residents.

Many of us have experienced this issue first-hand with our loved ones and are not surprised by the statistics. The Centers for Medicare and Medicaid Services (CMS) states that 45 percent of hospital admissions from SNFs could have been avoided.[2] Further, approximately one in five patients admitted to a SNF are readmitted to a hospital within 30 days.[3] Because of this, nursing home residents are unnecessarily exposed to health risks such as falls, delirium, infections, adverse medication interactions, and post-hospital syndrome.[4][5]

To combat these issues, I founded and built Call9. Call9 turns this equation on its head to save lives that otherwise wouldn't be saved, improve care for patients who need it, and save millions for the healthcare system. By bringing the emergency room to the patient instead of the patient to the emergency room, Call9 is able to treat patients in place approximately 80 percent of the time. Anytime a patient has an acute change of condition, Call9 first responders – who are embedded 24/7 in the nursing home to complement the skills of existing nursing home staff – go to the bedside of the patient and connect via telehealth to our emergency physicians. The emergency

[1] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf

[2] https://innovation.cms.gov/initiatives/rahnfr/

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5063303/

[4] http://www.medpac.gov/docs/default-source/reports/jun17_ch9.pdf?sfvrsn=0

[5] https://www.nejm.org/doi/full/10.1056/NEJMp1212324

physician then directs the care of the patient, which is delivered by the first responder and nursing home staff at the bedside of the patient. Our first responder and emergency physician then continue to monitor and care for the patient for days afterward until he or she returns to the baseline clinical state.

By replacing not only the emergency room visit, but also the subsequent hospitalization, Call9's data show that we are saving our commercial partners $8 million per 200 beds per year. I've included further data on our reduction in hospital transfers and patient quality in my written testimony.

Call9 currently operates in 10 nursing homes in New York state and partners with seven commercial payers; however, there is no way for Medicare to reimburse us for the care we deliver, which has severely limited our growth and ability to reach vulnerable patients – especially in rural areas. Call9 is lucky to have found investors who believe in the double bottom line – social good and profit – to invest in our model. To date, we have treated more than 3,500 Medicare Part B-enrolled patients at a financial loss to our company.

You may be asking – why didn't we go to CMS to secure reimbursement first? Unfortunately, Medicare only has two mechanisms under which to advance truly innovative models into the program – through a demonstration under the Centers for Medicare and Medicaid Innovation (CMMI) or through an act of Congress.

I fully support CMMI in their mission; however, it is constrained in both funding and flexibility. I'm sure a number of members of this Subcommittee have met with young entrepreneurs and we will likely all tell you the same thing – the success of any innovative company stems from the ability to fail fast, fail safely, learn from those failures, and correct the course. This mindset does not correlate to CMMI – who, rightly so – as stewards of taxpayer dollars, can only look at testing models that already have proven successes. While this works for some models, it cannot possibly work for all innovative models that could be beneficial for Medicare patients.

The alternate option for practitioners of truly innovative models is to work with you – Congress – to pass legislation to recognize new methods of care. Unfortunately, we all know that Congress does not move at the same pace as start-up funding timelines and many companies do not have the time nor resources to devote to passing legislation.

That is why we recommend Congress advance a third approach – Medicare value-based contracting. I could be asking you, like many others, to remove the current statutory restrictions (specifically 1834M) to reimbursement for telehealth under Medicare Part B. Many of my colleagues and members of this Subcommittee have fought for bills that would do just that, only to be met with unmanageable cost estimates from the Congressional Budget Office (CBO). While this is extremely frustrating to those of us who see the value of telehealth every day, it became clear to me that the problem wasn't telehealth, it is the reimbursement structure of Medicare Part B. There is a understandable case to be made that anytime you make it easier to access a service or add more services under a fee-for-service reimbursement structure, it will inherently cost more.

With this in mind, as members of the Health IT Now coalition we worked with forward-thinking staff from this Subcommittee, the Ways & Means Committee, and Representatives Griffith, Lujan, Smith, Black, and Crowley to craft legislation that would create a mechanism for CMS to enter into selective, voluntary value-based contracts with innovative physician groups, to be able to deliver care in new ways. The *Reducing Unnecessary Senior Hospitalization Act (RUSH) Act of 2018* was introduced on July 25, 2018 and would allow physician groups and the nursing homes they serve to contract with Medicare to use technology to reduce costly and harmful avoidable hospitalizations. If the program doesn't save money or quality metrics aren't met, CMS must end the program. If it does save money – and there are massive savings to be realized by avoidance of hospitalizations for this vulnerable population – the savings are shared with the physician group, nursing home, and Medicare. It aligns all incentives to deliver the best possible care to patients, all the while saving money.

As Jeff Lemieux, Chief Economist with Health IT Now, noted in his recent Health Affairs blog, Medicare's traditional approach to fee-for-service reimbursement has paid providers regardless of quality. CBO worries, as we all should, that if a new benefit is added and even low-quality providers are paid, Medicare's costs could expand quickly.[6] The solution is to reimburse for value, and Congress can create the mechanism for that solution.

Call9's motto is "do right by the patient and all else will fall into place," which is why we seek to enter into value-based arrangements with Medicare – it is right for the patient. I thank you for your attention and dedication to addressing the barriers that entrepreneurs, small businesses, health-care systems, nursing homes and others face in entering into these types of arrangements with Medicare and I look forward to answering your questions.

[6] https://www.healthaffairs.org/do/10.1377/hblog20180116.506486/full/

Addendum: Presentation on the *RUSH Act*

RUSH Act 2018

Reducing Unnecessary Senior Hospitalizations

THE PROBLEM

1.3 million patients suffer from transportation to the ED from nursing homes every year

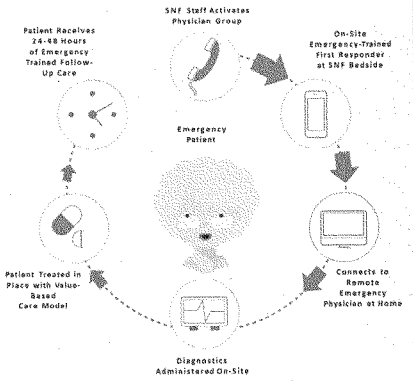
Two-thirds of those ambulance trips are avoidable per CMS

$40 billion of unnecessary costs incurred by the healthcare system



2

THE SOLUTION



BENEFIT TO STAKEHOLDERS:

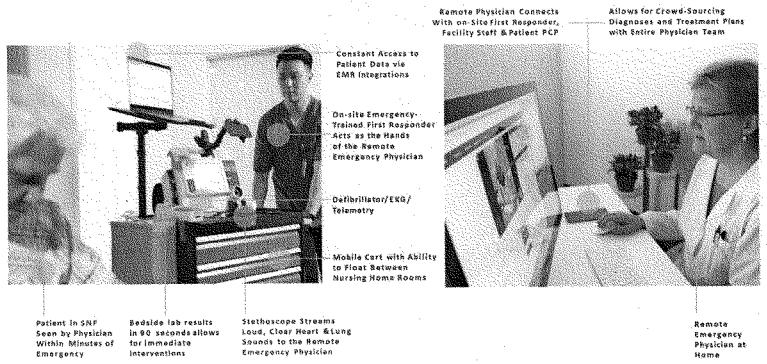
Patients & Families
avoid harmful transfers and hospitalizations

CMS
share $15-30K of savings

SNFs
retain revenue, improve CMS five-star rating, share in savings

8

TECH-ENABLED BEDSIDE CARE DELIVERY



6

TECH-ENABLED EMERGENCY BEDSIDE CARE DELIVERY

On-Site Emergency First Responder, Employed by Physician Group, extends SNF staff bandwidth and skill set via:

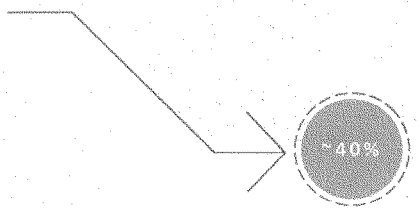
- **Experience in emergency situations**
- **Delivery of IV fluids**
- **Delivery of breathing treatments**
- **Administration of point of care labs**
- **Operation of ultrasound technology**
- **Administration of breathing treatments**
- **Collection of intake forms to risk stratify patients**
- **Rounding on patients following acute events**



7

REDUCTION RATE

Data on 3,500+ Medicare patients has shown a **40%+ reduction of hospitalization transfers**



8

RUSH ACT MODEL: 50 BED NURSING HOME

Present State:

11emergency events per month

Average cost: **$173,855**

Rush Act Model:

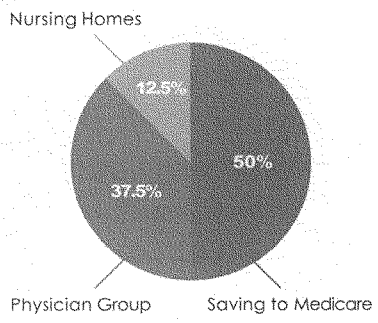
11emergency events per month

ED transfers avoided: **5**
Saving from avoided transfers: **$79,025**
Cost of physician group: **$15,390**
Total Savings: **$63,635**
Savings for Medicare: **$31,817**
Revenue for SNF: **$7,954**

9

VALUE-BASED CARE

On-site first responder model has proven to deliver **$4M a year in savings per nursing home**. The RUSH Act will deliver massive savings to Medicare, while incentivizing 1) physician groups to deliver superior value-based care, and 2) SNFs to provide environments that attract patients that formerly lost them money.



10

Thank You!



Mr. BURGESS. Thank you, Dr. Peck.
Dr. Weinstein, you're recognized for 5 minutes, please.

STATEMENT OF DR. MICHAEL WEINSTEIN

Dr. WEINSTEIN. Chairman Burgess and members of the subcommittee, thank you for inviting me to testify regarding the importance of removing barriers to value-based care in Medicare.

I am Dr. Michael Weinstein, a practicing gastroenterologist and President of Capital Digestive Care, an independent physician practice. I am also President of the Digestive Health Physicians Association, which represents 78 GI practices across the country.

Independent physician practices provide high quality, accessible care in the community at much lower cost than identical services in the hospital setting, yet value-based arrangements are generally not available to us. Physician practices are facing increasing challenges competing with mega-hospital systems that are favored by antiquated Medicare law and regulations.

Hospitals recently embarked on a buying spree of physician practices. The number of physicians employed by hospitals increased 50 percent from 2012 to 2015. This has impacted costs, as hospitals seek to recoup their investments by capturing highly profitable ancillary services. These are the same designated health services that are regulated by Stark self-referral law. Despite some reforms, significant disparities for high-volume services persist. For example, Medicare pays nearly twice as much for colonoscopies in the hospital outpatient department as in an ASC. There is no clinical reason that nearly half of the 2.7 million colonoscopies continue to be performed in the more expensive setting.

Policy makers should be doing more to encourage robust competitive market that allows independent practices to compete and deliver value-based care. Targeted policy changes will improve patient care and lower costs. Congress and CMS must improve the system the develop, evaluate, and approve alternative payment models.

A couple of years ago, CMS projected that 10 to 20 percent of physicians would be enrolled in an APM. Today, that number is just 5 percent.

PTAC was created to facilitate and recommend physician-developed APMs. It has examined 26 APM submissions with five recommended for implementation and six for limited scale testing. But CMS has yet to implement a single APM recommended by PTAC. Moreover, many stakeholders have refrained from submitting proposals because they cannot test them first.

The Medicare statute permits HHS to waive the Stark and other fraud and abuse laws on a case by case basis only for approved APMs. It does not allow testing. For example, PTAC recommended for pilot testing Project Sonar, an APM designed to promote coordinated care for patients with chronic inflammatory bowel disease. But that testing could not occur under the statute without explicit approval of CMS. This means that both clinicians and policy makers lack data to determine if the APM worked or if modifications should be considered.

Also, access to affordable utilization data is needed to model and develop innovative payment arrangements. CMS charges $4,500 for

one year of data from the HOPD and ASC setting, making multiple years of trend data cost prohibitive for many. Deidentified utilization information should be available to the public, researchers, and stakeholders for free on a public website.

The ACA created waivers from the Stark and fraud and abuse laws for ACOs. This creates an uneven playing field for independent practices that would like to participate in value-based arrangements but cannot. We do not advocate amending the Stark self-referral laws in the context of fee for service. But we do think the law needs to be modernized to encourage participation in APMs.

Explicit prohibitions on remuneration for value or volume make no sense under at-risk arrangements that limit Medicare cost exposure. Practices must be able to incentivize appropriate physician behavior for adherence to recognize treatment pathways. How can Medicare promote value-based care if physicians are explicitly prohibited for paying for value?

Finally, patients need better and more accessible information about their treatment options. For example, under the law, screen colonoscopy is covered regardless of where it is provided and the patient has no co-pay and patients have no idea that there is a substantial hospital versus ASC cost differential.

Similarly, patients should be able to access uniform quality and patient outcome metrics across sites of service for identical procedures.

Solutions are available and achievable. DHPA has joined 24 other physicians organizations in endorsing the Medicare Care Coordination Improvement Act. That bill would provide the secretary the identical authority to waive statutory impediments for physician-focused APMs as provided to ACOs.

It would also repeal the volume and value prohibitions for physicians participating in APMs and permits testing of formerly submitted models while they are under review by CMS. Enacting such improvements would dramatically increase physician participation in value-based care.

We look forward to working with the committee on these ideas to strengthen the Medicare program, improve patient care, and conserve resources.

Thank you.

[The prepared statement of Dr. Weinstein follows:]

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Testimony of Dr. Michael Weinstein

President, Digestive Health Physicians Association

Before the Energy & Commerce Subcommittee on Health

"Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

September 13, 2018

Chairman Burgess and Ranking Member Green,

Thank you for inviting me to testify regarding the importance of removing barriers to value-based care in Medicare. I am Dr. Michael Weinstein, a practicing gastroenterologist and President of Capital Digestive Care, an independent physician practice with 65 GI doctors in 17 locations in the greater Washington DC metropolitan area. I am also President of the Digestive Health Physicians Association (DHPA), which represents 78 GI practices in 36 states with more than 1,800 gastroenterologists. DHPA's member practices care for hundreds of thousands of Medicare beneficiaries each year.

Independent physician practices provide high quality, accessible care in the community at a much lower cost than identical services in the hospital setting, yet value-based arrangements are generally not available to them. Physician practices are facing increasing challenges competing with mega-hospital systems, in part, because antiquated Medicare law and regulations

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generally favor hospital systems. Congress and the Centers for Medicare and Medicaid Services (CMS) could do much to level the playing field, improve care coordination, cut costs and promote value-based delivery to patients by:

1) Promoting greater transparency for patients across sites of care;
2) Providing improved access to claims and utilization data in order to build innovative payment arrangements; and
3) Modernizing the Stark and associated fraud and abuse laws, which are an impediment to development and implementation of innovative alternative payment models (APMs), particularly for independent practices.

Together, hospital and physician services account for more than half of national health spending,[1] and their finances are increasingly intertwined. Hospitals recently embarked on a buying spree of physician practices, with the number of hospital-employed physicians increasing 50 percent from 2012 to 2015.[2] This has impacted costs, as hospitals seek to recoup these investments that typically far exceed the value of services the acquired physicians could possibly bill.[3] Hospitals make up this loss by capturing highly profitable ancillary services – the very same "designated health services" regulated by the Stark self-referral law.

[1] CMS. National Health Expenditures 2016 Highlights, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf

[2] Avalere and Physicians Advocacy Institute. Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012- 2016; http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/2016-PAI-Physician-Employment-Study-Final.pdf

[3] According to the Medical Group Management Association, losses of $200,000 per hospital-employed physician are not unusual. MGMA Cost Survey: 2013 Report Based on 2012 Data. http://www.mgma.com/resources/products/mgma-2013-practice-operations report.



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Provider consolidation has clearly led to higher costs of care.[4,5] Congress took a modest step in addressing consolidation in the Bipartisan Budget Act of 2015 by prohibiting a windfall of higher, hospital-based payments for future acquisitions of physician practices, yet significant payment disparities for high volume services persist.

For example, Medicare pays nearly twice as much for the two highest-volume colonoscopy procedures in the hospital outpatient department as the identical procedures in an ambulatory surgery center (ASC). There is no clinical reason that nearly half of the 2.7 million colonoscopies continue to be performed in the more expensive setting.

Policymakers should be doing more to encourage a robust, competitive market that allows independent practices to compete and deliver value-based care, which will improve patient care and lower costs.

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[4] A recent JAMA study that examined 7.4 million Medicare beneficiaries in 240 metropolitan areas from 2008 to 2012 concluded outpatient costs increased for hospital-acquired physician practices by $500 million. Neprash, H., Chernew, M., Hicks, A., Gibson, T., and McWilliams, J. (2015). Association of financial integration between physicians and hospitals with commercial health care prices. JAMA Internal Medicine, 175(12):1932–1939; https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591.

[5] Analogous results were observed on the commercial side; a University of California, Berkeley study that reviewed 4.5 million commercial HMO enrollees found hospital-owned organizations incurred 19.8 percent higher expenditures than physician-owned organizations for professional, hospital, laboratory and pharmacy services. Robinson, J. and Miller, K. (2014). Total expenditures per patient in hospital-owned and physician organizations in California. JAMA, 312(6):1663–1669; available at https://jamanetwork.com/journals/jama/fullarticle/1917439.

First, patients need better and more accessible information about their treatment options. For example, under the law, a screening colonoscopy – regardless of where it is provided – has no copay and the patient is likely to have no idea that there is a substantial cost differential to Medicare (and consequently, their Part B premium) when provided in the hospital rather in a physician-owned ASC. Similarly, patients should be able to access uniform quality and patient outcome metrics across sites-of-service for identical procedures. Disparate quality measures for each site-of-service do not allow for digestible apple-to-apples comparisons by patients considering their treatment options.

Second, Congress and CMS must improve the system to develop, evaluate and approve APMs. A couple of years ago, CMS projected that 10 to 20 percent of physicians would be enrolled in an APM by 2017. Today, that number stands at a paltry 5 percent. Hospital-employed physicians are often participating in an APM through system-sponsored ACOs. If independent physicians are effectively shut out of APM participation, they have very little chance to move from fee-for-service to value-based care, improve care coordination and compete with mega-hospital systems. Moreover, it means that Medicare is not moving to value-based models for much of specialty-related care delivered outside of hospitals.

One challenge is ready and affordable access to utilization data needed to model and develop innovative payment arrangements. To gain access to complete Medicare claims (Limited Data Sets Standard Analytical Files), stakeholders must send a request to CMS, which CMS

states can take up to eight weeks to process and respond. Moreover, access to this data is costly: CMS charges $4,500 for one year of data for the HOPD and ASC setting.[6] Multiple years of data are typically needed for meaningful trend analysis, making access cost-prohibitive for many. This de-identified Medicare utilization information should be available to the public, researchers and stakeholders for free on a public website.

Under MACRA, Congress established the Physician-Focused Payment Model Technical Advisory Committee (PTAC), to facilitate, evaluate and recommend physician-developed APMs in Medicare. Unfortunately, *CMS has yet to implement a single APM recommended by PTAC* despite PTAC's review of 26 APM submissions, with five recommended for implementation and six for limited-scale testing. More troubling, even if the PTAC system were operational, a very small portion of the Medicare population would be enrolled in APMs because many stakeholders cannot know whether those models would work in the real world and have therefore refrained from submitting proposals.

The Medicare statute permits the Department of Health and Human Services to waive the Stark and other fraud and abuse laws on a case-by-case basis for approved APMs. It does not, however, allow providers to test a submitted APM while it is pending approval.

[6] CMS, Standard Analytical Files (Medicare Claims), LDS Worksheet, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/StandardAnalyticalFiles.html

For example, two years ago DHPA member practice Illinois Gastroenterology Group submitted "Project Sonar" – a care management program designed to improve the management of patients with high-beta chronic inflammatory bowel disease (IBD), where outcome and cost are highly variable – to the PTAC. Project Sonar shifts management and care of patients from a reactive to a proactive model, inducing the transformation of the practice from fee-for-service to a value-based payment model. Although PTAC approved Project Sonar on a pilot basis, practices were not able to test the project while awaiting a CMS decision. This is disappointing, as Project Sonar would have allowed physicians to assume risk for their patients with chronic diseases and conditions (that are not triggered by a surgical procedure on an inpatient or outpatient basis) as well as improve patient outcomes and create shared savings. Testing would have provided both clinicians and policymakers with critical information on whether the APM had merit worthy of approval and implementation.

At the same time, the Affordable Care Act granted the Secretary the authority to waive the Stark law, the Anti-kickback Statute and Civil Monetary Penalties for Medicare Shared Savings Program accountable care organizations (ACOs), creating an unlevel playing field that generally favors hospital systems. Not only did this fuel provider consolidation as specialists were often threatened with being frozen out of networks unless they joined an ACO, but the ACOs have failed to produce meaningful savings to the Medicare program.[7] Independent

[7] The Medicare Shared Savings Program (MSSP) increased federal spending by $384 million from 2013 to 2016. Avalere Analysis on Medicare Accountable Care Organizations based on CMS data, available at http://avalere.com/expertise/managed-care/insights/medicare-accountable-care-organizations-have-increased-federal-spending-con

physicians are simply seeking the same waiver authority under MACRA that was afforded to ACOs under the ACA.

We do not advocate fundamentally amending the Stark self-referral law in the context of fee-for-service. But we do think the law needs to be modernized to encourage participation and success in APMs. Prohibitions on remuneration for "value or volume" make no sense under capitated or at-risk arrangements that seek to incentivize appropriate physician behavior for adherence to recognized treatment pathways. Medicare's fiscal exposure is limited but practices cannot penalize or reward their physicians with designated health services revenue based on their ability to deliver value. How can Medicare promote value-based care if physicians are explicitly prohibited from remunerating based on value in the statute?

Solutions are available and achievable. DHPA was delighted to join 24 other physician organizations from across the house of medicine in endorsing "The Medicare Care Coordination Improvement Act" (H.R. 4206), authored by Reps. Bucshon and Ruiz, which would make several important and targeted modernizations to the Stark law. That bill would provide the Secretary the identical authority to waive statutory impediments for physician-focused APMs as provided to ACOs. It would also repeal the "volume and value" prohibitions for physicians participating in APMs.

Finally, it permits physicians to test formally submitted and recognized models while they are under review by CMS. Enacting such improvements would dramatically increase physician participation in value-based care.

We look forward to working with the Committee on these ideas to strengthen the Medicare program, improve patient care and conserve resources.

Mr. BURGESS. Thank you, Dr. Weinstein.

Mr. Green, we went ahead with opening statements from the witnesses, and if it's all right with you, we'll conclude our last two and then I will recognize you for an opening statement, if that's agreeable to you.

Mr. GREEN. Mr. Chairman, I will just submit my opening statement for you and I apologize for being late.

Mr. BURGESS. That's not a problem. I know that there's a lot going on today.

Mr. Reed, you're recognized for 5 minutes for an opening statement, please.

STATEMENT OF MORGAN REED

Mr. REED. Thank you, Mr. Chairman.

My name is Morgan Reed and I am the President of the App Association and Executive Director of the Connected Health Initiative—a coalition of doctors, research universities, patient advocacy groups, and leading mobile health tech companies.

Our organization focuses on clarifying outdated health regulations and encouraging the move to value-based care through the use of digital health tools to improve the lives of patients and their doctors.

Demographics are set to overwhelm the Medicare system with, roughly, 70 million Americans enrolled by 2030. Yet, physicians and their teams are already reporting being overworked and burned out. Moreover, patients report a high level of frustration with the healthcare system. It simply takes too long and costs too much. And yet, this is the same world where every person can pay their mortgage, monitor their package delivery, review their child's homework, all while sitting in the waiting room of that very doctor.

What's going on that we can't better engage with patients using the tools every single one of you has in the palm of your hand right now or strapped to your wrist? Why is it that CMS reimburses nearly a trillion dollars a year, yet can't use those technologies to cover telemedicine in a meaningful way? Why doesn't the system help doctors use tools that lower administrative burden, allow doctors to treat a patient and not the keyboard?

Well, since I don't want to leave this committee in a state of depression—a condition, by the way, that has been proven to be treatable using digital patient engagement tools—I want to lay out what we see as the key questions to be asked and the pathway forward for our sector.

First—the first question we should always ask in this case is does the policy decision drive value for patients. Medicare beneficiaries—wait a minute, let's call them what they really are—people, who live in their districts, or better yet, how about—let's we call them constituents—have a simple goal.

They want to be healthy and they want to be independent, and for those with chronic conditions like type 2 diabetes they want treatment to help them stay as healthy as possible for as long as possible. For them, remote monitoring technologies are lifesaving tools.

One of our member companies, Podimetrics, is one such remote monitoring company. They make a foot mat that detects diabetic

foot ulcers up to 5 weeks before they become clinically present. This tech is not only more efficient than other methods but it also cuts down on hospital bills and ultimately saves limbs. Doctors like it because they stay engaged with the patient. But reimbursement under Medicare remains a question mark.

Second question—does the policy decision drive value for care givers? We are all familiar with the horror stories from physicians on EHR adoption and the epic burnout we see as a result. Patients rightfully complain that physicians seem disengaged when they're typing away at a keyboard. Meanwhile, doctors find they must subvert the system by typing asterisks or other characters in a field they don't use. This not only creates extra work for them but ultimately will prevent entered data from being used predictably as part of machine learning or augmented intelligence systems.

And finally, does it drive value for taxpayers? Taxpayer value comes from a system that incentivizes the right things at the right time.

When it comes to preventative health, this begins with expansion of the CBO scoring window. I want to thank all of you who supported the Preventative Health Savings Act—H.R. 2953—which would expand this window to 10 years. That's a good start. But preventative medicine can do much more.

For example, my friend, Congressman Harper, knows full well that the University of Mississippi Medical Centers' telehealth program would save the state $189 million in Medicaid if just 20 percent of Mississippi's diabetic population were enrolled.

Just think of the taxpayer savings for the country if CMS supported what UMMC is doing today. And here are a few actions that Congress and the administration can take to hit the mark. First, Congress should pass the Connect for Health Act—H.R. 2556—to clarify that Medicare covers tech-driven tools that enhance efficiency and clinical efficacy including the removal of the outdated restrictions under 1834(m).

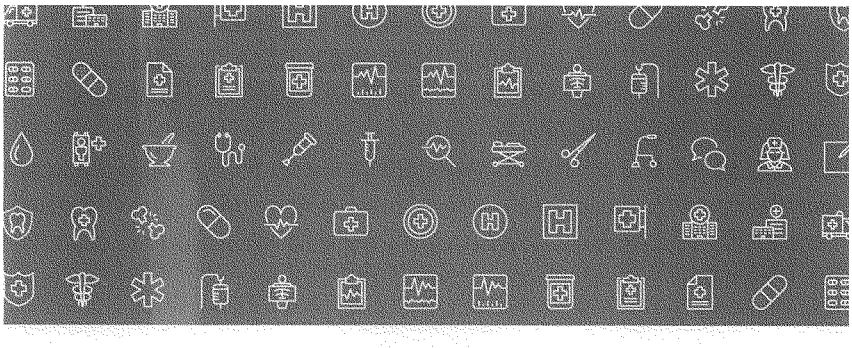
Second, for practices that still use the fee-for-service model, CMS should adopt billing codes that cover activities that use patient-generated health data and remote patient monitoring. CMS has done good work in unbundling CPT Code 9091 and the proposed new code CBCI(1) and CMS should continue to look at the ways that the Digital Medicine Payment Advisory Group can develop future codes that support new technology.

Third, Congress should file down regulations like the Anti-Kickback Statute in the Stark Law to allow providers to get technology into the hands of patients. And finally, Congress should support the use of unlicensed spectrum, sometimes known as TV White Spaces technology to help cover rural populations so they can have high-speed internet in places traditional carriers don't cover cost effectively.

I want to remind everyone here that we all are or will be part of the system, either as patient or caregiver. The least we can ask is for the system that treats us and the care teams that see us as real people, not just boxes on the spreadsheet.

Thank you very much.

[The prepared statement of Mr. Reed follows:]



ConnectedHealth

Testimony of

Morgan Reed
Executive Director
The Connected Health Initiative

Before the

U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Health

"Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"



I. Executive Summary

I am president of ACT | The App Association and current executive director of the Connected Health Initiative (CHI), an organization that has pulled together a broad consensus of healthcare stakeholders, including physician groups, patient groups, device manufacturers, software companies, venture capital firms, and research universities. We observe that Medicare, bound up in labyrinthine regulations and payment policies, presents serious challenges to the incorporation of tech-driven tools that can make healthcare more accessible and user-friendly.

This hearing takes place at a critical moment for American healthcare. Demographics are poised to apply new pressure to the system, as Baby Boomers move to Medicare. With the number of Americans over age 65 jumping from 40.3 million in 2010 to a projected 55 million in 2020—and up to 70 million in 2030—older Americans constitute an increasing percentage of the population. And as life expectancy increases, so does the expectation of staying home as we age. Currently, 87 percent of Americans over the age of 65 say they want to stay in their current home as they get older. The confluence of these demographic projections, along with buy-in from an unprecedented breadth of stakeholders who are recognizing the maturity of the technological tools at medical professionals' disposal, means the time is right to make substantial progress toward innovation-driven, value-based care.

As we evaluate and suggest policy positions for decision-makers, we ask three fundamental questions:

- **Does it drive value for patients?** When your constituents think about what they would change about healthcare, chances are they are fed up with a lack of access to care—from waiting in line to being unable to use the supercomputer in their pocket to manage their health. Medicare policies should enable innovators to make healthcare both more accessible and more effective for patients.

- **Does it drive value for caregivers?** Unfortunately, physicians report spending fully half of their time at work on electronic health records (EHRs) and other desk work.[1] Accounting for the other necessary activities, they are left with only 27 percent of their time dedicated to direct clinical face time with patients. It is critical that Medicare policies help caregivers spend more time with patients and less time at their computers.

- **Does it drive value for taxpayers?** The current cost spiral—in which Medicare incents caregivers to care for the sickest patients in expensive settings—is unsustainable. The question we ask is not whether a policy makes care "cheaper," rather, the question is whether a policy creates incentives for caregivers to avail themselves of cost-effective measures. Medicare policies should make cost-effective options the most attractive both for clinical and for financial reasons.

As the growth in demand for healthcare services outstrips supply growth, tech-driven tools like artificial intelligence (AI) are maturing from shiny objects into meaningful enhancements to the practice of medicine. In fact, experts are referring to AI in the healthcare context as "augmented intelligence," an accurate description of its current and predicted future roles in the medical profession. Stakeholders across the healthcare field recognize that connected care can be a multiplier of—rather than an impediment to—caregivers' ability to treat patients. However, in many ways, the policies dictating the use of technology have detracted from the time caregivers spend with patients, particularly because of the arcane nature of Medicare regulations and payment policies.

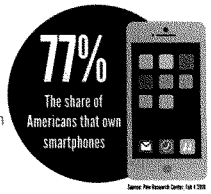
All is not lost. Other highly regulated industries have successfully overcome these obstacles and empowered innovators to drive convenience and cost-effectiveness. Financial services stands out as an example of an industry that features similar risks to those presented in the healthcare context. The misuse or misappropriation of financial accounts or information could have disastrous consequences, as could substandard healthcare or misuse of healthcare information. And yet, we can check our balances, transfer

funds, pay credit cards, and make any kind of purchase by a few taps on swipes on our phones. The financial services example illustrates that complex webs of regulation are not insurmountable. Why have we been unable to harness technologies like this in the healthcare context? Because the financial aspects of Medicare are misaligned. There are numerous levers policymakers can pull to enhance value for patients, caregivers, and taxpayers alike. For example, policymakers should take the following steps:

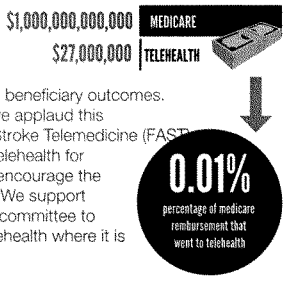
- First, policymakers should clarify that Medicare does not penalize—and in fact supports—the adoption of tech-driven tools that enhance efficiency and clinical efficacy, including by passing the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017 (H.R. 2556);
- Second, for practices that still use a fee-for-service model, the Centers for Medicare and Medicaid Services (CMS) should adopt billing codes that cover activities involving clinical enhancements using patient-generated health data (PGHD) and remote patient monitoring;
- Third, as more caregiving settings move from fee-for-service to value-driven models under Medicare, policymakers should file down regulatory vestiges—like features of the Anti-Kickback Statute and the Stark Law—intended to reduce fraud, waste, and abuse that can occur under fee-for-service practices;
- Fourth, Congress should peel away the overburdensome restrictions on telehealth under 1834(m) of the Social Security Act and consider requiring the Congressional Budget Office (CBO) to look beyond the 10-year budget window, including by passing the Preventive Health Savings Act (H.R. 2953);
- Fifth, policymakers should enhance interoperability and access to data through better guidance from the Office of Civil Rights (OCR) and finalize the "data blocking" rules; and
- Sixth, policymakers should support access to broadband, especially in rural areas—including using unlicensed spectrum—to enable connected health technologies to reach rural populations that suffer from high rates of chronic disease.

These are just a few examples of specific measures policymakers could take to enable advances in value for patients, caregivers, and taxpayers via innovations in connected and digital health tools.

II. Telehealth



Too often, telehealth services – defined as two-way live voice and/or video in Medicare – are not a meaningful option for Medicare caregivers and beneficiaries in the continuum of care. The barriers to using live voice or video as a means for patients and doctors to communicate are due to Section 1834(m) of the Social Security Act, which limits Medicare coverage for such telehealth services to highly specific "originating sites" and to areas with a healthcare professional shortage. **In other words, telehealth is really only available where patients aren't.** It's no wonder, then, that of the approximately $1 trillion the federal government spends on Medicare every year, a minuscule $29 million or so goes toward telehealth. We encourage policymakers to find ways to remove 1834(m)'s backward-facing restrictions that prohibit Medicare caregivers from utilizing telehealth services to improve beneficiary outcomes. The Subcommittee has already taken this on in specific ways. Specifically, we applaud this Subcommittee for the passage and enactment of the Furthering Access to Stroke Telemedicine (FAST) Act of 2017 (H.R. 1148) and for forwarding measures to expand access to telehealth for those impacted by opioid substance use disorder, including H.R. 5603. We encourage the Subcommittee to prioritize operationalizing the rollback of these restrictions. We support the Evidence-Based Telehealth Expansion Act (H.R. 3482) and urge the Subcommittee to consider proposals like this that would empower CMS to ease access to telehealth where it is



fiscally and clinically responsible to do so.

We do not propose to expand the definition of Medicare telehealth services beyond what CMS has interpreted from the statutory concept of telehealth—a live, interactive voice or video session. CHI strongly discourages any statutory changes that would expose new connected health modalities to the restrictions of 1834(m). We further note our appreciation and support for CMS' proposal in its draft Calendar Year 2019 Physician Fee Schedule to recognize of "communication technology-based services" that do not meet the Medicare telehealth services definition in Section 1834(m). While 1834(m) must still apply to the narrow set of defined Medicare services that fall under its definition moving forward, any inclusion of new modalities as Medicare telehealth services would harm the development of connected health technology innovations as well as their being made available to countless American Medicare beneficiaries.

a. Value for Patients



The mere thought of seeking preventive or prospective care may be exhausting for those who associate the healthcare experience with burdensome travel requirements, long waits, and other impediments to physician access. It is no surprise, therefore, that many patients who are sick or suffer from chronic conditions tend to wait for their illnesses to progress to a stage where it is more expensive and more difficult to address than if prevention and/or treatment had been provided earlier. And the experience could worsen, given trends in U.S. age demographic realities, guaranteeing that more Medicare patients will soon be seeking care from a system struggling to grow with the demand. Short-circuiting these tendencies to procrastinate in seeking care is only possible where access to care is enhanced, and we commend this Subcommittee for examining this area of need. The opportunities to enhance the value of healthcare are drastically increased for patients with smartphones, tablets, and other connected devices, representing an increasing majority of Americans, including Baby Boomers. This is especially true for rural Americans and those who otherwise lack convenient access to physical care.

b. Value for Caregivers

Surveys reflect that caregivers want to reach more patients where they are. In fact, the University of Virginia (UVA) seeks to scale telehealth encounters to 60,000 per year over the next two years, and Cleveland Clinic similarly aims to reach 35,000 telehealth encounters over the course of a year. These plans are not unique, with the American Hospital Association finding that 65 percent of hospitals have implemented telehealth in at least one care unit, with that number expected to grow by another 13 percent.[2] Providers' proposed adoption of telehealth is good news for patients, but the benefits of Medicare telehealth services pales in comparison to the improved outcomes and cost savings associated with the use of further connected health products and services (discussed in further detail below).

c. Value for Taxpayers

The benefits of telehealth for taxpayers are equally well-documented. The first 100 diabetes patients in the CHI steering committee member University of Mississippi Medical Center's (UMMC's) telehealth program, collectively saved an incredible $336,184 in healthcare costs.[3] Using this data, cost analyses estimate that if 20 percent of Mississippi's diabetic population were enrolled in the telehealth program, it would save the state $189 million in Medicaid dollars.[4] The AMA further found through in-depth interviews with members of its Digital Medicine Payment Advisory Group (DMPAG)—of which I am a member—that instead of merely supplementing patient utilization, digital medicine offerings (including telehealth) substitute for otherwise more expensive healthcare services.[5] This evidence from practitioners contradicts the often-overstated fears that telehealth could lead to a bonanza of overutilization.

To the extent that the cost savings telehealth could produce may not materialize for several years—insofar

as they are used for preventive care—the CBO's 10-year threshold is a barrier to adoption. For this reason, we support Chairman Burgess's and Rep. DeGette's Preventive Health Savings Act (H.R. 2953). Enabling committees to require CBO to analyze potential savings beyond the 10-year window for federal coverage of certain preventive measures would be a major step forward to unlocking the benefits of telehealth and other connected health modalities aimed at prevention.

III. Anti-Kickback Statute and Stark Law

The Anti-Kickback Statute (AKS) and Stark Law are prime examples of well-intentioned laws that frustrate CMS' progress as it seeks to evolve Medicare from fee-for-service to value-based care. We agree with CMS' assessment that the Stark Law and AKS provide important anti-fraud protections for Medicare. However, they are both out of date and present barriers to innovation, and considerations for new exceptions to the laws are needed. CHI notes its appreciation of the Department of Health and Human Service's (HHS') recent public solicitation for comments on the AKS and Stark Law's impact on innovation,[6] on which CHI has commented and urges this Subcommittee's to consider.[7]

We urge the creation of Stark Law exceptions that will responsibly facilitate the greater uptake of connected health innovations—be they hardware, software, or a combination of the two—throughout the continuum of care, including for Accountable Care Organizations. Moreover, the HHS' Office of the Inspector General (OIG) should provide clarification on questions regarding anti-kickback laws to reflect realistic engagement program requirements. Such issues include ensuring that giving patients a device (e.g., a tablet) to communicate with a care team is not considered patient inducement; or that providing physician platforms for telemedicine is not violating the AKS. We have raised our views regarding the AKS previously in more detail and urge for their careful consideration by CMS.

Please note CHI does not seek statutory changes to the AKS or the Stark Law; we believe HHS has clear authority to provide exceptions (in the case of the Stark Law) and much-overdue guidance (in the case of the AKS) to providers and other stakeholders, and we urge this Subcommittee to encourage HHS to take such steps as rapidly as possible.

a. Value for Patients

The value of re-orienting the AKS and the Stark Law lies in enabling a user-friendly patient experience. The HHS' OIG has made some strides in this regard and recognizes the opportunities to create safe harbors that enable patients to access products and services that make their healthcare experience more effective and easier. For example, in its efforts to address fraud and abuse in Medicare and state health programs, OIG recognized in its December 2016 safe harbor rulemaking that "[t]he transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers," and assured that "we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending." Both the Inspector General and the Chief Counsel to the Inspector General have indicated that OIG is interested in exploring ways to permit greater flexibility for value-based arrangements, while still guarding against the problems the fraud and abuse laws were designed to prevent.

We believe that the OIG could provide clarification on questions regarding anti-kickback laws to reflect realistic engagement program requirements. **Such issues include ensuring that giving patients a device (e.g., a tablet) to communicate with a care team is not considered patient inducement; or that providing physician platforms for telemedicine is not violating the anti-kickback statute.**

b. Value for Caregivers

Small practices, in particular, could benefit from the extension of the Stark Law donation exemption (scheduled to expire in 2021) for interoperable technology, along with an expansion of this exemption to allow for donations aimed to improve the exchange of health data through innovative application programming interfaces (APIs) and other tools. Permitting such donations would assist smaller practices facing resource constraints to advance

value-based care using connected health technologies. Under current conditions, EHRs demand ridiculous amounts of time and energy on the part of physicians. Layering on another set of digital tools is not likely to help physicians unless those tools are woven into the continuum of care in an intuitive and user-friendly way. These attributes, in turn, are only achieved where they are woven into clinicians' treatment regimens.

In the case of the AKS, providers seeking to use connected health tools face the risk of liability under AKS should they provide those tools to their patients. Such tools are demonstrated to improve patient engagement and outcomes, as well as to save caregiver team resources. Without guidance from HHS on AKS as applied to the use of connected health technology (e.g., tablets, software platforms, etc.), no physician could be expected to take the risk of violating AKS, and AKS will remain a significant barrier to innovation in healthcare.

The barriers AKS and Stark Law present make the seamless integration of digital tools and caregiving difficult and in some cases impossible. Removing or reducing those barriers could dramatically enhance value for caregivers.

c. The Value for Taxpayers

Congress' vision for value-based care, led by this Subcommittee, relies heavily on the development of risk-sharing models that are defined by flexible contracting arrangements. For example, a software company may partner with a device company to provide services to a mental health clinic. The contract between the software-device company joint venture and the clinic may contemplate higher or lower compensation for the joint venture depending on the effectiveness of the services and devices it provides the clinic. Unfortunately, this arrangement may run afoul of AKS, which prohibits the exchange of value in return for referrals or to generate healthcare program business.[8] Especially if the clinic is part of the joint venture, the Stark Law could also prohibit any value-driven discounts between the parties because it prohibits a physician from referring Medicare patients to an entity with which the physician has a financial relationship. These types of contractual arrangements—in which risk is shared, efficacy is rewarded, and ineffectiveness is penalized—are central to aligning value with Medicare's payment system. Identifying appropriate exceptions and mitigations for AKS and Stark Law prohibitions is, therefore, a key element of driving value for taxpayers as the system moves to value-based care. Without action by HHS, the AKS and the Stark Law will continue to present barriers to the use of connected health innovations and the demonstrated program savings their use brings.

IV. Clarification in Value-Based Models

The value proposition for clarifying CMS' expectations and requirements in the context of the Quality Payments Program (QPP) is similar to that of providing exceptions to and reinterpreting the AKS and the Stark Law. Providers want to know that the adoption of tech-driven tools integrated into the continuum of care is welcomed by CMS and that such adoption will not disadvantage them from a Medicare coverage perspective or expose them to liability.

The process by which the federal government recognizes new technologies and care modalities to fold them into the continuum of care is extremely long-winded. Nobody wants technology at the speed of government, but too often, that's what patients in the Medicare system get. Under the current procedure, the Center for Medicare and Medicaid Innovation (CMMI) must first approve a modality as something it has the authority and evidence base to begin testing it in a pilot project. Then, CMMI must obtain federal funding to carry out the study and create the study's parameters. After the study is conducted in a specific location drawing on a specific population with certain demographic characteristics, CMMI can finally issue the study, which is then thoroughly reviewed. After all of this, if the study stands up to review, the activities it covers might see Medicare reimbursement after at least a year of rulemaking exercises. Taken all together, this process can take 10 years. To put that in perspective, smartphones have been on the market for a decade, so imagine if we had to wait for CMMI to approve those before we could put them in our pockets. We would all have the first generation of iPhones, LGs, Galaxies, or Pixels. The current treatment of new technologies in the Medicare system is one that validates old ideas; it does not find new ones. We urge the Subcommittee to work with CHI to identify

opportunities for improving the process by which new technologies are approved and validated as cost-effective, clinically appropriate, and implemented with low risk of waste, fraud, and abuse.

The recent advancements made by CMS through both its Physician Fee Schedule (PFS) and QPP we have discussed above are significant, but they do not reduce the crucial role that CMMI plays (and will play) in exploring new innovations in Medicare and Medicaid. Nor do these changes alter the fact that, to date, the efforts of the CMMI in exploring the benefits of connected health technologies (both telehealth and remote monitoring) have been insufficient given the immense value these technologies provide. We support a new direction for CMMI and urge CMMI to truly explore these technologies potential as soon as possible through its efforts, building on recent advancements made in the PFS and QPP. CMMI should be ahead of this curve and not behind it. CHI commits to assist CMMI in any way possible to get to CMMI to the forefront of innovation in delivering care to Medicare and Medicaid beneficiaries.

a. Merit-Based Incentive Payment System (MIPS)

CHI supports CMS' efforts to incent the use of connected health innovations in the Merit-Based Incentive Payment System (MIPS) through providing modality-neutral approaches to Improvement Activities (IAs) and flexibility for program participants. Specifically, CHI supports CMS' adoption of CHI's proposed MIPS IA – IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care) for care coordination incenting providers to leverage digital tools that collect PGHD for patient care and assessment outside the four walls of the doctor's office using an active feedback loop.[9] CMS not only adopted the IA, but also assigned high weight and linkage to an Advancing Care Information bonus to it, signaling to providers that CMS acknowledges the important role connected health tools can play in improving health outcomes and controlling costs. This Subcommittee's Medicare Access and CHIP Reauthorization Act (MACRA) calls for an IA inventory that "shall include activities such as . . . remote monitoring or telehealth," and we encourage continued congressional oversight to ensure the continued adoption of IAs that pave the way for the adoption of digital tools.

CMS' previous policy of providing bonus points in the Promoting Interoperability (PI) category represented CMS' understanding that connected health innovations play a key role in improving outcomes and incent physicians to incorporate technology into their practice workflows and clinical activities. With regard to how connected health tools could better support the feedback related to participation in the QPP and quality improvement in general, we believe that the CMS' evaluation must reflect the fact that remote monitoring and telehealth—across patient conditions—offer key "health information technology [IT] functionalities," including the automatic collection and transmission of important biometrics for timely caregiver review and analysis.

Many CHI members develop truly unique applications that benefit both providers and patients. However, CMS' regulation that includes misplaced Certified EHR Technology (CEHRT) incentives drive EHR development to focus on measurement and reporting, rather than patient and clinician needs. Similarly, providers are not rewarded for health IT use consistently across all MIPS components. For instance, the PI component is solely focused on CEHRT use, while the IA category rewards for the use of both CEHRT and non-CEHRT.

This Subcommittee should ensure that CMS shifts away from rigidly requiring the use of CEHRT to an outcomes-based approach that would permit the use of non-CEHRT across the entire MIPS program. CMS should also seek to minimize administrative burdens (e.g., lengthy documentation reporting requirements) on Medicare caregivers. Such steps must serve as a cornerstone of CMS' effort to provide flexibility for MIPS-eligible clinicians to effectively demonstrate improvement through health IT usage. Further, changes in MIPS are inherently linked to other important rules CMS is responsible for, including the PFS which has recently begun to incent the use
of asynchronous tools that will bring PGHD into care. Efforts to revise MIPS measures and objectives generally should be made in alignment with non-CEHRT use (e.g., remote monitoring technology) which can greatly improve patients' care and wellness. CHI commits to work with this Subcommittee to maximize the value of MIPS.

b. Alternative Payment Models

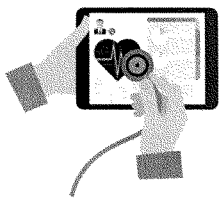
CHI also supports Congress' goal of realizing innovative Alternative Payment Models (APMs) and continues to work with stakeholders to find innovative alternatives to MIPS. APMs, with their financial and operational incentives, should demonstrate the best uses of remote monitoring or telehealth tools. To date, CMS has not discussed telehealth and remote monitoring's key role in the success of APMs in its heavily relied upon annual rulemaking. CHI maintains that this glaring oversight forces eligible clinicians, as well as other key stakeholders and organizations, to conclude that telehealth and remote monitoring do not have a role in APMs. We call on CMS to provide this crucial commentary and insight in the next final (CY2019) QPP rule. Such a step would also be consistent with CMS endorsement of telehealth and remote monitoring in MIPS.

Further, the current restrictions of 1834(m) are particularly inappropriate for APMs. We strongly support relieving APMs from the onerous Medicare telehealth restrictions in 1834(m). In a limited set of circumstances, CMS has taken steps to provide relief from section 1834(m)(4)(C) to pre-QPP APMs, demonstration projects, and Innovation Center models. For example, CMS provided this limited relief to Next Generation Accountable Care Organizations (ACOs). In addition, in the Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, CMS waived the rural geographic requirement and allowed telehealth services to be covered in patients' homes or place of residence.

The ongoing annual MACRA implementation rulemaking presents CMS with a golden opportunity to endorse the use of connected health technology innovations in APMs and to provide waivers from all of 1834(m)'s restrictions. To attract participants to the APM program, the flexibility to utilize the range of connected health innovations can be a reward and a competitive advantage. APM quality and performance measures paired with the ability to collect and quickly analyze data collected through these tools will protect against fraud and Medicare's traditional fee-for-service utilization controls.

c. Value for Patients

If an APM is allowed the flexibility to use connected health technologies for patients with specific at-risk chronic conditions, those patients would benefit from much more user-friendly and effective care. If CMS provides certainty for providers that it considers whether they integrate remote monitoring to improve quality, while reducing per capita total costs of care, providers will be more likely to adopt those measures as part of an APM and patients would benefit. CHI Steering Committee member UMMC adopted a remote monitoring strategy out of necessity, and the evidence shows improvements to outcomes as well as ease of use for UMMC patients. The 100 diabetes patients enrolled in the telehealth program saw a 1.7 percent reduction in their A1C levels, zero hospitalizations, and zero emergency room (ER) visits.



Similarly, MIPS programs that incorporate remote patient monitoring enable patients with chronic conditions to access better care in the form of remote monitoring and interactive care. CHI member company Podimetrics, for example, manufactures the SmartMat™, which—pursuant to clinical trials—can detect diabetic foot ulcers about five weeks before they present clinically. Diabetes patients at risk for developing a diabetic foot ulcer (DFU) may be required to undergo skin grafts or even amputations if DFUs develop. Preventive treatment is therefore exceedingly important for diabetic patients at risk for DFUs. Fortunately, MIPS providers should be more likely to adopt technologies like the SmartMat™ because the MIPS program recognizes the analysis of PGHD as an IA. Further improvements for patients could include shifting away from rigidly requiring the use of CEHRT to an outcomes-based approach that would permit the responsible use of non-CEHRT by MIPS caregivers. CMS should also seek to minimize administrative burdens (e.g., lengthy documentation reporting requirements) on Medicare caregivers. Such steps must serve as a cornerstone of CMS' effort to provide flexibility for MIPS eligible clinicians to effectively demonstrate improvement through health IT usage while also measuring such improvement.[10]

d. Value for Caregivers

Increased flexibility in the APM and MIPS programs would produce obvious benefits for caregivers, most notably by allowing them to access the technologies of their choice, in a manner that augments—rather than impedes—their ability to practice medicine. Moreover, effective use of RPM technologies allows providers to prioritize patients with more urgent needs, in many cases guided by the software. This is especially true if CMS were to allow MIPS providers to use technologies beyond CEHRT. In its proposed Query of Prescription Drug Monitoring Program (PDMP) measure, CMS has acknowledged the use of health IT beyond CEHRT. Providers' use of this technology is also important in the MIPS context, so we would support CMS allowing providers the flexibility to adopt technologies that build on CEHRT, for example. This enhanced flexibility and choice for caregivers would make integration of tech-driven tools using PGHD more user-friendly and enable them to see the full potential of these tools to enhance the caregiving experience and reduce EHR and desk time.

e. Value for Taxpayers

Enabling MIPS providers and APMs to adopt tech-driven tools like remote patient monitoring and care coordination platforms helps effectuate MACRA's goal of aligning participating providers' incentives with those of taxpayers. By using a software platform like the one by CHI Steering Committee member Rimidi—which enables diabetes patients and their care teams to manage diet and other inputs in real-time and with customizable settings—MIPS providers and APMs can more effectively create an environment that responds to patients' needs in a cost-effective manner. A failure to either acknowledge digital medicine in APM rules or reward it in MIPS scoring dissuades providers from selecting tools that can enhance cost-effectiveness and clinical efficacy. At the same time, the incentives that exist in a fee-for-service system—where providers are tempted to order services like imaging and lab tests because each is reimbursed separately—are not present in the same way with MIPS scoring or APM rules. The incentives in MIPS are for the provider to implement IAs and report on quality measures (which are designed to improve cost-effectiveness and clinical efficacy) that increase its score. Similarly, the rules incent APMs to implement quality measures demonstrating cost-effectiveness and high-quality care. Digital tools that enable providers to treat and consult patients in less costly settings, more directly, and with greater customizability help providers achieve the APM and MIPS goals so rules governing the programs should avoid dissuading providers from using them.

Further, we completely disagree with the notion that a service provided by a caregiver using digital tools raises inherently more serious waste, fraud, or abuse risks than if the service were provided in person. In fact, in addition to the benefits described above, enabling the use of digital tools in value-based settings provides a more streamlined and accurate way of tracking transactions, patient engagement, and service provision. Thus, digital tools can actually help assure taxpayers that the products and services Medicare pay for are put to their proper use in ways that are unavailable without them.

V. Fee-for-Service Updates to Facilitate the Transition to Value-Based Care

As more Medicare services and funding shifts to QPP, the PFS will remain an important means of reimbursing providers for healthcare services for Medicare patients. But one key component to an effective transition is for the PFS to acknowledge and support modern digital health modalities so that providers who rely on the PFS can be reasonably compensated for adopting efficiency- and quality-enhancing digital health tools. A failure to cover the time clinical staff spends in providing care using PGHD, or resources spent integrating software platforms and devices that help facilitate preventive care, would have the perverse effect of pushing providers to spend valuable time and resources on less cost-effective care measures when conditions are worse and where settings are costlier.

In its 2018 PFS rulemaking, CMS distinguished between "remote monitoring" services and "telehealth," and permitted separate payment for remote physiological data monitoring by activating and unbundling Current

Procedural Terminology (CPT) Code 99091 ("physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver"). The code, which has several limitations, allows reimbursement to physicians and qualified healthcare professionals who rely upon remotely gathered physiologic data to monitor patients.

CHI strongly supports CMS' current proposals to activate each of the three new CPT codes developed to address chronic care remote physiologic monitoring (990X0 [Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment]; 990X1 [Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days]; and 994X9 [Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/ physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month]).[11] Each of these codes was developed through concerted and thoughtful deliberations of the DMPAG, which is comprised of experts in digital medicine services as well as coding, valuation, and coverage. The DMPAG, in turn, submitted applications for the creation of these new codes to the independent CPT Editorial Panel which vetted and approved the applications for new codes. The CPT Editorial Panel considered, among other relevant factors, significant supporting clinical documentation. We understand that the AMA's relative value scale (RVS) Update Committee (RUC) undertook a valuation of these codes to which CMS has access. We urge this Subcommittee to ensure that CMS covers, prices, and pays for those new CPT codes utilizing the RUC information. The RUC relied on an existing body of evidence demonstrating that these services will increase value and improve patient health outcomes, particularly for patients with multiple co-morbidities, chronic conditions, and those facing access barriers due to geography, limited mobility, or medical fragility. Moving forward, this Subcommittee should ensure that CMS release and study related claims data that will yield important and unique insights on how these services are being employed.

Across these three CPT codes developed to address chronic care remote physiologic monitoring, we urge CMS to provide as inclusive of a framework as possible to maximize the value of remote monitoring to Medicare beneficiaries. We believe that CMS can maximize the value of these new remote monitoring codes by, among other steps, clarifying that:

- Patient-reported physiological data collected via automated remote monitoring technology fits within CMS' definition of physiological data.
- A device used can be caregiver- or patient-provided and need not be prescribed. Requiring that the provider order such a device via a prescription may exclude devices already in use/available, and would reduce needed flexibility in use of 990X0, 990X1, and 994X9 services for both caregivers and patients.
- An established relationship between a provider and a patient exists after such a relationship is created by a provider in that practice.

CHI is deeply engaged with CMS in its regulatory process to support these new codes' activation and in attaining the clarifications above (along with others).

Separately, the Home Health Prospective Payment System (HH PPS) is a payment program for home health agencies (HHAs) which is relevant to this hearing. In its current draft HH PPS rule, CMS proposes to include evidence-based remote patient monitoring expenses used by an HHA to augment the care planning process as allowable administrative costs that are factored into the costs per visit.[12] Such a change will ensure that use of remote patient monitoring is fairly considered on a cost per visit basis when it is used by an HHA to augment the care planning process and will result in a more realistic HHA Medicare margin calculation. However, CMS proposes to define RPM very narrowly as the "collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA." This description does not fully capture RPM elements such as the supply of devices; set up and instruction; data collection [attended, unattended with algorithmic alerts, and unattended]; transmittal; and report preparation

of quantitative results. Further, it makes more sense to use a consistent definition of RPM across its beneficiary programs (e.g., consistency with recently proposed technical codes 990X0 and 990X1). We have asked CMS to shift away from its definition proposed in the draft rule and to align this definition of remote patient monitoring with that proposed for 990X0 and 990X1 and urge this Subcommittee to ensure that CMS takes these necessary steps.

VI. Access to Data and Interoperability

The efficacy of precision medicine, population health, clinical decision support—and AI driven tools in particular—is dependent in large part on the availability of massive data sets. The free flow of information and interoperability are therefore important, potentially life-saving conditions. CHI is committed to advancing health data interoperability throughout the continuum of care.

Electronic health information and educational resources are critical tools that empower patients to engage in their own care. A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called "store-and-forward") technologies (ranging from medical device remote monitoring products to general wellness products) with two-way open APIs that allow the integration of PGHD into EHRs. Data stored in standardized, interoperable formats facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector, and help eliminate information silos, data blocking, and barriers to patient engagement.

Interoperability must not only happen between providers, but also between RPM products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks can be seen in the communications technology industry, which has flourished globally. In addition to testing and finding consensus on industry standards, this Subcommittee should prioritize encouraging the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products. This practice could also be used to measure the interoperability of EHR products. A system demonstrating "widespread interoperability" will provide useable data from various sources, not just from CEHRT and CEHRT systems. A good example of industry-led efforts to establish standardized implementation of a standard is the Argonaut project, which helps standardize the implementation of the Fast Healthcare Interoperability Resources (FHIR) standard. But even private sector efforts like Argonaut can become too focused on compliance-driven efforts in order to meet perceived regulatory requirements. There must also be an incentive to communicate and pass information from one party to another. We also note that MACRA[13] provides that incentive in a value-based healthcare environment—one which engages patients, reduces costs, and documents quality metrics.

We believe this Subcommittee shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD. We strongly encourage this Subcommittee to ensure HHS' interoperability efforts prioritize data generated by patients outside of the traditional care setting. Providers serving the beneficiaries of federal health plans will come to expect access to seamless and secure patient data across the care continuum, where "[i]ndividuals are able to seamlessly integrate and compile longitudinal electronic health information across online tools, mobile platforms and devices to participate in shared decision-making with their care, support and service terms."[14] Moreover, we would support efforts to incent software developers and patients to make use of Medicare claims data. This Administration's Blue Button 2.0 initiative, which would help make this claims data usable via APIs to developers is a good start and this Subcommittee could supplement those efforts by ensuring that Medicare covers tools that enable patients to use, analyze, and share their claims data.

A diversity of APIs are emerging to assist in bringing PGHD into the continuum of care, but we stress that not all of these are necessarily well integrated with EHRs. While CEHRT will be required to support APIs, many vendors will enable "read only" access, allowing for data to only flow out of the EHR rather than both in and out. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards. Creating "special effort" to develop applications and undue burden and costs for our members. CHI reiterates our concern with, and lack of confidence in, any

presumption that the 2015 ONC CEHRT standards will facilitate seamless interoperability.

Further, privacy laws like the Health Insurance Portability and Accountability Act (HIPAA) also tend to—contrary to the name of the law itself—impede the portability of a patient's data from one provider to another. Although we do not suggest statutory changes to HIPAA, we have urged HHS' Office of Civil Rights (OCR) to provide updated and clear guidance to covered entities and business associates such that providers may observe the spirit of HIPAA's requirements without fear of "gotcha" enforcement tactics. CHI supports OCR's use of the fines it collects through enforcement for proactive educational efforts by OCR to improve the privacy posture of covered entities and business associates, rather than simply using those funds to bring further enforcement actions.

Within Medicare, moving away from the Meaningful Use program's "pass/fail" approach, CMS has adopted a Promoting Interoperability scoring regime that is less prescriptive and burdensome. CHI continues to work with CMS to ensure that compliance burdens for PI participants are as low as possible to maximize participation, and we support proposed changes to the PI scoring regime and measures proposed with increased flexibility and lower compliance burdens in mind (e.g., scoring measures at the objective level; and moving away from numerator/denominator scoring, and instead utilize a yes/no attestation; and aligning the hospital and physician PI programs by extending the 50-point score standard – recently finalized for hospitals in the IPPS – to physicians). The Subcommittee could encourage CMS to adopt the scoring approach across beneficiary programs to promote simplicity and certainty for digital health stakeholders.

CHI, like many others, is anticipating ONC's release of its draft information blocking rulemaking required under the 21st Century Cures Act. As information blocking is defined in law, we see the rule providing key insights into what is not info blocking. For example, CHI believes that the rule should make it clear that an entity is not data blocking in the event that patients cannot access their entire medical record through a mobile app and cannot receive their entire medical record in a format of their choosing (e.g., an app). This data may be limited for a few reasons, including security concerns regarding their own system(s) or recipient's system(s), as our members rely on strong encryption to protect sensitive health data; data segmentation (for privacy); and lack of access to information (e.g., no connectivity). While the 2015 Edition CEHRT includes API functionality that requires patients have access to at least the common clinical data set (CCDS), which is 21 data elements, expectations about what can be accessed through an app may need to be managed. CHI commits to work with this Subcommittee, HHS, and other stakeholders in encouraging the use of APIs that pull more than CCDS. Further, CHI anticipates the information blocking rulemaking to clarify:

- What constitutes "special effort" in eliminating blocking and promoting interoperability;
- How "should have known" is defined;
- How patient access is measured;
- How its rulemaking interacts with HIPAA requirements, ONC certifications, the Trusted Exchange Framework and Common Agreement (TEFCA), etc.;
- What constitutes a "violation," and the informal and formal pathways to complaint adjudication;
- Whether OCR will offer safe harbors utilizing constructs such as the TEFCA/ U.S. Core Data for Interoperability (USCDI), the ONC Interop Standards Advisory, etc.;

This Subcommittee may also be able to help by ensuring that CMS works in concert with sister agencies that are working to address the same issues now. For example, the National Coordinator for Health Information Technology (ONC) is currently developing TEFCA and U.S. Core Data for Interoperability (USCDI) to advance interoperability, on which CHI has provided its detailed input; further, an information blocking rulemaking must be advanced by ONC at some point. The Federal Trade Commission also plays an important role. We urge the Subcommittee to ensure that the agencies within HHS align their approaches and to ensure that they minimize compliance burdens on affected stakeholders. As such, CHI supports CMS' proposal to have participation

in the TEFCA qualify as a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. CHI strongly supports incentives to ensure the secure exchange of information. We urge that reporting requirements present as low a burden as possible and that the new CMS rules do not have the effect of incentivizing taxing data dumps that have little practical value.

VII. Providing Broadband Infrastructure to Support a Connected Health Continuum

CHI supports the efforts to provide much-needed infrastructure for broadband connectivity generally, and in the healthcare context specifically, particularly in rural parts of the United States that face both chronic diseases (e.g., diabetes, heart disease, and COPD) and a lack of accessible health care facilities.[15] For example, in Mississippi, the American Diabetes Association approximated that 371,662 Mississippians (15.4 percent of the state's adult population) live with diabetes and about 810,000 Mississippians (37.5 percent of the state's adult population) have pre-diabetes blood glucose levels.[16] Despite alarming rates of diabetes, Mississippi has only 53 physicians per 100,000 people, painting a dire picture for the treatment of this otherwise manageable condition.[17] Nationally, every year, physicians diagnose 1.5 million Americans with diabetes, adding them to the 30.3 million Americans already battling the disease. More than 320 million people in the United States could require health care services at any time.[18]

As of last year, about 8 percent of Americans still lack access to broadband.[19] Meanwhile, new and innovative internet of things (IoT) technologies and deployments, requiring robust mobile broadband connections, are almost ubiquitous in today's economy.[20] And of the approximately 24.5 million Americans who continue to lack access to broadband,[21] most are in rural areas. Compounding the issue, rural Americans also suffer from higher rates of chronic disease than in metropolitan areas[22]—conditions that can be improved substantially with connected health tools like remote patient monitoring and telehealth. The critical nature of the healthcare sector mandates that improvements be made to America's critical infrastructure, and this includes broadband infrastructure and measures to give healthcare providers the ability to use connected health technology products and services throughout the continuum of care, both inside and outside the doctor's office.

CHI supports increased connectivity for rural health care and recognizes the Federal Communications Commission's (FCC) role in this respect. While the Commission's Rural Healthcare Fund (RHCF) has been a useful means for connecting eligible healthcare facilities, support for connectivity to enable remote monitoring is lacking to the detriment of countless rural American patients in need. The FCC has identified numerous barriers to broadband infrastructure deployment and has recently proposed several measures to address these barriers.[23] The FCC has committed to close the digital divide by establishing a "Gigabit Opportunity Zone" program, which would "bring broadband and digital opportunity to our nation's most economically challenged areas."[24] Even more recently, the FCC has proposed to establish a Connected Care Pilot Program to provide broadband services
to connect rural patients with healthcare facilities utilizing cutting-edge remote monitoring tools. CHI has urged the Commission to continue this trajectory to ensure that the necessary infrastructure is in place to facilitate more innovative mobile broadband solutions. We remain committed to assisting this Committee and the FCC in bringing the power and utility of the connected-health revolution to every American.

As the FCC considers options for greater broadband connectivity, it is important that the FCC utilize every spectrum resource it has available, whether licensed or unlicensed. For example, television white spaces (TVWS), unused portions of the television band, have the proven capabilities to deliver broadband connectivity to wide-ranging areas, without sacrificing bandwidth strength or speed. More importantly, TVWS does not require an extraordinary amount of infrastructure to deploy as TVWS-enabled broadband simply requires a TVWS device that can connect to an existing transmission tower, even if it is many miles away. Several pilot programs have even shown that TVWS-enabled devices do not require grounded electricity to be functional. Lastly, TVWS bands can help ease the programmatic strains associated with "last mile" connections, helping paying consumers avoid unnecessary increases in USF service charges on their next phone bill. We urge FCC action to unlock the ability to use TVWS for rural healthcare connectivity.

VIII. Conclusion

Digital medicine can save lives—but only if we let it. Inextricable from the story of connected health is the fact that the American healthcare system for decades was driven not by value but by a constant stream of services. Now, digital medicine could help revolutionize healthcare as mobile technology has fundamentally improved banking. Alternatively, bureaucratic inertia and red tape could keep the cloud-plus-mobile improvements that have redefined our daily lives in countless other ways forever on healthcare's sidelines. We applaud the Subcommittee for shedding light on the existing barriers to the adoption of innovative means of enabling an American healthcare system that is more valuable to patients, providers, and taxpayers alike.

Endnotes

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Mr. BURGESS. Thank you, Mr. Reed.

And Dr. Robertson, you're recognized for 5 minutes, please.

STATEMENT OF DR. MICHAEL ROBERTSON

Dr. ROBERTSON. Chairman Burgess, Ranking Member Green, and members of the subcommittee, thank you for the opportunity to testify on behalf of the National Association of ACOs.

NAACOS is the largest association of accountable care organizations representing more than 6 million beneficiaries through more than 360 ACOs. I share my perspective as a practicing internal medicine physician since 1986 and currently as Chief Medical Officer of Covenant Health Partners and Covenant ACO in Lubbock, Texas.

Covenant Health Partners formed in 2007 and we have had a clinically-integrated network for 11 years now. Through our network we have instituted robust health information technology, contracts for hospital services, and quality metrics for measures like hospital-acquired infections.

We then branched out to commercial contracts and in 2014 made the quantum leap to a 3-year Track 1 Medicare Shared Savings Program agreement. If we had not already had a clinically integrated network in place where we had already done much of the work to get ready for MSSP participation, it is unlikely we'd have made the decision to participate in the MSSP.

It is also important for us that we didn't have to be concerned about taking downside risk since we were in a share savings only model. We learned that moving to value-based care is a massive undertaking that requires changing the behaviour of multiple providers.

We've had to change physician behavior, hospital behavior, skilled nursing facility behavior, home health agency behavior, and the list goes on. In looking at our MSSP financial data we came to understand that much of our cost was coming from post-acute care, namely, skilled nursing facilities whose costs are 180 percent higher and home health agencies whose costs were 250 percent higher than national normative data.

We had to work closely with those providers to see costs go down and that took time and effort. By developing and working with providers in our preferred post-acute care network, we eventually got to a place where we have seen quarter by quarter decreases in costs in these areas.

Participation in the MSSP has allowed us to reinvest in technology and infrastructure to manage our patient population. In our first year of participation in the MSSP, we saved Medicare $5 million and our share of that was $2.5 million through the gains sharing arrangement.

We used the bulk of those funds to reinvest in our IT infrastructure and developed a physician dashboard for quality data such as adhering to evidence-based practices for chronic disease management and preventative care like pneumococcal vaccines and colonoscopy for our patients are displayed.

We also invested in an analyst to review and manage our financial and quality data. One challenge we've had there is that finan-

cial data for Medicare is only available on a quarterly basis and then we receive that data some 4 to 6 weeks after that.

So any change in our process can be delayed. We also hired care coordinators and invested in software to manage care. We now receive real-time alerts through our care coordination system when our patients arrive at the emergency department that allow us to push a care plan for the patient to the emergency room physician so that he or she isn't working blind and can assist us in providing high-quality cost efficient care.

All of these things take time and money. Pushing too quickly to achieve results and take on risk without giving ample time for providers to develop the necessary infrastructure will mean providers will not participate.

In year one of our Track 3 agreement, we ended up with a small profit. But based on early actuarial work, at one point we thought we would have to repay CMS $1 million to $4 million because that financial reconciliation for the MSSP was is delayed by about 8 months after the contract ends. Had my physician board of directors been told they would even have to pay back $1 million, there's no way that we would have continued participation in the MSSP.

From a provider perspective, it doesn't make sense to assume financial risk to take care of Medicare patients as this entails accepting responsibility for costs the physicians cannot control such as the increasing costs of pharmaceuticals like chemotherapy.

I think CMS has had some very positive changes in the new proposed rule. The expansion of the 3-day SNF waiver and the increased stability in the rule are both great improvements.

I do have significant concerns about the speed at which the agency is asking people to move to risk though as well as the proposal to cut shared savings from 50 percent to 25 percent.

Two years is not enough time to take on risk. It took us 11 years and we are still hard at it, and the reduced shared savings amount is going to keep providers out of this program because it doesn't allow them to retain enough savings to reinvest in the IT infrastructure and care coordination that is needed to make these programs work.

Furthermore, the limitation of the risk score adjustment between positive 3 percent and minus 3 percent over an entire 5-year contractual period will also be harmful as it will penalize physicians financially for taking care of patients who are sicker.

I commend this committee on its work to examine ways to increase the use of value-based models and arrangements in the Medicare program.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Robertson follows:]



Statement

of

Michael Robertson, MD

Chief Medical Officer, Covenant Health Partners

on behalf of the

National Association of ACOs

to the

U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Health

Re: Examining Barriers to Expanding Innovative, Value-Based Care in Medicare

September 13, 2018

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Michael Robertson, MD, Chief Medical Officer, Covenant Health Partners

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Re: Examining Barriers to Expanding Innovative, Value-Based Care in Medicare

September 13, 2018

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee, thank you for the opportunity to testify on behalf of the National Association of ACOs (NAACOS). NAACOS is the largest association of Accountable Care Organizations (ACOs) representing more than 6 million beneficiary lives through more than 360 ACOs, NAACOS works on behalf of ACOs across the nation, including Medicare Shares Savings Program (MSSP), Next Generation, and commercial ACOs, to improve the quality of Medicare delivery, population health and outcomes, and health care cost efficiency. NAACOS shares the goal of the Committee to accelerate value-based transformation and I appreciate the opportunity to provide my and the Association's views on barriers to expanding innovative, value-based care in Medicare.

I share my perspective as a practicing internal medicine physician since 1986 and, currently, as the Chief Medical Officer of Covenant Health Partners and Covenant ACO in Lubbock, Texas. Covenant Health Partners formed in 2007 and we have had a clinically integrated network for 11 years now. Through our network, we have instituted robust health information technology, contracts for hospital services, and quality metrics for measures like hospital-acquired infections. We then branched out to commercial contracts and, in 2014, made the

quantum leap to a 3 year Track 1 Medicare Shared Savings Program (MSSP) agreement. If we had not already had a clinically integrated network in place, where we had already done much of the work to get ready for MSSP participation, it is unlikely that we would have made the decision to participate in the MSSP. It was also important for us that we didn't have to be concerned about taking downside risk, since we were in a shared savings-only model.

We learned that moving to value-based care is a massive undertaking that requires changing the behavior of multiple providers. We've had to change physician behavior, hospital behavior, skilled nursing facility behavior, home health agency behavior—the list goes on. In looking at our MSSP financial data, we came to understand that much of our cost was coming from post-acute care, namely skilled nursing facilities—whose costs were 180% higher and home health agencies whose costs were 250% higher than national normative data. We had to work closely with those providers to see those costs go down and that took time and effort. By developing and working with providers in our preferred post-acute care network, we eventually got to a place where we have seen quarter by quarter decreases in costs in these areas.

Participation in the MSSP has allowed us to reinvest in technology and infrastructure to manage our patient population. In our first year of participation in the MSSP, we saved Medicare $5M and our share was $2.5M. We used the bulk of those funds to reinvest in our IT infrastructure, and developed a physician dashboard where quality data such as adhering to evidence based practices for chronic disease management and preventative care like pneumococcal vaccines and colonoscopies for our patients are displayed. We also invested in analysts to review and manage our quality and financial data. One challenge we had there is that the financial data is only available on a quarterly basis, and then we receive the data about four to six weeks after that, so any change in our process can be delayed. We also hired care coordinators and invested in

software to manage care. We receive real time alerts when our patients arrive at the emergency department (ED) that allow us to push the care plan for a patient to the ED physician so that he or she isn't working blind and can assist us in providing high quality, cost efficient care.

All of these things take time and money; pushing too quickly to achieve results and take on risk, without giving ample time for providers to develop the necessary infrastructure, will mean people don't participate. In year one of our Track 3 agreement, we ended up with a small profit, but based on some earlier actuarial work, at one point we thought that we would have to pay $1-4M back because the final financial reconciliation for the MSSP is delayed by eight months after the performance year is concluded. Had my physician Board of Directors been told that they would have to pay back $1M, there is no way that we would have continued participation in the MSSP. From a provider perspective, it doesn't make sense to assume financial risk to take care of Medicare patients as this entails accepting responsibility for costs that physicians cannot control such as the increasing cost of pharmaceuticals such as chemotherapy.

It's important to note that ACOs save Medicare money. In 2017, 472 ACOs caring for 9 million beneficiaries participated in the MSSP, generating gross savings of $1.1 billion based on the CMS methodology for setting financial benchmarks.[1] According to 2017 CMS performance data, 60 percent of ACOs saved money in 2017 and 34 percent of ACOs earned shared savings, up from 56 percent and 31 percent, respectively, in 2016. After accounting for shared savings earned by ACOs in 2017, net Medicare savings were $314 million. Notably, the 2017 results also show a continued trend where ACOs that are in the program longer are more likely to earn shared savings and save money overall for Medicare. We also know that ACOs produce better

[1] Centers for Medicare & Medicaid Services. "2017 Shared Savings Program (SSP) Accountable Care Organization (ACO) public-use file (PUF)," available at https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Savin/2017-Shared-Savings-Program-SSP-Accountable-Care-O/gk7c-vejx/data.(August 30, 2018).

quality. For example, a 2017 U.S. Department of Health & Human Services Office of Inspector General (HHS/OIG) report found that ACOs achieved high quality and, in particular, noted progress on important measures such as reduced hospital readmissions and screening beneficiaries for risk of falling and depression.[2]

As the Chief Medical Officer of an ACO that has succeeded over time in the MSSP program, I have observed the work of the Centers for Medicare & Medicaid Services (CMS) to improve and accelerate the program closely. On August 9th of this year, CMS issued a proposed rule that would set a new direction for the MSSP, referred to as the "Pathways to Success" Program.[3] The proposal would improve the existing MSSP in a number of ways, including: lengthening agreement periods from 3 years to 5 years; providing an additional 6-18 months in one-sided risk for 82 current ACOs that would otherwise be required to move to risk on January 1, 2019, if renewing participation; implementing ACO-specific payment rule waivers—such as the expansion of the three-day SNF waiver—and beneficiary incentives; and decreasing burdens related to meeting Electronic Health Record (EHR) requirements. Some of these improvements will lend stability to the program, which is very positive.

The proposed rule also includes three measures which will likely have the unintended impact of discouraging participation of new ACOs. First, the rule shortens the onramp to taking on downside financial risk for new ACOs from 6 to only 2 years. Two years is not enough to take on risk; it took us 11 years and we are still working on it. And, based on a NAACOS survey

[2] Office of Inspector General, U.S. Department of Health & Human Services. "Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality," (OEI-02-15-00450) (August 2017).
[3] Centers for Medicare & Medicaid Services. "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations – Pathways to Success," 83 FR 41786 (CMS-1701-P) (August 17, 2018).

conducted earlier this year, this will likely result in more than 70 percent of early ACOs leaving the program.

Second, the proposed rule cuts shared savings in half for shared savings-only ACOs, from 50% to 25%, which could severely undermine the business case to join the program and begin the transition to value-based payment for new ACOs. The reduced shared savings amount is going to keep providers out of this program, because it does not allow them to retain enough savings to reinvest in the IT infrastructure and care coordination that is needed to make these programs work.

Third, the limitation of the risk score adjustment of +/-3% over the 5-year contractual period will also be harmful as it penalizes physicians financially for taking care of patients who are sicker. In order to avoid having physicians refusing to accept and provide care to medically complex patients, the risk score adjustment must be reflective of the true risk of the patients under the care of the ACO and it must change, either positively or negatively, as the risk of the patient changes.

I am hopeful that, in light of these significant concerns, the final rule increases the allowed time in upside-only ACOs to at least three years for BASIC Levels A and B (previously Track 1) ACOs—and, for certain ACOs that meet quality and cost standards, allow additional years—and rescinds the proposed decrease in the shared savings rate. Furthermore, I would like for the final rule to be modified to allow for annual adjustments in the risk factor adjustment for patients that is truly reflective of their individual risk and not limited to an arbitrary adjustment which is cumulative over the 5 year contract.

On the topic of barriers to value-based care, I urge the Committee to review barriers which inhibit ACO access to real-time care coordination information. It is widely recognized that

giving timely, actionable data to healthcare providers allows them to work closely with beneficiaries to effectively manage chronic conditions or prevent health conditions from worsening. However, to effectively manage a beneficiary's health, ACOs need more timely and in-depth data. CMS should set standards for timeliness and data set definition to be used across ACOs to effectively manage populations. The data available in the HIPAA Eligibility Transaction System (HETS) is very meaningful and should be provided in real time to ACOs for their beneficiaries. This would allow ACO providers to communicate with treating providers at the hospital and to work with the beneficiary upon his or her release to ensure optimal treatment, medication adherence and follow up care. We urge the Subcommittee to work with CMS to develop a mechanism to share more robust health data, including that from HETS, with ACOs in real time to enhance care coordination, improve outcomes, and reduce costs.

As we look toward the future of value-based care in this country, ACOs should be encouraged to succeed and grow in numbers so that every Medicare beneficiary has the option to join an ACO. Policies which would shrink the pool of ACOs are going in the wrong direction; we should remove barriers to ACO growth, not impose new barriers.

I commend this Committee on its work to examine ways to meaningfully evaluate and responsibly increase the use of value-based models and arrangements in the Medicare program. Thank you for the opportunity to testify.

Mr. BURGESS. And thank you, Dr. Robertson, and thanks to all of our witnesses for spending time with us this afternoon.

Mr. Green, I will once again offer to recognize you for an opening statement. If not, we'll go directly to questions.

Mr. GREEN. I think we'll go directly, and I ask unanimous consent to place my statement into the record.

Mr. BURGESS. And without objection, so ordered, and——

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Good afternoon and thank you all for being here today.

Today's hearing is titled, "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare."

I want to thank the Chairman for having this hearing and I thank all of our witnesses for joining us today.

Today's hearing focuses on the current transition in the Medicare Program away from fee-for-service and towards a value-based payment system that is centered on the patient.

One of the main ways the Affordable Care Act sought to reduce healthcare costs is by encouraging doctors, hospitals and other healthcare providers to form networks that coordinate patient care and become eligible for bonuses when they deliver that care more efficiently.

ACA took a carrot-and-stick approach by encouraging the formation of accountable care organizations, or ACOs, in Medicare.

Today, there are 472 ACOs operating in the United States, caring for 9 million beneficiaries.

In 2015, our committee passed the Medicare Access and CHIP Reauthorization Act (MACRA), which expanded on the ACA to further encourage the use of value-based compensation by encouraging providers to create incentives to participate in new care delivery models that increase quality and reduce costs.

Starting next year, Medicare providers must participate in either the Merit-Based Incentive Payment System (MIPS) or an Advanced Alternative Payment Model. Both options are value-based systems. This has led providers in recent years to adopt new care delivery systems.

Studies have shown that value-based care systems lower costs to the overall health system while improving patient outcomes, a win-win that everyone should support.

ACOs saved Medicare an estimated $1.1 billion in 2017, with a net savings of $314 million after bonuses were paid out. This is a significant improvement over previous years and a clear sign that ACOs are succeeding as intended.

Additionally, the experience with the Shared Savings Program has shown that ACOs do better over time, both in terms of performance on quality measures and at generating savings, as they gain experience with care transformation.

Studies have shown that ACOs have reduced readmissions from skilled nursing facilities, generated fewer emergency department visits and hospitalizations, and had less Medicare spending overall relative to comparison groups.

I am concerned with the proposed rule the Centers for Medicare & Medicaid Services (CMS) issued on August 17 that would shorten the onramp for new ACOs to take on downside financial risk from 6 to only 2 years.

I am also concerned that the proposed rule cuts shared savings in half for certain ACOs from 50 percent to 25 percent.

I am looking forward to hearing from our witnesses who have managed or have experience with ACOs on their views on the proposed rule and whether this proposal may be harmful to current and new entrants.

I know some stakeholders are interested in making changes to the Stark Act and AntiKickback statute. I agree that Congress should be open to revisiting current laws if these regulations are bona fide barriers to value-based care.

However, the Stark Act and Anti-Kickback statute were put in place to protect patients and taxpayers from potential abuses, including subjecting patients to unnecessary testing and referring patients to lower quality services.

According to the Government Accountability Office last year, improper payments in Medicare accounted for $51.9 billion. The Stark Act and Anti-Kickback statute continue to serve important roles in protecting taxpayers from waste, fraud, and abuse.

Any effort to reexamine these laws must place the importance of protecting patients and taxpayers from excessive costs and abuse at the top of the priority list.

Thank you again, Mr. Chairman, for holding this hearing, and I yield the remainder of my time.

Mr. GREEN. I will share it with all of you all. You can read it on the way home.

[Laughter.]

Mr. BURGESS. The chair would remind all members that all members' opening statements will be made part of the record, filed following Mr. Green's missive.

So I will recognize myself 5 minutes for questions and, Dr. Weinstein, thank you for being here. You represent I guess what we would describe as independent physicians. Is that a fair assessment?

Dr. WEINSTEIN. Yes, independent gastroenterologists—about 1,900 across the country.

Mr. BURGESS. So you raised the issue of independent physicians—the difficulty they might have in accessing the alternative payment model and being able to participate in that.

Could you just kind of go over what are the major obstacles for the independent physician to be able to participate in an alternative payment model?

Dr. WEINSTEIN. Yes, certainly. Thank you.

Independent physicians, particularly sub-specialty physicians take care of chronic disease. We don't do primary care. We are used when a patient needs a particular service or has a particular disease.

So in a standard ACO type APM, we are technicians, in general. But an independent practice like ours takes care of a lot of patients with chronic inflammatory bowel disease, chronic liver disease. These are very high cost, high beta, high variable cost patients that generally are managed—even their primary care is managed by gastroenterologists.

In developing an alternative payment model for inflammatory bowel disease, we grouped. Our association got together and used actuaries, did the data analytics using our own data to determine what a model to take care of patients over a long period of time would be.

Project Sonar was that APM. It was actually the first APM presented to PTAC when PTAC started. It received a tentative approval for testing and then got stuck. It does use technology to engage patients in their own care so that we could do outreach and try and identify patients before they show up in the emergency room, before they show up in the hospital.

So the difficulties in developing that APM, obviously, there was a cost burden in getting the actuarial data. There was an inability to test to model because of the Stark prohibitions and then not knowing how to modify it, obviously, it makes it difficult.

So we are sort of shut out of APMs as gastroenterologists because we don't have any alternative payment models that we can participate as independent physicians.

But we are very willing to invest in the technology to do that.

Mr. BURGESS. Sure. If we can overcome some of those obstacles and those obstacles would be what you just delineated. I may get

back to you in a written question form about PTAC because I've got a particular sensitivity to that. PTAC was a creation of, basically, this subcommittee a couple Congresses ago and, conceptually, PTAC was there so that physicians would be back in charge of quality metrics as opposed to leaving that all up to the agency.

So it is very important to me the PTAC work and I am discouraged to hear that you're having trouble. So I may follow up with you on that because I do feel that it's such an important concept.

But Dr. Anand, let me just ask you, in moving to downside risk models to allow a system like Adventist to integrate independent physicians into your networks, is that a possibility?

Dr. ANAND. Great question, Mr. Chairman.

From a philosophical perspective, two-thirds of our clinically integrated networks are independent physicians, and so we have always approached with the philosophy that we want to have the best clinicians to be part of our networks.

Sometimes it's the best employed physician. Sometimes it's the best independent. But we hold ourselves to high standards. We want physicians who are going to be focused on quality at the best experience at an efficient cost.

So with that, as we transition into the post-MACRA world and being part of an advanced APM becomes more important to our independent physicians, we've seen that as a great way for us who are in a Medicare shared savings model to align with our physicians who are going to be either subject to a penalty or a possibility of a bonus in the MIPS program or, alternatively, who are interested in taking more holistic care in moving towards an advanced APM model.

So MACRA is one of the big opportunities that's going to allow us to partner with their physicians. Too, taking downside risk allows us to coordinate care more across the continuum with the waivers that are present, with the ability to bring in more components of the delivery system.

We talked a lot about post-acute. We talked about our specialists. Bringing all those providers together in the—and some are going to be independent, some will be academic, some will be employed—that's going to allow us to coordinate care more holistically.

It's also going to allow us to share tools and technologies to achieve that coordination—sometimes apps, sometimes EMR-integrated tools that are going to be part of it. There's an upside potential that could also be—if the ACO is successful that's also going to be an attractive component for the physicians as well. So there's several components. In my mind, I think the MACRA component, especially as we transition into the later years of the MACRA model into the advanced APM model I think there's going to be a lot of synergies with independent physicians.

Mr. BURGESS. And I just want to address for you, since you brought up the interoperability title of 21st Century Cures, the oversight of the implementation of 21st Century Cures has been front and center in front of this subcommittee because the scientific aspects, the FDA NIH aspects. There was actually a mental health title.

So we've had separate hearings on both of those and the third, of course, was the interoperability title, which I thought deserved

its own oversight or its own subcommittee implementation hearing. Because of the delay from the rule coming from the office of the national coordinator I was actually talked into postponing that last June.

In retrospect, perhaps we should have pushed again with the hearing. But and, obviously, we are up against some other things in the calendar which you may have heard about in the papers.

But at some point this year, I intend to have that interoperability title implementation hearing that you said would be critical for you.

Mr. Green, I recognize you 5 minutes for your questions, please.

Mr. GREEN. Thank you, Mr. Chairman, and I thank you for your effort to make the system work.

Dr. Weinstein, about 2 weeks ago I was invited to speak to the gastroenterologists in Houston, Texas, and I was surprised after I got up and talked about MACRA and how we are trying to stay attuned to it as members of Congress, watching what the agency does.

At the end of it, which is not usual, I didn't have any questions at all. So I wasn't sure that the physicians were aware of what's going on.

Have you seen that? And that's not just one specialty. That was just one I happened to speak to a while back.

Dr. WEINSTEIN. I think the largest physician groups around the country have their ears to the ground as to what's happening with MACRA and MIPS. In a gastroenterology practice it's unfortunate that there really isn't a way for us to participate in APMs and we are looking at having to implement MIPS, which is a very expensive way to gather data and a very inefficient way to gather data and yet it has never been proven to help patient care.

So I think smaller groups are unaware of what's happening. I am not sure——

Mr. GREEN. Although in the Houston area we should have a whole lot of gastroenterologists.

Dr. WEINSTEIN. There's some very large groups in Houston. I am familiar with a couple of them.

Mr. GREEN. OK.

Dr. Robertson, welcome to our committee. The chair is from north Texas. I am from Houston, and, obviously, we speak the same language, coming from Lubbock.

Can you speak for a little more on your organization's initial decision to transition in the ACO model and why this model was the best fit for your organization?

I think you answered some of that. You were already on that road that you thought the ACO would work.

Dr. ROBERTSON. We were on the road because we had already gone into Track 1 in 2014. We were making a decision as to whether we wanted to participate another 3 years in Track 1 or move to a different model when a law called MACRA became on our horizon, and like many things in life, timing is everything.

This was fortuitous timing. We looked and the more we began to discover about MACRA, the more we knew we wanted to be qualifying providers under an advanced APM as opposed to being thrown in the briar patch of MIPS. The positive and negative vari-

ations in reimbursement under the MIPS systems is going to be very disruptive for physician practices, especially small physician practices.

Our ACO has a large employee medical group in it that's owned by Covenant Health. But 50 percent of our organization is composed of independent physicians, which are just one- or two-person groups.

The amount of money that has to be put into that to make those folks work under a MIPS system is horribly expensive and together, collectively, we thought that we could do better if we were in a risk-bearing program. We'd already had some experience under Track 1.

We saw what we could do from a quality perspective and we had been decreasing the amount of spend. The difference is, though, the way they calculate your financial benchmarks under Track 3. Totally different than Track 1, and we really didn't have a good understanding of that when we entered into Track 3. So that's made that a little bit problematic for us.

Mr. GREEN. Going from what you were, what type of infrastructure changes and provider education and training did your organization undertake to implement the ACO model? Was it—from where you went to what you're doing now?

Dr. ROBERTSON. We started in 2007 and initially just took commercial contracts. But we started then developing a way of showing physicians their individual performance. Every physician believes that they are the world's greatest physician and they provide absolutely good quality care.

The problem is our system is so broken that it encourages just transactional care. You're there for 15 minutes and then good luck to you, or you get to the hospital dismissal driveway—good luck to you.

Doing this requires you to think differently. You own that patient 365 days a year, 24 hours a day, and you have to have access to some data to help you understand where the spend is occurring and then you have to invest not only in IT systems to show physicians how they're performing but you have to hire a lot of people to help patients do things that you need for them to do.

You can't imagine that a patient is going to be able to take everything you tell them in a 15-minute visit. Our care coordinators can move out into the community with them, help them stay on track, help them set goals for self-care, and provide them some other opportunities to find medications that we sometimes prescribe that we have no idea are so expensive and get them access to the medications they need at a better price.

Mr. GREEN. Well, I've been on the committee since 1997 and it's, like, I got so tired of hearing about how bad the SGR was and that's why this committee wants to stay on top of it because the last thing we want to do is recreate the problems physicians had under the SGR, and that's why I appreciate the whole panel to be here.

By the way, my son-in-law is a gastroenterologist and my daughter is in infectious disease so and they do think they can cure everything.

[Laughter.]

Mr. BURGESS. They probably can.

Mr. GREEN. And I am glad they can.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, the vice chairman of the subcommittee, 5 minutes for your questions, please.

Mr. GUTHRIE. Thank you very much, and the first question is for Mr. Reed, and I think I wrote it down. I was trying to write as you were saying it but I am not that quick.

But you talked about making changes and you said in your testimony make changes in the Stark and anti-kickback laws in order to get the technology in the hands of patients. I think that's pretty accurate what you said.

How does the anti-kickback statute prevent providers from giving patients the tools that may help them, and if we update the statutes how do we effectively protect against fraud and abuse?

Mr. REED. Well, I think that's at the core of the question and I was very pleased to hear several other folks of this panel talk about the fact that the way that, especially in the ACO space, it works is, as I understand it, if a physician group wants to provide technology into the hands of a patient for remote patient monitoring or other patient engagement that might have—part of it would be a referral that it kicks into a consideration under the anti-kickback.

The problem with that is that the very tool that I might put into the hands of a patient, a tablet like this one or anything like that, that I am going to use to gather data on the patient, I am going to want to necessitate a referral if one of the things that shows up from the evidence that I am collecting on that patient says, hey, they need to see a gastroenterologist.

And so the moment that I do that I am in trouble with the law. As far as where the fraud lies, the reality is the fact of remote patient monitoring and digital services it's a whole lot easier to monitor exactly what the use of that device is doing, what it's entailing, how long it's used for.

In fact, the very data that we need to show effectiveness is also going to be very useful to demonstrating that it's not being used fraudulently.

So we think that removing that barrier for good recommendations to good gastroenterologists or infectious disease specialists like Mr. Green's daughter are the kind of tools that we need to make available, and the idea that a patient is now limited because I can't give them the tech that they need, that's just crazy.

Mr. GUTHRIE. I don't disagree with you.

So, Dr. Peck, how are healthcare apps and telehealth services changing the Nation's healthcare access? Sort of mentioned here, and how do we encourage telehealth, from our perspective?

Dr. PECK. Thank you.

In terms of the apps question and technology, I do agree that there is the component that whenever I suggest to have an app in the hands of a patient, when they start to use it if it does generate the idea that they now need to see another physician that can cause a lot of problems in terms of self-referral.

So but moving into telemedicine, there's a lot of talk of 1834 and of Social Security Act, and lifting that. I would like to make the point that lifting that in 1834(m) seems to be a plug into the hole that fee-for-service Medicare beneficiary program has created for itself.

Because smaller companies, startups, innovations even of larger companies and of healthcare systems don't have a way necessarily to value-based contract with Medicare directly, they have no way to get paid for innovative programs that are outside the fee-for-service schedule.

If you have something that's innovative, new, better, cheaper, faster, and brings higher quality, well, that's perfect for value-based care.

So why can't we have a provider contract with Medicare? CMMI is one of the ways to do that. But, again, this is a long, arduous, expensive, and not very flexible process.

The RUSH Act, which I talked about, was introduced and the RUSH Act works for nursing homes but I want to broaden that out. I think what's important about the RUSH Act, when you take a look at it, is that has this value-based arrangement idea with Medicare.

It allows the providers, the doctors, the nursing homes who are housing the patients, and Medicare to all share in any savings that are generated.

And then there's down side risk as well.

Mr. GUTHRIE. I've only got about 30 seconds. To anybody on the panel, so we are talking with Medicare here and how difficult it is to innovate and change things.

Are you seeing it when you're dealing with private health insurance and others?

Dr. PECK. I am talking about Medicare.

Mr. GUTHRIE. I know you are, but do you see it in your private world it's quicker to adapt and you're seeing these changes?

Dr. PECK. Yes.

Mr. GUTHRIE. So that we would lose these changes if we just went to pure Medicare for everybody?

Mr. REED. Absolutely. There are problems on the innovation side, and here's one of the problems.

As we noted earlier, it's a trillion dollars. So anyone, any venture capitalist, when our members are looking at raising money, the VC is going to ask, well, what's the total addressable market, and when you have to describe that one-third of your total addressable market is Medicare and Medicaid, the next question is so how do we get paid out of that system.

So when you look at 1834(m) as a plug that prevents—and I am going to do something unheard of—I am going to say something nice about a government agency—CMS has actually done some good things lately to try to break free of where 1834(m) has been preventing forward progress.

But to your direct question, even though in the private sector there are ways around Medicare and Medicaid reimbursement, there's a trillion dollars of addressable market there that any wise venture capitalist is going to say how do we get to it, and with barrier like 1834(m) it's staving off our ability to move into that space.

So yes, it harms our ability on the Medicare and Medicaid side, and yes, it harms our ability to grow our businesses to cover more people.

Mr. GUTHRIE. Thanks. I am out of time. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from New Mexico, Mr. Luján, 5 minutes for your questions, please.

Mr. LUJÁN. Mr. Chairman, thank you so very much for this important hearing and I want to thank our ranking member, Mr. Green, as well.

I would also like to acknowledge Chairman Walden and Ranking Member Pallone for looking at how telehealth services can be used to improve access to quality care, to save patients and Medicare time, energy, and money.

Dr. Peck, you point out in your testimony that if skilled nursing facilities across the country are to implement telehealth services to scale then something needs to change within the billing system.

The skilled nursing facility value-based purchasing program authorized by the Protecting Access to Medicare Act is shifting Medicare's reimbursement for skilled nursing facilities to a value-based system.

SNFs are now evaluated on a hospital readmission measure that provides incentive payments to encourage SNFs to keep patients healthy.

Dr. Peck, how does Call9 and models like Call9 affect nursing homes' performance under this new reimbursement system?

Dr. PECK. Thank you for that question.

The new reimbursement system and models like Call9 that decrease hospitalizations—unnecessary and avoidable hospitalizations—increases the payments to nursing homes and rewarding them for that good behavior.

And I would mention in my testimony that one of our first nursing homes just finally got their value-based score and they are receiving a large bonus from that.

What that program doesn't do is incentivize the providers—the physician groups who are delivering that care. That program does give the bonus to the nursing home itself but not to the providers, the doctors.

So it's a good program and I think it will help a lot and incentivize a lot of nursing homes to reduce hospitalizations but leaving out the physician groups.

Mr. LUJÁN. I appreciate that very much, especially in light of your testimony and the testimony of others that found that 19 percent of transfers to the emergency department are from skilled nursing facilities—one in five.

You mentioned in your testimony that Call9 model uses additional clinical staff to complement the nursing home staff. Can you elaborate on how the Call9 staff work with nursing homes to treat patients?

Dr. PECK. Certainly. So our particular model we place first responders. These, by training, are EMTs, paramedics. They can be nurses with emergency experience—CD techs.

What unites them all is that they understand emergencies and acute care. I think this is a key point. A broader point is that what we do is we bring the emergency department to the nursing home in this way with the physician who is remote in this onsite.

Nurses in nursing homes are great at chronic care. That's what they do, and if the nursing homes had faculties and staff that could take care of emergencies, we wouldn't have 19 percent of the patients going to emergency department coming from nursing homes.

So what we do is put the emergency care in there to supplement but not—and complement, excuse me, but not supplement what they do—not replace what they do.

Mr. LUJÁN. Many members of the subcommittee worked on recent provisions to expand telehealth reimbursement for telestroke, end-stage renal disease, accountable care organizations, and Medicare Advantage plans.

Dr. Peck, how does the RUSH Act build on this successful legislation?

Dr. PECK. Right. So all of those legislations help address the CBO issue of the CBO scoring telehealth usually as an additive program. The reason for this is they count it as a duplicative measure.

Telestroke—I will key in on that one—end-stage renal disease, we can key on that as well. It's very hard to make more strokes. It's very hard to make more sessions of dialysis every week for a patient.

So it controls itself in terms of the volume that's there and that lends itself perfectly to value-based arrangements and value-based contracting.

Our model is working with emergencies. It's very hard to rack up new emergencies and make more emergencies out of thin air. So when you have that kind of cap on a certain condition I think that's a nice place to start to focus on to start to chip away at bringing value into Medicare.

Mr. LUJÁN. And the requirements under the RUSH Act speak to additional workforce. What qualifications will these people have and is there a way to train existing staff to accomplish the same goal or is there value to bringing in a new person?

Dr. PECK. Yes, I think there are ways to have existing staff become more trained in emergencies, have more skills for emergency medicine, be more comfortable in CPR type settings.

However, I do believe it's important to have additional staff if you're going to retain patients in a nursing home and more patients who are sick. Having the existing staff there and not augmenting with another person I think will take away from the care of the rest of the patients who don't have emergencies.

Mr. LUJÁN. I appreciate that. Thank you, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for your questions, please.

Mr. LATTA. Thanks, Mr. Chair, and to our panel today, thanks very much for being here on this very important topic.

If I could start, Dr. Anand, with you. Do medical professionals or health practice of health practices face barriers, regulatory or otherwise, to adopt new technologies?

Dr. ANAND. Yes, great question. So I think we've alluded to several comments on the barriers that we face. One is related to being able to financially support the costs that go into implementing new technologies and tools.

With our independent physicians, when I was in Texas the average practice size was about one and a half for the independent physicians. Some places are a little bit larger.

But independent physicians don't have the capital in order to be able to make those purchases. When you're in an ACO construct and you apply the Stark waiver and the Stark exemptions, you can now, as a system, come together and allow them to access those tools and technologies and apply it across their patients.

The challenge we find is those tools and technologies, and it's a question that we've struggled with, is can you apply those tools and technologies only for Medicare beneficiaries or apply them broader, more widely, across all of the patients or the provider panel that the patients see.

And that's been a big struggle for us. We'd love to see the Stark waiver expanded and, in an ACO structure, provided at the provider level because as clinicians we can't sort out who's in which program and when a member is in another program.

We can use this tool and technology that's going to change care for this patient but we can't use it in that other patient situation.

So those are some of the challenges that we face. I think if we could, in the ACO construct, we are coordinating care basically—provide these tools and technologies and allow them to use those tools and technologies for all of their patients I think we'd be in a much better situation.

Mr. LATTA. Let me ask you this—just follow up on that. You're talking about the independent practitioners out there. Would that also—these barriers be disproportionately affecting small and rural providers because—who could benefit quite a bit from telemedicine?

Dr. ANAND. We do. In our health system we have several markets that are in rural markets. We have one in Asheville, North Carolina—a campus that's there. We also have one in Manchester, Kentucky, and in those settings what we are finding is it's becoming harder and harder to have specialists and particular services provided in those markets.

Now, in our system, we have a great skill set and great number of specialists in our Orlando market and we would love to be able to provide that cognitive expertise to those folks in Manchester, Kentucky, as an example.

The reimbursement models we struggle with we'd love to be able to support the providers that are providing primary care services with the specialists that we have.

And so we struggle again with the Stark rules that go with it. But rural services, at least in my opinion, are going to continue to be harder to come by, especially with specialty services, and when we have these large centers that can provide those services if we could figure out a way through the Stark exemption and payment

models to transpose that cognitive skill to those markets our beneficiaries will be able to get much better care.

Mr. LATTA. Well, if you look at what we could do in Congress, what would you like to see us do specifically?

Dr. ANAND. I think if we could do two things—one is allow us in certain, especially rural markets and critical access and hospitals that don't have access to larger partnerships—allow us to provide those tools and technologies through a Stark exemption.

Number two is if we could figure out a payment model where we could reward those services and cover some of the infrastructure costs that go with it I think that would allow us to be able to provide that service on a larger scale and, again, it would allow better access for beneficiaries and the patients that live in those smaller rural areas.

Mr. LATTA. Mr. Reed, with my last minute I have, I am a firm believer that data has the power to spur change and data allows us to recognize important trends and patterns that, in turn, influences decision making and ultimately finds solutions.

How could Congress reduce these barriers to sharing health and patient data without compromising that patient privacy?

Mr. REED. Well, it's a great question and, of course, it's always good to remember that the P in HIPAA stands for portability, and I think that's at the core of where we stand.

We would urge Congress to do everything in your power to address what Dr. Burgess said earlier and that is let's see ONC's report on info blocking, because ultimately, as we are moving into this space where data has to be available and interoperable, we know that the only way to get a patient the solution that they need is to find out what's wrong with them, and the more data that all of these gentlemen here at this table, and Mary, can have, the better chance we have of correctly identifying the disease and, more importantly, getting you the right treatment at the right time.

So, first of all, we need to do better on interoperability. Second, we need to continue to push forward on finding the right terms and glossaries so that the notes fields, which are a key aspect of how a doctor communicates your story, not just your test results, becomes part of a record that can be used by every single person at this table. And so it starts with ONC. Let's see what they have to say.

Mr. LATTA. Thank you very much.

Mr. Chairman, my time is expired and I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair now is pleased to recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions, please.

Mr. GRIFFITH. Thank you very much, Mr. Chairman.

First, before I do that, I have a letter that has been sent in support of the RUSH Act, which Dr. Peck was so kind to make nice comments about earlier that Mr. Luján and I of this committee have signed onto along with a number of others, including Adrian Smith. But I have a letter, without objection, if we could submit that for the record.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. GRIFFITH. We'll get that down to you. All right, I appreciate that.

And, Dr. Peck, again, thank you for your kind comments on the bill and I know we've got a lot more to do, and this just gets us started and you made some comments in that regard as well.

You also mentioned in your testimony that Call9 treats 80 percent of the patients you see in the nursing home versus transferring them to the emergency department.

How do you interact with the other 20 percent of patients that are still transferred to the emergency department?

Dr. PECK. It's a great question. That's where we get to save a lot of lives that otherwise wouldn't be saved. That's why I left my job as a traditional emergency physician. Someone took my job as an emergency physician after I left, right.

But these patients who we can't get to in their moment of emergency in these nursing homes they otherwise would be pulseless. They otherwise would be having very severe problems.

But with our program and other programs in nursing homes we can get to them at that point, and the average—when you put all the numbers together after you call 911 it takes about 64 minutes including the wait to see an emergency physician. If you're pulseless, across the country that can be 36 minutes. So yes, being with people at the moment of emergency saves lives.

Mr. GRIFFITH. And that's very good. But I guess I am trying to figure out, OK, what happens once they go off to the emergency room? You have decided that you all can't take care of it and you're getting 80 percent of them right there in the nursing home—they never have to make that trip and, as you describe in your opening statement, with the bright lights that are confusing and the long wait and the ride in the back of a van. It's an ambulance. But when you're sick and not feeling well, it's just the back of a van.

Dr. PECK. Yes. Yes.

Mr. GRIFFITH. So how are you able to continue to interact with that 20 percent that's at the hospital?

Dr. PECK. Right, and we talk a lot about interoperability and pushing data over, and writing—even being able to write notes in the same language that an emergency department needs to see and streamlining the data transfer is where there's a lot of opportunity to help those patients. Yes.

Mr. GRIFFITH. All right.

And in your testimony, you stated that Call9 currently operates in 10 nursing homes in New York—and this was in your written testimony—but has not spread to more rural areas.

Yet, how would Medicare's reimbursement of technology-enabled care delivery models allow for these models to reach more rural areas?

Dr. PECK. Yes. So right now, we are dependent on the Medicare Advantage and commercial payers to be able to make this happen. So we have to go to areas where those MA penetrations is as high as possible, which is usually urban areas as well as larger nursing homes where there's more MA patients.

So we can't possibly go to smaller nursing homes or Medicare-heavy nursing homes right now. We would lose the company.

Mr. GRIFFITH. Now, you said Medicare heavy. What about Medicaid-heavy nursing homes?

Dr. PECK. Right, so long-term care Medicaid patients are usually dual eligible for the most part because they're over 65 for the most part, or disabled for the most part. So Part B is where these payments are coming from, not from the Medicaid program.

Mr. GRIFFITH. OK. I appreciate that.

Representing a fairly rural not affluent district, this is one of the reasons that I am pushing for these ideas because my constituents deserve to get just as good care as those folks in the urban areas or in the wealthier areas.

Let's see if I have time to get one more in.

Dr. Peck, one issue policy makers have faced in advancing telehealth legislation is the lack of data, and I know everybody's talked about data, but the lack of that data on the effects of telehealth on actual Medicare beneficiaries, this is a hard barrier to overcome because without reimbursement for providing these services to Medicare beneficiaries there are few who are going to be able to take the financial loss to build enough meaningful data.

How can Congress continue to support entrepreneurs in generating these meaningful data points?

Dr. PECK. Yes, it's vehicles to be able to get these models through after they're proven, the PTAC being one of those. We have held back our PTAC application at this point until we understand more about what the program intends to do.

We also see this opportunity—the RUSH Act as the tip of the spear to be able to have Congress directly allow Medicare to contract with startups and entrepreneurs and innovative programs.

We need those on that side to be able for me, as an entrepreneur, to go to the venture community and raise money. They're not going to give it to me unless there's a way to make return on that investment.

Mr. GRIFFITH. Right. Well, I appreciate it and appreciate all of you all being here. This is an important subject and I look forward to working with all of you as we move forward.

I yield back.

Dr. PECK. Thank you.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for questions, please.

Ms. MATSUI. Thank you, Mr. Chairman. I want to thank the witnesses for joining us today. I am pleased that we are hosting this hearing to discuss how we transition toward rewarding value over volume in our healthcare system.

Thanks to the Affordable Care Act, the MACRA providers today have more opportunities than ever before to redesign how they deliver care to their patients.

Moving to value-based care is important. But we can't lose sight of the importance of the Stark Law in protecting the Medicare program from waste, fraud, and abuse.

Although a shift to value-based care may require re-examination of certain policies, the self-referral laws continue to serve an important purpose.

It is important to differentiate between changes to Start Law that would lead to more value-based payment models and coordinated care and changes that would gut the intention of Stark and allow the pay for play at the expense of patients.

Several of you note that the secretary has authority to waive the Stark Law for innovative value-based arrangements.

Mr. Reed, your testimony notes that you believe that HHS has clear authority to provide exceptions to the Stark Law. Can you expand on what steps you believe the secretary can take to modernize Stark to encourage high quality value-based care?

Mr. REED. Well, I think you have heard from the multiplicity of the witness perspectives here that essentially the secretary needs to look at the Stark and any kickback from the perspective of what is your ultimate goal.

You said the ultimate goal is to make sure that we don't have waste, fraud, and abuse. I would posit the primary goal of Medicare is to make sure that people over the age of 65 have the kind of care that helps them stay healthy and be independent.

And so when I look at it from the perspective of what is the capability of the secretary to waive, you used some key words, which was innovative technologies that can help improve the outcome.

And so I think that with each request for an exception I think it falls under that waiver authority. But I also would note that we have to be very careful with waiver authorities to something that Dr. Peck said earlier, which is when it only happens every year enough to renew, it makes it quite difficult when you sit down with a venture capitalist and your new board to say our entire business model is dependent on our hope that a waiver will continue to the next year.

Ms. MATSUI. Yes.

Mr. REED. And while we are not only bidden to the VC community, we have limited resources. It changes where you focus your time and energy if you have that possibility hanging over your head.

So I would like the waiver to be exercised on those innovative technologies but in a manner in which allows us to really build and grow them and not just worrying about——

Ms. MATSUI. OK.

Mr. REED [continuing]. Where there might be an overuse.

Ms. MATSUI. OK. Now, I want to get into telehealth, because over the years a group of us on Energy and Commerce have worked together to advance the adoption and use of Telemedicine.

As CMS implements MACRA, we want to make sure that the new health technologies are integrated into new models of care from the start.

And, Mr. Reed, in MACRA Congress intended for telehealth and remote monitoring to be rewarded within the MIPS clinical practice improvement activities.

Can you comment on CMS' recent efforts to support and expand the use of these services?

Mr. REED. Absolutely. We are very pleased that the MIPS program included IA activities. Especially, we think it's very important that they allowed for small practices to see their number—to get an appropriate reward for engaging with their patients when

it comes to using telemedicine and remote patient monitoring products.

I think what's really important though is for the parts that you're mentioning, which are critical, and are worthy of note, we don't think we should forget the fact that the APMs—that there was no mention of remote patient monitoring as part of the APMs——

Ms. MATSUI. Right.

Mr. REED [continuing]. And I think it's important to note that, from our perspective, we appreciate what you have been doing both as a cosponsor of Connect for Health and as a cosponsor for the evidence-based Telehealth Expansion Act.

So we appreciate the work you have done in this space and we think that that all needs to be continued.

Ms. MATSUI. OK. Now, as CMS continues implementing MACRA, in what ways should Congress be thinking of program oversight with regards to promoting the use of telehealth and remote monitoring services?

Mr. REED. Evidence. That's the real crux of this issue. We always take the perspective that every physician—and the whole system has three real questions: does it work, will I be in trouble for using it, and then, finally, does it make economic sense.

And so that first question of evidence becomes critical. You have heard multiple people here talk about CMMI. I think it's ironic that CMMI—we met with CMMI the other day. Love them, great people over there. But they told us, hey, we are going to move really fast and get this study out in 10 years.

[Laughter.]

Ms. MATSUI. OK.

Mr. REED. Just recently all of you know that 10 years ago there were no smart phones.

Ms. MATSUI. That's right.

Mr. REED. That's when that started. So and we are looking at the evidence that we need to bring to the fore. We cannot wait for CMMI and a 10-year study that hopefully shows how it all works.

We are going to have to use other sectors.

Ms. MATSUI. OK.

Well, thank you, and I've run out of time so I yield back.

Mr. GUTHRIE [presiding]. Thank you, and I appreciate the gentlelady for yielding back and the chair now recognizes Mr. Bilirakis from Florida for 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much and I thank the panel for their testimony today.

Dr. Anand, thank you for being here and I have a couple questions for you.

Adventist Health System has a sizeable, as you know, presence in Florida. You stated that earlier, and throughout the Tampa Bay area—and I represent parts of the Tampa Bay area—I want to commend you also for making such tremendous improvements to Florida Hospital North Pinellas, which is my hometown hospital, and the community has really rallied around the hospital. So thank you so very much. A wonderful place.

Dr. Anand, how many of your doctors are involved in and how many independent physicians are part of your accountable care organization?

Dr. ANAND. Great question. When you look at the State of Florida, we've set up one accountable care organization that serves approximately 55,000 Medicare beneficiaries.

When you add our ACOs and our clinically integrated networks in the State of Florida, we have approximately 3,900 physicians of which two-thirds are independent physicians.

We partner with them in the Tampa market, for example. The numbers may vary a little bit but that statistic, about two-thirds, holds pretty true.

Mr. BILIRAKIS. OK. You have set up again and operate a number of ACOs. Is that correct? And where exactly in Florida? Is that at the Orlando area or is that in several hospitals in the Tampa Bay area?

Dr. ANAND. Good question.

So what we've done, in order to help improve the care in Florida we've actually set up one statewide Medicare shared savings program—one ACO—that encompasses the whole area.

It's in the Tampa market, goes into the Orlando market, brings together providers from the Daytona, Volusia, Flagler, Highlands, Hardee County. In the future, we'll actually be part of it as well.

And so what we are hoping to do is starting to bring together an improvement model where we can actually improve the care and wellbeing of all the patients in Florida.

Mr. BILIRAKIS. Very good. Very good.

What makes your ACO unique when compared to other ACOs and how has your ACO been successful? How has it been successful in reducing costs and increasing outcomes?

Dr. ANAND. Great question.

Mr. BILIRAKIS. Increasing outcomes—that's the bottom line—the quality of care. But go ahead, please, sir.

Dr. ANAND. Great question.

So let me tackle the first question—what makes our ACO different.

Mr. BILIRAKIS. Yes.

Dr. ANAND. So from a organizational perspective, we fundamentally believe in holistic care. We believe that medical care is a small portion of the overall health and wellbeing of our patients and beneficiaries.

And so we focus on things that affect their social determinants of health—their mental wellbeing, their spiritual wellbeing, some of their financial issues that we have.

And so we really take a holistic picture and approach to improving the health and wellbeing of those patients. The literature has confirmed over and over that when you apply that holistic approach you're going to get better health outcomes.

If you come and treat the emergency medicine physician as well—if you treat the patient in the emergency department and then they go off and they don't have the services that they need, they will be back in the emergency department over and over again.

And so that's been one of the fundamental approaches from the beginning is that we want to make sure we incorporate all of those elements into——

Mr. BILIRAKIS. Cost reduction is a factor as well.

Dr. ANAND. Correct. From a cost reduction perspective, we focused on where the variation lies in care and there is tremendous variation as you go from region to region as well as provider to provider.

And what we do is we help provide the tools, the technology, the data, the analytics that empowers physicians to have the information that they need to provide the best level of care.

We are looking at pathways related to issues such as back pain where we can actually provide interventions and treatments that are going to make a lasting improvement such as physical therapy, rather than just going straight to surgical therapy, which may not improve outcomes initially.

Mr. BILIRAKIS. I like that.

Can you talk about some of the challenges you face in structuring your particular ACO when dealing with the Stark Law?

Dr. ANAND. Yes. That's a great question.

So we had several challenges with the Stark Law. I think we've covered a lot. But just to summarize, if it was permanent I think that would be a big help.

Two, there's a lot of questions about the applicability of the Stark waivers for all patients. Some of our providers have 10 Medicare beneficiaries. Some of them have Medicaid beneficiaries.

Some of them have a hundred or 1,500 Medicare beneficiaries and what we would like to do is actually see the Stark waivers apply down at the provider level so that the provider doesn't have to realize that this patient is a Medicare beneficiary that's in an ACO program. This Medicare beneficiary is not—this other one may be, but we are not quite sure right now.

It's too hard to operationalize from a physician perspective and so we'd like the Stark Law to apply to provider level. If we can do that, we can coordinate care effectively because we have the pathways. We know what the clinical pathways are and we can share it with the physicians and allow them to provide the best care.

The tools and technologies that we've talked about we have those available and we'd love to be able to share them with the physicians. But we still have confusion on if they can share it with just—and use them just on their Medicare beneficiaries or if they can use it on all patients.

And so we love the direction that the committee is headed. We'd like to see an expansion in those particular instances.

Mr. BILIRAKIS. Very good.

Thank you very much, Mr. Chairman. I yield back.

Mr. GUTHRIE. The gentleman yields back.

The Chair now recognizes Mr. Long from Missouri for 5 minutes for questions.

Mr. LONG. Thank you, Mr. Chairman.

And Mr. Reed, in your testimony you talk about the value telehealth can have for taxpayers. You state that evidence from practitioners contradicts the often overstated fears that telehealth could lead to a bonanza of over utilization.

Instead, telehealth could substitute for otherwise more expensive healthcare services. Could you talk about what the evidence has shown so far on the cost savings that telehealth could produce?

Mr. REED. Absolutely, and I know it's a rival state but the also great State of Mississippi has done some amazing work with telemedicine and remote patient monitoring, particularly in the area of type 2 diabetes care.

What you see out of the University of Mississippi Medical center is an effort to directly engage with patients, particularly in the Delta, who have no care or no facility or an originating site within 2 hours.

It was crushing the state economically. But by putting a tablet in the hands of folks at home with the necessary high-speed connection that exists in those areas what changed was the nurse practitioner could notice, hmm, your blood glucose is kind of high—let's get on the phone. Oh, it was a family reunion? OK, stay off the pecan pie for the next week—let's get that down.

And so what you saw is you didn't see an over utilization. What you saw was a stoppage of the kind of danger symptoms that went on. So instead of that person ending up on the pathway to blindness, on the pathway to losing a leg, you saw them engaging with a nurse, maybe with a little nagging, to say hey, back off that—don't have that second piece—let's get you in for a test.

So when you think of it in very simple terms, you're right—maybe telemedicine means that they go have a face to face visit.

But if that face to face visit is a conversation about how they stay healthy, that's a whole lot cheaper than a face to face visit that results in an amputation or blindness or a treatment that they'll never recover from.

So I am OK with telemedicine leading to a lot of physician engagement because it's the kind of engagement that keeps people on the front side of the wave and not the back.

Mr. LONG. So that's where the savings comes in then?

Mr. REED. Absolutely.

Mr. LONG. So how long would it take these cost savings to materialize?

Mr. REED. Well, here's what's amazing. In states like Mississippi and in other places, they've seen 100 percent reduction in readmissions in certain types of type 2 diabetic problems and they've had those results in a matter of 2 to 3 years.

So a lot of it is what kind of nurses you have—we've had a lot of discussion about skilled nursing—what kind of nurses you have and what elements you have to engage.

But we are not talking about a decade to see an improvement. We are talking about a short matter of years, depending on the condition and where those people are in terms of their education.

Mr. LONG. OK. When you're talking about that they're using telehealth and monitoring their type 2 diabetes—their glucose monitor, I guess, or whatever—so these people are pricking their finger at home and then relaying to the nurse or practitioner, doctor——

Mr. REED. Yes.

Mr. LONG. Over the iPad? Is that correct?

Mr. REED. That's correct, and here's the part that's really good. It isn't just that that result goes. It's not passive. They put that result in. They get information and feedback on how they're doing.

The most dangerous thing, and I know every physician here knows, is a passive patient. A patient who's engaged in their care, they're on top of it. When they see that number on that iPad, they say to themselves, well, how does that look. Oh, it doesn't look good—what did I do. And then the nurse calls up and says hey, I didn't like what you're seeing, and here's the really good part. What if they're doing a great job? What if that is a great number?

Mr. LONG. More pecan pie.

Mr. REED. That's right. But more importantly, then that pecan pie—what's even better is the next step. The next step is the nurse calls up and says, you're doing a great job, and that creates an active engaged patient. That's where your savings come from. That's what eliminates people. We are talking about numbers here but we are also talking about lives and quality of life. So it's important that we deal with the numbers but let's never forget about the people that are involved here.

Thank you.

Mr. LONG. How do we ensure the long-term savings from telehealth are factored in beyond a 10-year window?

Mr. REED. Well, I think that's something we've all been talking about here on the move that you and I believe your cosponsor on the Preventative Health Savings Act to try to move that ONC window.

I think that realistically, given the speed of technology—like I said, there were no smartphones 10 years ago and then now none of you would ever be 3 feet away from your smart phone.

So think what you have to look at is let's extend the 10-year window but then let's also be cognizant of the fact that we are probably going to see some major shifts in the way that people are engaged in their daily lives with technology.

There's this concept that tech is just about kids. That's not true. Any of you have grandkids? I bet you you FaceTime with your grandkids on your mobile device.

If you think about where adults over the age of 65 are with technology it's a myth that people over 65 can't tech because they can tech just fine.

Mr. LONG. And these new watches that Apple rolled out yesterday with the telehealth applications on there.

Mr. REED. Correct.

Mr. LONG. Pretty amazing stuff of what they—I can't remember the CEO's name. Is it Cook now? Or whatever, but rolled out yesterday.

Mr. REED. I will be happy to come by and show you one on September 22nd, I think.

Mr. LONG. OK. Very good. Thank you, Mr. Chairman. I yield back.

Mr. BURGESS [presiding]. Chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for your questions, please.

Mr. CARTER. Thank you, Mr. Chairman, and thank all of you for being here. This is certainly a very important hearing.

I want to start with you, Dr. Weinstein.

Full disclosure—before I became a member of Congress I was an independent retail pharmacist so I appreciate independent healthcare practices.

When I talk to my colleagues about the problems that we are having hanging on to independent retail pharmacies they think I am only talking about independent retail pharmacies. But I am not. I am talking about independent healthcare practices.

That, to me, is a real big problem here and one of the things I wanted to ask you to begin with is I am really troubled to hear that your practice is having trouble with participating in some of these cost-saving arrangements with Medicare because of the outdated CMS policies.

And I just wanted to ask you what do you think are some of the advantages that perhaps the big hospital systems have over you, being an independent practice? Can you think right off of some?

Dr. WEINSTEIN. Well, hospital systems are really just people. So, the big hospital systems—I guess you might say that for the really complex tertiary care—complicated surgical infectious—somebody with a multi-system disease needing multi specialists, obviously—hospital systems are important.

But many of the diseases that we take care of are really isolated to gastroenterology or maybe gastroenterology and surgery. So one or two specialties, and the idea is to be able to get to those people, engage those patients before they need major hospitalization.

Mr. CARTER. Right. Right.

Dr. WEINSTEIN. That's where the savings is, and engaging those patients. The Project Sonar that I mentioned before, which was tentatively approved by PTAC but then didn't move forward, is a technology engagement with patients to determine how they're doing on a basis where they might ignore symptoms from time to time and engage them before they get to a hospital.

So there is certainly need for hospital systems for the very acutely sick. But the majority of patients, hopefully, can avoid hospitals.

Mr. CARTER. Absolutely. Well, thank you and good luck. I am pulling for you. Trust me.

Dr. WEINSTEIN. Thank you.

Mr. CARTER. Mr. Reed, I want to go to you because I'm very interested in this. I've had a company in my office that—and help me to articulate this because I suspect you know about it better than I do.

But they're coming to Georgia now and they are involved—they have an app that they've created because in Georgia right now it takes 3 weeks on average to get an appointment with a primary care physician and in some areas, particularly in the area that I represent—south Georgia, a very rural area—it may take even longer to get that.

Well, they've come out with an app that can take advantage of cancelled—cancellations or changes in a schedule and you can use that app but they're telling me that the only way they can bill for it outside of the private pay—the only way they can bill for it for the Medicare patients is if they do it by flat fee and they want to

do it on a per usage basis. Again, I am sure you understand that much better than me. But the rules are so antiquated that they can't do it.

Mr. REED. That's correct. I had my staff, prior to this hearing, poll through my written testimony and come up with a glossary of 44 different acronyms that I used—just from my testimony—and I am pretty sure that everybody here has the same number—but that really represents the status that your company in the great State of Georgia is dealing with.

The problem that they face is they also get completely differing answers. For example, on the one you're talking about, when you look to share that information on an application like that on how you bill, you have got to deal with a couple of different systems, not only from an interoperability perspective but also how do you do the data sharing.

Right now, they can do a flat fee that somebody pays but if you try to do a per physician basis pay, there's no mechanism by which it processes through the Medicare or Medicaid system.

So they're really stuck out there in the fee-for-service or private payer model and it makes no sense because, as you say, when somebody drops off of an appointment that they can't get to, especially in areas like yours with a healthcare professional shortage area, this is the exact time that you want somebody to say hey, I need that patient, and as I said at the beginning, this demographic problem is only going to get worse, not better.

So when it comes to the model, we really don't see MACRA and—and I am sorry, we don't see CMS really providing pathways for those kind of innovative products at all.

Mr. CARTER. OK. OK. Well, I see I am out of time. Thank you, and I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Indiana, Dr. Bucshon, 5 minutes for questions, please.

Mr. BUCSHON. Thank you, Mr. Chairman.

Dr. Weinstein, can you talk about the challenges in developing and testing an APM like Project Sonar and also do you think that the current volume and value prohibitions in the Stark Law make it difficult to test APMs?

Dr. WEINSTEIN. I do. Thank you for the question.

The problem with APMs in developing care pathways and determining how you're going to share the care of a patient, potentially, with other physicians outside of the convener, whether—if the convener is an independent physician, if the convener is even a hospital system—if you're going to interrelate with other physicians then you can't test that to see whether the technology communication is correct, whether the in-patient engagement is correct. You can't share the data because you will buck up against certain Stark regulations.

So it would be great to be able to test an APM all the outcomes, the technology that's needed, in a way before you get to a PTAC decision once the application is submitted and the current regulations don't allow you to test.

So, hopefully, I answered——

Mr. BUCSHON. You did. It's pretty clear there are Stark and anti-kickback problems that are making it difficult. The Medicare Coordination Improvement Act, which I've introduced with my Democrat colleague, Dr. Ruiz, would allow practices legitimately developing and implementing an APM to essentially be exempt through waivers from these provisions.

Do you think this would encourage more practices to develop APMs?

Dr. WEINSTEIN. I do. I think when we've polled, at least in the Digestive Health Physicians Association, I think these very large groups are very interested in modeling opportunities to take care of patients under lower cost/better outcome care.

They've built the infrastructure to be able to do that. They're willing to take risk to do that. So I think more people would be willing to look into other diseases, not just inflammatory bowel disease but chronic liver disease and such, and thank you for submitting that bill.

Mr. BUCSHON. You're welcome.

I yield back, Mr. Chairman.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions, please.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I apologize for not being here. I've learned everything about forestry services, wildfires, prescribed burns, and the health effects of wildfires in the air. So that's where I've been the last 2 hours.

We wanted to get up here to make sure we set the records for some public policy. So some of the questions that I had have already been answered through the question and answer period. But I want to state that promoting greater value within our healthcare system is a worthy goal and I strongly support efforts to promote value-based models within our Medicare program and throughout our healthcare system. But current progress has been slow.

As elected officials, we need to find ways to increase the value opportunities in the Medicare program to address issues of program solvency and improve the patient experience, both for beneficiaries and, just as important, their loved ones.

Reforms that empower all healthcare entities to engage in value-based reforms can lead to meaningful value for all, unleashing private sector innovations within the program at a time when our benefits to care and programmatic spending are sorely needed.

As this committee considers opportunities to promote value-based models, I recommend we consider two things. One is to explore opportunities to support all stakeholders—patient, payers, manufacturers, vendors, and providers—to enter in and benefit from participating in value arrangements; ensure that any reforms that are in this area are implemented in ways that ensure patient care and program spending are protected.

Medicare beneficiaries and taxpayers should benefit from our efforts, not be hurt by them. Hence, your discussion and debate, which I missed a lot of, on the anti-kickback statutes, the Stark Laws, and the like.

Also, you also talked about, obviously, the patient care and the protection of the taxpayers, spending.

So, Mr. Chairman and Ranking Member Green, although he's not here—we see the Honorable Congresswoman Matsui in his place—I firmly believe that legislative approaches in this area should empower all Medicare entities to drive value throughout the program, ensure that beneficiary care and program spending are protected, and promote opportunities for beneficiaries to directly benefit from these reforms.

That's why I've asked my staff to begin developing legislation that creates avenues for all stakeholders—patients, providers, payers, manufacturers, and others to enter into and succeed in value-based healthcare models throughout the Medicare program, not just within the constraints of CMMI.

I hope to work with you, Mr. Chairman and Ranking Member Green, and my colleagues on both sides of the aisle in developing an advocacy of such an approach.

Mr. Chairman, I would like to enter into the record a letter in support of the legislative efforts by the Breaking Down Barriers to Payment and Delivery System Reform Alliance and a letter from Advocate Aurora Health containing comments filed with CMS in response to its request for information regarding physician self-referral.

Mr. BURGESS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. SHIMKUS. And with that——

Mr. GRIFFITH. Would the gentleman yield?

Mr. SHIMKUS. I will yield.

Mr. GRIFFITH. Mr. Reed has talked about how we didn't have smart phones 10 years ago and the beauty of this is is that while our nursing homes might not be able to use telemedicine, you can go back and watch all the testimony later via your smart phone.

Mr. SHIMKUS. And you don't think I've done that?

Mr. GRIFFITH. I don't think you have done it yet. I think you will do it on the way home.

Mr. SHIMKUS. You bet. Thank you, and I yield back my time.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

I believe that all the members of the subcommittee have been recognized for questions and we'll now recognize Mr. Ruiz of California, who's not on the subcommittee but has presented himself here, and you're recognized 5 minutes for questions, please.

Mr. RUIZ. Great. Thanks for letting me sit in here and listen to this wonderful presentation and also participate in this very important conversation.

I was pleased to partner with my colleague and fellow physician, Congressman Bucshon, to introduce H.R. 4206, the Medicare Care Coordination Improvement Act, which would modernize Stark Laws to make it easier for physician practices to successfully develop alternative payment models, or APMs, incentivized in MACRA, and it will also incentivize us to fully reach a value-based payment model that the ACA encourages.

I believe that Stark Law is important but it needs to be tweaked because currently physician practices are hampered from fully and successfully participating in APMs.

So the Stark Law was created to help curb some of the quantity-based payment models that we have developed in the past and oftentimes this Stark Law prevents physicians from referring to other physicians that they know in a medical home model-based in order to achieve a value-based payment model, which we want to move toward.

So we need to update and we need to tweak it so that we can encourage a value-based payment model and alternative payment model.

So this bill will give CMS the authority to give a narrow exception to Stark just for the time that the APM is being developed, which is the same waiver authority that was given to ACOs in the ACA.

So, Dr. Weinstein, thank you for being here today and for your testimony in support of this legislation. In your testimony, you referenced the slow pace at which independent physicians have been developing alternative payment models.

I am also concerned that in order for MACRA to succeed, we need to break down barriers encourage more innovation and care delivery models to be put forward.

Can you give us a specific example of how, if we are able to pass this narrow exemption, an independent gastroenterology group like yours could improve patient care for your patients?

Dr. WEINSTEIN. Again, thank you for the question and thank you for submitting the bill.

As a specific example, we want to be able to reward physician behavior for following better care pathways and as opposed to just performing individual services.

So if I am going to work with a surgeon and I want to work with a particular surgeon in an APM for dealing with inflammatory bowel disease, then I want to reward that surgeon for following the care pathways to lower the cost of care.

If I am doing that then—if I am rewarding him for value, for better outcomes, well, that actually flies in the face of some of the language of the original Stark Laws.

And I said it in my testimony—we are not in favor of removing Stark prohibitions on fee-for-service standard, self-referral, and things like that. That has nothing to do with modernizing the Stark rule for an alternative payment model, a model where groups of independent physicians are sharing risk in managing a better outcome for a patient and in doing that in a way that does not violate the Stark Laws.

Mr. RUIZ. Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back.

Seeing that there are no further members to ask questions, Mr. Reed, I do want to just point out you have graciously mentioned several times today the Public Health Savings Act—the bill that I introduced with Diane DeGette some time ago—actually, several Congresses ago—and I had actually hoped to have a hearing on that before we concluded this year, it's on the list just like the data blocking bill from the Office of National Coordinator.

But it is an extremely important concept to be able to look for preventative healthcare at a wider window than the 10-year typical budgetary window that the Congressional Budget Office allows.

So I thank you for bringing that up and I am going to use that as additional gas in the tank to see if we can't get that hearing structured.

Mr. REED. No, we'd love to help you gain more cosponsors. Thank you.

Mr. BURGESS. Thank you.

Well, seeing that there are no other members wishing to ask questions, I do again want to thank our witnesses.

I do want to submit the following documents for the record from Advo Med, from the College of information—I am sorry, from the College of Healthcare Information Management Executives, Cancer Treatment Centers of America, National Association of Chain Drugs Stores, Medtronic, the American Society for Gastrointestinal Endoscopy, and Jeff Lemieux and Joel White article in "Health Affairs."

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record and I ask the witnesses to submit their responses within 10 business days upon receipt of those questions.

And without objection, the subcommittee is adjourned.

[Whereupon, at 3:16 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today's discussion is important to help Congress understand the different ways we might expand innovative, value-based care in our Medicare program.

The Affordable Care Act (ACA) took major steps towards improving the quality of our healthcare system by creating new models of delivery within the Medicare program. These new models were intended to transform clinical care and shift from a volume- to a value-based care model, such as Accountable Care Organizations (ACOs) and Patient Centered Medical Homes (PCMHs).

With the passage and implementation of the Medicare Access and CHIP Reauthorization Act (MACRA), we entered the next phase of healthcare delivery system reform. MACRA built on the ACA's efforts by offering opportunities and financial incentives for providers to transition to new payment models known as Advanced Alternative Payment Models, or A–A-P–Ms. AAPMs require providers to accept some financial risk for the quality and cost outcomes of their patients.

MACRA also created the Merit-Based Incentive Payment System, or MIPS, an alternative path for clinicians to make the shift away from a volume-based system to a value-based system that focuses on quality, value, and accountability. Together these new programs were designed to influence doctors to make change and the law gives them great flexibility in choosing the right model for the right provider.

Unfortunately, I have been disappointed thus far with the Trump Administration's progress on building on these successes and their lack of actions to move the Medicare program to a value-based system.

Most notably they have rejected the goals made under the previous administration, to make 50 percent of all Medicare payments to hospitals and doctors through value-based models by the end of 2018.

They have not taken meaningful action to expand the number of Alternative Payment Models available to Medicare providers. They have failed to test or implement any physician-focused payment models and have cancelled or scaled back a number of bundled payment models.

Meanwhile, CMS has taken steps to undermine MACRA's MIPS program, by exempting 60 percent of Medicare physicians from its requirements. While I understand that there are challenges with MIPS, I don't think the answer is to just exempt providers from its requirements. Nor do I think that is what Congress envi-

sioned. By exempting these doctors entirely, the Administration is choosing not to engage small providers-a lost opportunity to say the least.

I am also concerned that the Administration's proposed regulation on ACOs will dampen enthusiasm for engaging in these models. The evidence is unequivocal that ACOs have both improved the quality of care for Medicare beneficiaries, and saved the Medicare program money.

As our two witnesses with experience with the ACO program will testify today, the kind of cultural change required to implement an integrated, patient-centered, system like an ACO takes time and investment in people and in systems. While I support efforts to get more ACOs to embrace financial risk, the proposed rule could potentially cut the program off at its knees by requiring ACOs to take on risk within two years, and by lowering the shared savings rate.

Let me conclude by addressing the issues of Stark and the AntiKickback Statute. I know some stakeholders view these laws as a barrier to value-based payment reform. I would be interested in hearing about specific instances in which Stark and the AntiKickback Statute have posed barriers to value-based payment arrangements. But I also want to stress the continuing importance of these laws, which are intended to ensure that doctors do what is best for patients, not what is best for their bottom line. There is empirical evidence that these laws operate to prevent overutilization in Medicare. This is bad for both patients and taxpayers. So, we must proceed with great caution in making changes to these laws.

I also want to underscore-eliminating or reducing the effectiveness of the Stark and Anti-kickback laws is not a delivery system reform agenda. On its own, deregulation does not move us to value. That will require transformative leadership at HHS, and an industry-wide commitment to align financial incentives with healthcare quality and performance, with the patient always at the center.

I look forward to discussing these and other issues with the panel today. I yield back.

September 12, 2018

The Honorable Adrian Smith
320 Cannon House Office Building
Washington, DC 20515

The Honorable Joseph Crowley
1035 Longworth House Office Building
Washington, DC 20515

The Honorable Diane Black
1131 Longworth House Office Building
Washington, DC 20515

The Honorable Ben Ray Lujan
2231 Rayburn House Office Building
Washington, DC 20515

The Honorable Morgan Griffith
2202 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Smith, Black, Griffith, Crowley, and Lujan:

The undersigned organizations are writing to express our support for the *Reducing Unnecessary Senior Hospitalization (RUSH) Act of 2018* (H.R. 6502). We thank you for your leadership in bringing much-needed innovation to the Medicare program.

The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to implement the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP) to link Medicare payments to each SNF's rehospitalization rate. Additional tools and resources would be helpful as this program continues. In particular, information technology resources and policies that would support further improvement is a barrier for SNFs. SNF providers were not included in the *Health Information Technology for Economic and Clinical Health (HITECH) Act* and are struggling with razor thin margins. The combination of these elements makes development of telehealth functions and interoperability extremely challenging.

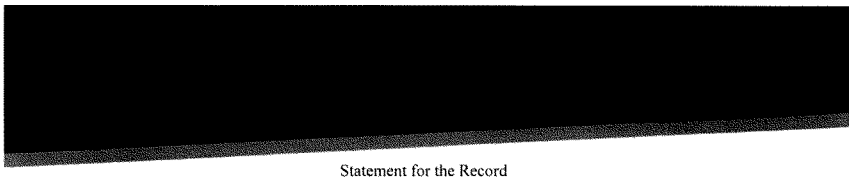
By allowing Medicare to selectively enter into value-based arrangements with innovative medical groups to provide acute care at SNFs instead of transferring to the hospital, the *RUSH Act* would provide new and effective care delivery options. The on-site first responder, connected via telehealth to an emergency physician and equipped with mobile diagnostics, would be able to treat the acute care needs of SNF patients instead of transferring to the hospital. This model has been proven to reduce hospital transfers by approximately 50 percent and increase quality in nursing homes.

Thank you for your leadership on this important issue. We look forward to working with you to ensure the RUSH Act becomes law.

Sincerely,

Coalition to Transform Advanced Care
Health IT Now
Nassau Queens PPS

Philadelphia College of Osteopathic Medicine
The Michael J. Fox Foundation for Parkinson's Research
University of Rochester Medical Center



Statement for the Record

Hearing of the Energy and Commerce Committee,
Subcommittee on Health
on
Examining Barriers to Expanding Innovative, Value-Based Care in Medicare

September 13, 2018

The Breaking Down Barriers to Payment and Delivery System Reform Alliance ("the Barriers Alliance") applauds the Energy and Commerce Health Subcommittee for holding a hearing entitled "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare."

The Barriers Alliance is comprised of providers, payers, patient groups, device and pharmaceutical manufacturers, health IT vendors and other organizations with a common interest – working to reform regulatory and legislative barriers that impede opportunities for all stakeholders to engage in value-based arrangements within federal health care programs.

Whether the arrangement is an Alternative Payment Model (APM), Accountable Care Organization (ACO), Value-based Contract (VBC), or other new payment model, the Alliance believes that all those who operate, deliver, or receive care and coverage under a federal health care program can participate in activities that better manage the cost, delivery or outcome of a health care encounter. Patients, providers, manufacturers, vendors and payers all have role to play, and having all parties working together to support the same value proposition offers the best chance for Medicare beneficiaries and the Medicare Trust Fund to realize the benefits of alternative value payment arrangements.

For example, a key determinant of success in several of the Medicare APMs that have been implemented by CMS is effective care coordination. By incenting providers within an episode of care to coordinate care plans and delivery of services, care fragmentation and variability can be reduced and utilization of services optimized to meet the patient's needs, resulting in improved outcomes and lower cost. We believe that these types of collaborative approaches, when encouraged under any form of value-based model, can achieve similar results.

Federal statute and regulations have shaped the operation of federal health care programs like Medicare for decades, many of which were created at a time when the needs of patients, availability of medical products and treatments, and social considerations with regards to quality of care and spending were much different than they are today. While these requirements play an important role regulating the programs to safeguard patient safety concerns and prevent fraudulent activity today, we recognize that these approaches may also create administrative barriers that hinder development of novel health care delivery and payment models. Regulations under the Medicare program that prohibit a health care beneficiary or entity from engaging in an activity, regardless of whether it is fraudulent or not, may limit improper behavior but also

activities that can improve care quality and manage costs more effectively. Consider the fact that the sharing of data and analytic capabilities between two stakeholders attempting to effectively target wasteful or inappropriate practice patterns can be impeded by federal law and regulation, and therefore might not be allowed under the program.

Therefore, we are grateful for the Committee's efforts to examine statutory and regulatory barriers (include the Anti-Kickback Statute and Stark Law) that prohibit activities designed to improve care coordination, allow stakeholders to manage costs more effectively, and encourage better outcomes for beneficiaries. We believe that efforts by lawmakers to identify and address such barriers can only improve efforts to create more value within federal health care programs.

When considering ways forward, the Alliance believes that lessons learned from the establishment and operation of the Centers for Medicare and Medicaid Innovation (CMMI) can be instructive. CMMI was established by Congress through passage of the Patient Protection and Affordable Care ACT (PPACA) to promote "innovative payment and service delivery models to reduce program expenditures …while preserving or enhancing the quality of care."[1] CMMI is able to facilitate new payment and service delivery models through the use of waivers from federal statutes and rules. This waiver authority, supported by rules governing how entities are to operate within these models, is designed and used by CMS to allow organizations the flexibility needed to succeed within a value-based model while ensuring for beneficiary care and the financial health of the program.

The Alliance recommends that Congress take a similar approach by identifying a process for multiple stakeholders – health plans, manufacturers, and others – to enter into and use alternatives to current statutory and regulatory requirements within alternative payment and service delivery models. Specifically, we recommend that Congress consider establishing a set of criteria that CMS could use to designate eligible organizations with waiver authorities outside of CMMI. Responsibility for satisfying these criteria would fall on organizations willing and able to take on the obligation of ensuring spending and beneficiary care on behalf of the program. By establishing a process where beneficiary and federal spending protections are established up front, we believe that a greater freedom to identify, adopt, and employ successful value based models in the Medicare program would be realized as a result. We anticipate that this approach could be developed in such a way that direct and tangible benefits could be realized by individual beneficiaries, and improve fraud protection for the program.

We again commend the Committee for its leadership and would like to offer our help moving forward.

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[1] CMS website: https://innovation.cms.gov/About/index.html

AdvocateAuroraHealth
Advocate Health Care Aurora Health Care

August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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Re: Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma:

Advocate Aurora Health, the nation's 10th largest not-for-profit health care system, with more than 500 sites of care across Illinois and Wisconsin, is pleased to provide our comments on the Request for Information (RFI) regarding the Physician Self-Referral Law (a.k.a. the Stark Law).

As an overview, Advocate Aurora Health supports modernization of the Stark Law to eliminate the regulatory barriers it is imposing on providers and integrated delivery systems that are seeking to move to a value-based care system. The Stark Law was originally enacted in 1989 with the intention of curbing self-referral and inappropriate or overutilization in Medicare. In principle, the law was necessary and well-intended, but now, in 2018, often impedes innovation by prohibiting essential care coordination and financial arrangements. Our health system is now more accountable than ever for financial and patient outcomes across the entire continuum of care. Yet, the Stark Law and its implementing regulations fail to recognize that relationships between payers, providers, physicians, and patients have transformed significantly over time and that those new relationships already address many of the risks that the Stark Law was enacted to prevent.

To improve the Stark Law regulations, we support the following modernization efforts, which fall under four distinct categories:

(1) Create a Value-Based Arrangements Exception: The exception would protect all arrangements where compensation is reasonably related to value-based goals, such as bundled payment models and Accountable Care Organizations (ACOs), regardless of whether entities are participating in a Medicare value based model. This would avoid creating separate exceptions for different type of models or payers, which only adds complexity to compliance requirements.

(2) Addressing Strict Liability: A major problem with the Stark Law is that it is a strict liability statute; intent to violate the law is not considered, and all noncompliance, however minor or innocent, constitutes a violation of the law. This strict liability means that providers are often not willing to enter into value-based arrangements if there is even a remote possibility of violating Stark. While we understand that Congress would likely need to act to change this requirement, policymakers should encourage removing or otherwise mitigating this significant impact on providers.

(3) Provide Clarifying Language: We ask that CMS provide clarity on three key terms – fair market value, volume and value of referrals, and commercial reasonableness – that are commonly used in Stark Law exceptions. These terms should have bright-line rules that providers can use to ensure they are compliant.

(4) Make Technical Changes to Reduce Burdens on Providers While Protecting Patients and Taxpayer Resources: HHS should focus resources on violations that directly harm beneficiaries as opposed to mere technical violations. In particular we urge:

- Using the advisory opinion process to clarify and give certainty to providers regarding the proper interpretation of the regulations.
- Mitigating enforcement of technical violations that pose little or no harm to beneficiaries (e.g., compliance with signature requirements).

Below we provide more detail on improvements that can be made and respond to specific questions included in the RFI.

ANSWERS TO SPECIFIC QUESTIONS

Question 1: Please tell us about either existing or potential arrangement that involve DHS entities and referring physicians that participate in APMs or other novel financial arrangements, whether or not such models and financial arrangements are sponsored by CMS.

Advocate Aurora Health is committed to value-based reform and has successfully participated in many advanced care models, but the Stark Law has limited our efforts to fully engage in arrangements that could further improve care coordination. Our system includes a number of different ACO models, including commercial global capitation, commercial shared savings, Medicare Advantage global capitation, Medicaid Managed Care shared savings, and the Medicare Shared Savings Program (MSSP). Under the MSSP, we were able to make use of Stark law waivers and achieved millions in cost savings (in 2016 Advocate's MSSP ACO achieved over $60 million in savings and Aurora's ACO cut costs by $200 per beneficiary) while maintaining the highest standards in quality of care. Yet, our organization has continued to face barriers in pursuing broader incentive-based or gainsharing arrangements that could further enhance care quality and facilitate the movement to coordinated care.

Specifically, we have sought to implement arrangements that adjust to reward high quality, cost-effective care, such as amending our compensation arrangements to account for value. The Stark Law, however, impedes us from making meaningful reform by preventing us from implementing a program that would pay our physicians a portion of realized shared savings. Such a program would save our system, patients, and the government money and would improve care by providing high quality and efficient services. Yet, we found that this could be construed as a Stark violation because the sharing of savings is not fully covered by an exception and, in turn, could be viewed as payment on the basis of the "volume or value of their referrals." As a result, we adopted a gainsharing program on a limited basis, which we believe poses reduced risk under Stark, but also does not harness the fullest potential in improving patient care, reducing costs, and increasing quality.

Question 2: What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physician who participate in the same alternative payment model? Specifically what additional exceptions are necessary to protect accountable care organization, bundled payment models and two-sided risk models in a FFS environment?

Existing waivers do not protect all APMs or only provide temporary relief, which undercuts a provider's ability to adopt permanent changes across all patient populations. For example, waivers used for certain models developed by the Center for Medicare and Medicaid Innovation (CMMI) are done on a case-by-case basis and oftentimes program applicants do not have up-front guidance regarding which requirements will or will not apply. In addition, some waivers provide only limited protections, are only applicable to Medicare payments, or do not include certain downstream entities. Furthermore, every model and every model's waivers are different. This continues to create complications, especially for those stakeholders who are seeking to make broad healthcare improvements that cut across different sectors and integrate different levels of care.

Since properly structured APMs typically have built-in safeguards, such as careful monitoring by CMS and a payment system that rewards value and inherently protects against inappropriate self-referral and over or mis-utilization, we urge CMS to adopt a broad exemption. The exemption should protect arrangements where compensation is reasonably related to value-based goals. We believe a single exception, rather than exceptions for each type of model, is the most effective and efficient way to provide the certainty and protection hospitals and physicians need to join forces in achieving coordinate care.

In addition, the value-based exception should not be limited to arrangements with providers or a single payer. Rather, the exception needs to address all the patients we see in our system and the new role of innovative technologies that are now driving the trend toward value-based care. Collaborations with manufacturers and inventors should therefore be included in the development of new models. For example, a model could focus on a health information technology and the achievement of clinical outcomes associated with this new tool.

We also ask that any new exception not require two-sided or downside financial risk. While we believe that controlling cost is a key component of any model, there are so few arrangements, at this time, that meet this criteria that we believe it would significantly limit the utility of a value-based exception. We also believe that the exception should be sufficiently flexible to recognize future delivery arrangements that may take different approaches to controlling costs and improving quality.

By adopting a new value-based exception, we expect more health care providers will be willing to commit the time and resources needed to transform to a value-based system. It will also address some of the specific barriers we are now seeing to fully coordinate care, which is currently divided by payers and care settings due to the fragmented structure of some of the existing Stark exceptions and waivers. More explicit and predictable guidance on when an arrangement will or will not prompt federal government action under the fraud and abuse laws

could have the dual effect of safeguarding against patient or program abuse while facilitating desired delivery system reform.

Question 3: What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements that involve integrating and coordinating care outside of an alternative payment model? Specifically, what types of financial arrangements and/or remuneration related to care integration and coordination should be protected and why?

Even outside of APMs, there are several efforts to coordinate care that have faced barriers due to the Stark Law as well as other program integrity rules and regulations. The following are examples of such efforts that we believe would significantly benefit our patients and pose little risk of harm to the Medicare program. CMS should consider new exceptions or provide guidance so that providers can participate in these important care coordination activities without risking unintended implications of the Stark Law.

a. **Community Partnerships and Addressing Patient Needs**

As Wisconsin's and Illinois' largest Medicaid and Medicare provider, we serve a diverse population. Many of our patients have significant needs that extend well beyond access to health care. We have considered services such as complimentary transportation, housing, and nutritional programs that support our patients' ability to live well, but are challenged with fraud and abuse laws that prohibit providing such conveniences to patients for fear of subjecting the organization to penalties and potential liability.

One specific example is our collaborative work with Federally Qualified Health Centers (FQHCs) to help provide care for underserved populations. Our health system wanted to financially support an FQHC to open urgent and primary care centers within one of our urban hospitals so that patients would have immediate access to appropriate care and not end up in more fragmented and costly settings, such as the emergency department. After further evaluation, we did provide the funding, because it was the right thing to do for these patients, but also recognize that this contribution was made with legal risk. In addition, every time one of our employed physicians provides services at this location, we have to align their compensation with burdensome Stark requirements. A broader exception that could protect investments in improving community partnerships would help us to continue to provide and enhance these benefits for our patients.

b. **Data Analytics**

Other innovative efforts that have been restricted due to compliance with Stark include limitations on the use of health information technology. Specifically, Stark hinders our ability to both use and invest in technology in the ways that will truly add value to our overall health care system. Congress wisely provided an exception from Stark that permitted health systems to provide a subsidy to physicians to acquire an electronic health record (EHR). Yet, while the EHR is a necessary step to succeed in the value world, it is not just collecting the data in the EHR but developing the analytical tools physicians need to guide their decision-making. Similar exceptions could be made for other tools and technologies that provide analytic capabilities or are not interoperable with an EHR. Physicians need access to these tools and

technologies to succeed in a value-based system and, without subsidies, the chances of physicians obtaining them are significantly reduced.

c. **Innovation**

We would like to promote our physicians who already work with us and know our patients. Many times these physicians are best at developing innovative services and technologies that can help improve care quality within our system. Ironically, because of Stark, it is riskier for us to work with a physician that provides care to our patients than with a physician who is completely apart from our system. It is also much harder to determine fair market value (FMV) of a start-up than an established business, making it more difficult to accurately evaluate Stark Law requirements and comply with the regulations.

As a specific example where our efforts to spur innovation have run into difficulty, Advocate Aurora recently became a sponsor of a Chicago based start-up incubator. In so doing, we agreed to jointly launch a health-tech competition where early stage companies could submit their business ideas and plans. The winner and runners-up would receive an investment or grant from Advocate Aurora and/or access to some Advocate Aurora resources (e.g., subject matter experts, business units). Because of Stark, we were advised by outside counsel to exclude from the competition any business entering the incubator that had an investor that was a physician (or an immediate family member) on the medical staff of one of our hospitals or that made referrals to Advocate Aurora. Again, we believe CMS could address these barriers and allow us to better work with our physicians.

Questions 9-12: Please share your thoughts on possible approaches to defining "commercial reasonableness", "fair market value", "take into account the volume or value of referrals" and "take into account other business generated".

Central to many of the Stark Law exceptions are broad definitions, such as commercial reasonableness, fair market value, volume or value of referrals, and others that depend upon an evaluation that has no precise standard. Many stakeholders feel that these terms lead to more confusion and compliance burdens.

As a solution, we recommend that CMS provide clarity regarding some of these key definitions. While we understand that a narrow definition may not be possible, we would welcome bright-line guidance that providers can use to help ensure that they are compliant or can meet this standard with a reasonable degree of certainty. Explicit examples and/or limiting the use of such broad terms would be a significant improvement over the current compliance regime.

In addition, we would welcome CMS to consider a greater focus on harm to beneficiaries as opposed to these vague terms that only look at the financial components of an arrangement. CMS could better use its advisory opinion process to give certainty to situations that pose little to no risk of abuse. This could include more appropriate guidance on how to address mere technical violations, like signature requirements, keeping documentation etc., that are inadvertent actions and do not directly impact the quality of care.

Question 16: Please share your thoughts on the role of transparency in the context of the physician self-referral law. For example, if provided by the referring physician to a beneficiary, would transparency about physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address?

Advocate Aurora is committed to empowering patients with the information they need to understand their out-of-pocket costs. Such information helps not only patients to make informed decisions but increases engagement and helps us to move toward a value-based care system. We believe that disclosing information about price and patient out-of-pocket costs could mitigate the problems the Stark Law is intended to address and should be seen by CMS as a safeguard. Where entities have sought to improve price transparency for patients, CMS could potentially relax some of the more complex or burdensome aspects of the Stark requirements, thus promoting transparency efforts. In particular, Advocate Aurora has worked to standardize our charges for routine services and procedures across our broad network and have patient service representatives that can help navigate and provide accurate cost estimates for ordered and scheduled services. We are also working to pro-actively provide cost information to our patients and generally promote additional transparency efforts. We would welcome further engagement with CMS to discuss these issues in more detail.

Question 18: Please share your thoughts on compliance costs for regulated entities.

For Advocate Aurora, and many other health systems, more and more resources are being directed at complying with Stark Law and other laws rather than patient care. As an example, our employed physician arrangements require thorough analysis, which often necessitates regular engagement of valuation consultants to ensure minimal Stark risk. Engagement of consultants can cost in excess of $20,000 to review a single physician compensation agreement to ensure compliance with Stark requirements. Because Aurora enters into thousands of contracts with physicians each year, this cost can become astronomical, yet is needed to document compliance even when we know that no payment is being made in exchange for referrals.

The law's strict liability regime and potential for massive penalties is a major reason for an overly cautious approach. Even with regulatory exceptions and guidance, the law has an extremely broad prohibition on physician referrals that prevents us from considering many types of value-based arrangements because we would not want to run the risk of facing enormous penalties. For example, even when the objective of a model is to improve patients' outcomes, an arrangement focused on best practices may be viewed as an effort to induce future referrals and still be subject to stiff penalties under Stark because it is a strict liability statute. This means we are trying to craft innovative care models in a way that essentially excludes physicians or truly doesn't address the main drivers of cost, poor quality, and waste in our health care system.

CONCLUSION

Our organization maintains a strong commitment to moving toward value-based care and supports HHS' launch of its "Regulatory Sprint to Coordinate Care." We encourage CMS to take the most wide-

ranging and comprehensive regulatory action needed to eliminate the Stark Law's extensive regulatory burdens. Advocate Aurora stands ready to work with federal policymakers to identify regulations, requirements, and provisions that are thwarting the transformation of our nation's health care system.

Sincerely,

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U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
HEARING ON "EXAMINING BARRIERS TO EXPANDING INNOVATIVE, VALUE-BASED CARE IN MEDICARE"

SEPTEMBER 13, 2018

STATEMENT FOR THE RECORD OF
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The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to submit comments to the Subcommittee for the hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare." We welcome the Subcommittee's attention to this important topic and look forward to continuing to work with you and the members of the Energy and Commerce Committee as you consider legislative efforts to lower or remove barriers to value-based arrangements.

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing health care technology purchased annually in the United States and globally. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. The devices made by AdvaMed members help patients stay healthier longer and recover more quickly after treatment, allow earlier detection of disease, and treat patients as effectively and efficiently as possible.

AdvaMed's medical technology manufacturer members are well-positioned to support the ongoing transformation of the healthcare industry to value-based care. Manufacturers are experts in how their technologies may affect clinical outcomes and have the specialized knowledge to design solutions to optimize care in a cost-effective manner—often using data generated from devices themselves. Medical technology manufacturers understand the importance of training, support services, data analytics, care coordination and other support for providers and patients to realize the potential of technology to improve outcomes and reduce costs.

AdvaMed supports a legal framework that protects patients and the federal health care reimbursement programs from fraud and abuse. Our member companies further recognize the importance of ensuring ethical interactions between medtech companies and providers so that medical decisions are centered on the best interests of the patient. That is why AdvaMed developed a Code of Ethics[1] (also known as the "AdvaMed Code") to distinguish beneficial interactions from those that may inappropriately influence medical decision-making.

Background on the Anti-Kickback Statute

From the medtech industry's perspective, the primary barrier to broader engagement in patient-centered, Value-Based Arrangements (VBAs) is the deterring effect of the Federal Anti-Kickback Statute along with the narrow scope and outdated design of the existing regulatory safe harbors, which were designed for a fee-for-service/product (volume-based) framework. Our use of the term "Value-Based Arrangement" is limited to outcomes-based or results-based contracts, which are built around shared accountability for clinical outcomes and cost.

The Federal Anti-Kickback Statute (AKS) proscribes the knowing and willful offer, payment, solicitation, or receipt of any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in return for or to induce a referral of services or goods payable in whole or in part by a Federal health care program.[2] Congress enacted the AKS in 1972, in the context of Medicare's

[1] AdvaMed Code of Ethics on Interactions with Health Care Professionals, https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf

[2] 42 U.S.C. § 1320a-7b(b)

then-retrospective reimbursement system. In a fee-for-service/product environment, the AKS was intended to discourage overutilization of Medicare-reimbursed items and services by prescribers motivated by their own financial interest.[3] Congress was further concerned with: (1) possible harm to beneficiaries; (2) increased Medicare and Medicaid costs; and (3) the potential of kickbacks to freeze competing suppliers from the system, mask the possibility of government price reductions, and misdirect program funds.[4] The Anti-Kickback Statute originally prohibited only "bribes and kickbacks,"[5] but Congress extended its reach in 1977 by substituting "any remuneration" for the "bribes and kickbacks" language[6] and increasing the severity of the penalties from a misdemeanor to a felony.[7]

Aspects of VBAs at tension with the AKS include:

(1) the services that must be bundled in to develop and operationalize the VBA (e.g., data collection, tracking, analysis, reporting);

(2) the services and technologies that are a part of the solution to achieve the targeted outcome (e.g., care coordination, monitoring, optimizing care pathways, and technology integration to help clinicians make needed interventions); and

(3) elements of the outcomes-based pricing (e.g., front end discounts, rebates, performance payments, and penalty payments) and outcomes-based warranties (e.g., rebates and providing complimentary or alternative services when a warranted outcome is not achieved).

Each of these aspects of VBAs can be considered to have value that encourages or rewards the use of a medtech product.

Challenges posed by current OIG safe harbors

Even in the fee-for-service/product (volume-based) context, Congress recognized that the expansive reach of the AKS created uncertainty as to which routine commercial arrangements are permitted,[8] and it excluded certain types of payments from consideration by the statute, including

[3] 59 Washington & Lee Law Review 3/1/02 (The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age), citing Jost & Davies "The Law of Medicare and Medicaid Fraud and Abuse" 100 (2001-02 ed. 2000) (listing concerns that "patients will suffer, program funds will be unnecessarily depleted, and taxpayer dollars will be wasted" if kickbacks are permitted).

[4] See 56 Fed. Reg., 35952 (July 29, 1991) (original safe harbors, citing United States v. Ruttenberq, 625 F.2d 173, 177, n.9 (7th Cir. 1980)).

[5] Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329,1419 (1972) (codified as amended at 42 U.S.C. § 1320a-7b (1994))

[6] Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (1977)

[7] See Pub. L. 95-142, 91 Stat. 1175 (1977).

[8] See S. REP. 100-109, 27, 1987 U.S.C.C.A.N. 682, 707-08 ("It is the understanding of the Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, **708 in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution under the new section 1128B(b) and that will not provide a basis for exclusion from participation in Medicare or the State health care programs under the new section 1128(b)(7).")

discounts.[9] However, when the Office of Inspector General (OIG) promulgated final implementing regulations, the "safe harbor" for discounts/rebates was very narrowly drawn.

OIG recognized in its December 2016 safe harbor rulemaking that "[t]he transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers," and assured that "we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending."[10] Both the Inspector General and the Chief Counsel to the Inspector General have also indicated that OIG is interested in exploring ways to permit greater flexibility for value-based arrangements, while still guarding against the problems that the fraud and abuse laws were designed to prevent.

AdvaMed and other commenters requested OIG to create new safe harbors or revise existing safe harbors to accommodate value-based arrangements because the breadth of the anti-kickback statute is inappropriately deterring manufacturers, providers, payors and others in the health care industry from engaging in beneficial value-based arrangements to help improve care, reduce costs and improve the patient experience. As we and other commenters have pointed out, many of the barriers faced by parties desiring to enter into value-based arrangements stem from provisions contained in existing safe harbors that have not been updated to accommodate new and innovative technologies or clearly and appropriately consider the numerous changes in health care payment and reimbursement occurring since they were originally adopted. Thus, the existing safe harbors effectively discourage progressive arrangements and undermine the general trend toward value-based health care.

For example, numerous provisions of the discount safe harbor are focused on making sure that buyers which report their costs on a cost report appropriately reflect the discounted price on such report. While such a requirement may have made sense when the discount safe harbor was originally adopted, the reality of today's reimbursement system is that it is extremely rare for providers to be paid based upon their costs, even where they continue to report such costs on a cost report. As such, the fraud and abuse risks stemming from incorrect reporting of such costs are much less significant than they once were. Even so, the discount safe harbor continues to contain provisions that could be interpreted to exclude from protection discounts under various value-based pricing arrangements to which these criteria are not applicable or for which these criteria cannot be satisfied. For example, a cost-reporting buyer must earn a discount "based on purchases of that same good or service bought within a single fiscal year of the buyer," and the buyer must "claim the benefit of the discount in the fiscal year in which the discount is earned or the following year."[11] It may not be possible to satisfy these criteria for an outcomes-based rebate that is determined to be payable more than a year after a buyer's purchase of the relevant product, due to the need to measure patients' clinical outcomes over a longer timeframe. Due to these and similar limitations on the discounts that qualify for safe harbor protection, parties may decide that the benefits of entering into such arrangements do not outweigh the risks of potentially being accused of violating the anti-kickback statute, with enormous potential liabilities under the False Claims

[9] 42 U.S.C. § 1320a-7b(b)(3).

[10] "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 81 Fed. Reg. 88368, 88370 (Dec. 7, 2017).

[11] 42 C.F.R. § 1001.952(h)(1)(ii).

Act, as a consequence of doing so.[12] Such decisions are particularly unfortunate where patients and/or the health care system as a whole could stand to greatly benefit from the value-based proposal in question.

Other existing safe harbors also inhibit beneficial value-based arrangements. For example, the warranty safe harbor precludes a seller from paying providers for "any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself." This requirement could be read to preclude sellers from agreeing to pay for an alternative therapy (e.g., surgery) if a warranted clinical outcome from using the manufacturer's product were not achieved—clearly at odds with the goals of value-based care. Indeed, a manufacturer putting such an arrangement into place could face allegations that it has violated the anti-kickback statute (and, as a result, the False Claims Act) simply because of having stood behind its product through such a warranty.

In addition to aspects of the existing safe harbors that are out-of-date, we note that many courts' treatment of certain safe harbor requirements has further confused the issues, compounding the risk for our member companies. For example, in one case, a Federal district court declined to apply the discount safe harbor to protect discounts provided by a manufacturer to a buyer/supplier because there was no showing "that [the buyer] has provided certain information concerning the discounts to a government agency pursuant to its request"—even though there had been no allegation that any governmental agency had ever made such a request, as necessary to trigger such disclosure obligation for the charge-based buyer at issue under the discount safe harbor.[13] Similar cases have been noted by other commenters.[14]

AdvaMed proposals to modernize legal frameworks to support value-based arrangements

I. Prioritize the creation of new value-based AKS safe harbors that can integrate all contributors to health care into value-based arrangements.

To maximize the potential of value-based health care, a goal that is shared among lawmakers, industry, and consumers of health care alike -- we need to integrate all of the contributors to health care, including medtech manufacturers, who can play a pivotal role in delivering solutions to help physicians and hospitals meet the triple aim of achieving better outcomes, lowering costs, and improving the patient experience. The Administration should prioritize the OIG's development of value-based safe harbors in its work plan and allocate additional resources to the OIG if needed to accomplish this.

In response to last year's OIG annual solicitation for new or revised safe harbors, AdvaMed and several other commenters submitted comments identifying various appropriate and beneficial arrangements to provide value-based care that require greater clarity and certainty than what

[12] Other aspects of the discount safe harbor which inappropriately prevent value-based pricing arrangements are detailed in the letter we submitted last year, as well as in other commenters' letters.

[13] *United States ex rel. Herman et al. v. Coloplast Corp. et al.*, C.A. No. 11-12131-RWZ, Opinion and Order at 3 (D. Mass, Aug. 24, 2016).

[14] See, *e.g.*, letter of the Pharmaceutical Research and Manufacturers of America, dated Feb. 27, 2017, submitted to OIG via Regulations.gov in response to last year's annual solicitation, at 5-6, *available at* https://www.regulations.gov/document?D=HHSIG-2017-0001-0007.



current fraud and abuse laws provide.[15] In AdvaMed's case, we proposed text for two new safe harbors for value-based arrangements: one relating to value-based pricing arrangements, and the other to value-based warranty arrangements[16] These are revised versions of the two safe harbors that we proposed in 2017.[17] These proposed AKS Safe Harbors would protect arrangements where contributors to health care can share accountability for achieving clinical outcomes and the total cost of care for a patient or population. Our submission of proposed text for these new safe harbors was intended to provide concrete criteria that, if satisfied, would allow interested parties to engage in such arrangements, subject to appropriate fraud and abuse safeguards. Notably, while the safe harbors we proposed would be available to manufacturers, they would also be open to other buyers and sellers of items and services reimbursable under Federal health care programs, including payors such as Medicare Advantage and Part D plans. AdvaMed appreciates the interest that OIG expressed in our proposals, and its willingness to discuss them further.

The AdvaMed proposed Value-Based Pricing Arrangements Safe Harbor would allow for price adjustment (e.g., front end discount, rebate, performance / incentive payment) based on the achievement of a measurable outcome (clinical, cost or patient experience). Our proposed Value-Based Warranty Safe Harbor would allow manufacturers of products to make certain clinical and/or cost outcome assurances and provide an appropriate remedy if such outcomes are not achieved. In other words, the outcome warranty would allow a manufacturer to share risk by providing a payment, item, or service when a targeted clinical or economic outcome is not realized. In other words, the outcome warranty would allow a manufacturer to share risk by providing a payment, item, and/or service when a targeted clinical or economic outcome is not realized. Both proposed safe harbors would allow for the bundling of Value-Based Services, which are limited to software, equipment, analysis, information and services provided for one of the following purposes:

(1) determining the terms of the VBA;
(2) operationalizing the VBA (measuring, collecting, calculating, or reporting metrics and the resulting pricing adjustment or warranty remedy);
(3) optimizing the effectiveness and clinical utility of reimbursable items or services; or
(4) otherwise achieving clinical and/or cost outcomes on which the VBA is based.

The proposed safe harbors include many features of the existing discount and warranty safe harbors but are cast in terms appropriate for value-based arrangements within today's health care reimbursement system, using provisions less likely to cause confusion regarding their requirements.

In the common scenario of a hospital purchasing a medical device, a manufacturer's provision of value-based services to help the hospital's patients who use the device achieve clinical goals is

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[15] *See, e.g.*, AdvaMed letter dated Feb. 26, 2018, submitted via Regulations.gov, *available at* https://www.advamed.org/sites/default/files/resource/advamed_2018_aks_safe_harbor_proposals_for_value-based_arrangements_0.pdf.

[16] We also noted that we were also open to modifying existing safe harbors as an alternative way to clarify the regulatory status of beneficial value-based arrangements and reduce current barriers inhibiting the adoption of such arrangements. We remain open to either approach.

[17] AdvaMed letter dated Feb. 27, 2017, submitted via Regulations.gov, *available at* https://www.advamed.org/sites/default/files/resource/advamed_letter_to_oig_re_aks_safe_harbor_proposals_for_value-based_arrangements_20170227.pdf

plainly a benefit to the patient, and potentially a benefit to the hospital and the health care system as a whole. Importantly, however, this is not the problematic type of benefit to a purchasing health care provider, that is unrelated to the purchased product, and that the anti-kickback statute was designed to preclude as improper "remuneration." Accordingly, safe harbor protection should be available to facilitate such offerings. Moreover, while such value-based services frequently are provided in connection with a value-based pricing adjustment (an increase or a decrease), we do not believe that safe harbor protection for such value-based services should be limited only to those arrangements in which such a pricing adjustment is contemplated, and the proposed safe harbor is drafted accordingly.

II. The Center for Medicare & Medicaid Innovation (CMMI) should use its waiver authority to integrate medtech manufacturers as risk-sharing collaborators in current and future demonstrations.

In the interim period before new value-based AKS safe harbors are promulgated, the CMMI should use its waiver authority to integrate medtech manufacturers as risk-sharing collaborators in current and future demonstrations to capitalize on and demonstrate the benefits of medical technology manufacturers sharing in the risk to deliver on clinical and cost outcomes. AdvaMed proposes instituting waivers and guidance across existing and future demonstrations, which include protections for patients and Federal health care programs, while allowing for greater involvement and investment in demonstrations. These waivers could be structured similar to AdvaMed's proposed AKS safe harbors for value-based arrangements.[18]

Conclusion

AdvaMed strongly supports value-based health care arrangements centered on collaborations between medtech manufacturers, providers and other key stakeholders such as payers to improve outcomes, enhance patient satisfaction, and reduce costs. We appreciate the increasing level of interest shown by both Congress and the Administration in understanding and addressing barriers to VBAs, including the recent requests for information issued by the U.S. Department of Health and Human Services on Stark Law and AKS reforms, the request for information from the congressional Health Care Innovation Caucus, and the hearing held by this Subcommittee and others. We look forward to additional opportunities to develop legislative and regulatory solutions that allow providers, hospitals, payers, and manufacturers to work together to provide the highest level of care possible, across the care continuum, for patients. Thank you for the opportunity to submit these comments.

[18] *See* AdvaMed letter to CMMI dated Nov. 20, 2017 submitted via email, *available at* https://www.advamed.org/sites/default/files/resource/advamed_comment_letter_-_request_for_information_regarding_innovat.pdf

Statement of the College of Healthcare Information Management Executives

House Committee on Energy and Commerce
Subcommittee on Health

Hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

2322 Rayburn

September 13, 2018

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit a statement for the record for the September 13, 2018 hearing entitled, "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare." We appreciate the Committee's leadership and continued interest in the transformation of Medicare to better meet patient needs by leveraging technology.

CHIME represents more than 2,700 chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders at hospitals, clinics and other health organizations nationwide. CHIME members are responsible for the selection and implementation of clinical and business systems that are facilitating healthcare transformation through technology.

Technology adoption and robust data sharing are vital to enhancing the quality of care and efficiency of the nation's healthcare system. Our members have experience implementing technology that must interoperate with dozens of independent systems, ranging from diagnostic imaging and biomedical devices to financial and remote access systems. Several converging factors, including the passage and ongoing implementation of the 21st Century Cures Act, present policymakers with a unique opportunity to pursue and implement policies to bolster the digital infrastructure that will play a pivotal role in transforming care delivery.

Leveraging Technology to Modernize Healthcare

Since enactment of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), the healthcare industry has made a significant shift in the way technology is used to treat and engage with patients. The prolific adoption of electronic health records (EHRs) and other health IT resources by clinicians and patients will pay dividends as the nation's health system transitions to value-base care.

The transition away from fee-for-service reimbursement is not to be understated. Technical challenges and opportunities associated with generating reliable performance data to determine reimbursement will be a challenge with existing technology. For providers to be successful in new payment models, including those facilitated by the Medicare Access and CHIP Reauthorization Act (MACRA), a robust digital health infrastructure will be key. But, it is not enough to have data – there is already a prolific amount of data generated by our healthcare

system. The data must be able to be harnessed for the purposes of informing and bettering patient care. To ensure providers can leverage the data needed to enable a value-based, outcomes-driven care environment, the Committee should consider actions to:

1. Foster interoperability.
2. Reduce the burden of quality measure reporting for providers.
3. Enable innovation in healthcare technology.
4. Enhance the cybersecurity posture of healthcare providers.

Promoting Interoperability

Improving the quality of care and lowering costs will be contingent on the free flow of patient data across care settings, a must for delivery system reform. Unfortunately, today patients and care providers are missing opportunities to improve people's health and welfare when data about care or health status is not easily available. Notably, robust information exchange and nationwide interoperability can flourish only once we can confidently identify a patient across providers, locations and vendors.

Patient Identification for Interoperability
The concept of a longitudinal healthcare record, which necessitates interoperability, should reflect the patient's experience across episodes of care, payers, geographic locations and stages of life. It should consist of provider-, payer- and patient-generated data, and be accessible to all members of an individual's care team, including the patient, in a single location, as an invaluable resource in care coordination and for public health purposes. Without a standard patient identification solution, the creation of an accurate longitudinal care record is simply not feasible.

Congress acknowledged the lack of a national solution to identifying patient is an interoperability and patient safety issue in the FY17 Omnibus Committee Report[1]. Congress then went on to clarify that the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare and Medicaid Services (CMS) can provide technical assistance to private-sector patient identification efforts. Efficiencies in care coordination, as intended by Congress in the HITECH Act, would be enhanced by a national strategy for patient identification. Congress could promote private-sector led solutions by encouraging CMS' Center for Medicare and Medicaid Innovation (CMMI) to include criteria that advances private sector-led solutions which facilitate unique patient identification or projects focused on this intended outcome.

Standards-based Interoperability
There is great potential to improve patient care and reduce healthcare costs through care coordination in an interoperable healthcare ecosystem. While a focus on data standards may seem overly simplistic, a more defined technical infrastructure is needed to catalyze innovations in digital health. Improved data standards will help ensure the data exchanged is valuable and useful to the receiving party. Our members feel that without this, we are destined to repeat mistakes by hoping the mere exchange of data will indeed result in improved outcomes. Without the ability for disparate systems to recognize and successfully use data, we are simply moving data, and in a very difficult and expensive way. For example, the current attempts by third-party developers to force electronic health record vendors to create one-off, custom FHIR interfaces,

[1] Committee Report, H.R.244, Consolidated Appropriations Act 2017 (115th Congress) https://www.congress.gov/114/crpt/hrpt699/CRPT-114hrpt699.pdf

rather than implementing standardized FHIR interfaces is only adding to the difficulty and cost of interoperability – not improving it. To cure what ails this is a single set of named standards must be used by all parties.

The 21st Century Cures Act[2] declared Congress' interest in an interoperable health IT infrastructure. We recognize the work underway at ONC to tackle these challenges, nonetheless barriers remain and maintaining the status quo will stifle future progress. It's imperative that ONC continue to leverage relationships with the private sector to capitalize on the progress made to date across the industry. Standards-based interoperability should thus be a top priority for ONC. Understanding how the lack of ubiquitous interoperability and meaningful data exchange is impeding care delivery and making necessary policy recommendations must be a priority as they promulgate the Trust Exchange Framework and Common Agreement (TEFCA), as well as forthcoming rulemaking pertaining to information blocking. The Committee should direct ONC to ensure that the directive to focus on standards and implementation specifications included in the statute is executed.

Navigating Privacy and Consent Laws
The exchange of data among providers in various locations and settings will require the harmonization of state and federal privacy laws. As an example, consent policy varies by jurisdiction and personal health information (PHI) type, and similar to most privacy policies, there is no national patient consent policy. CHIME calls on Congress to lead an open dialogue to help states align privacy and consent policies that enable cross border exchange of health information in a secure manner; this should include re-examining certain provisions of Health Insurance Portability and Accountability Act (HIPAA) and 42 CFR Part 2 to further align patient consent policies around release of mental health and substance abuse data.

Healthcare organizations dedicate highly valuable resources to navigating these complexities to demonstrate compliance with its regulators and to meet patient demands. If a streamlined regulatory framework were in place, these resources could be better leveraged. Instead the patchwork of laws creates a burdensome environment which is costly and time-consuming to meet and detracts from, rather than supports, patient care. Congress should pursue legislation that harmonizes other privacy, security and information risk management requirements to eliminate the complex patchwork of regulations across industries and state lines. This effort should include a robust dialogue about patient privacy and consent laws, especially as they relate to sensitive health conditions. CHIME supported the Overdose Prevention and Patient Safety Act (H.R. 6082), which would remove an outdated regulatory barrier to allow providers to have access to the full medical history of patients suffering from substance use disorders.

Improving Quality Outcomes

The future of value-based reimbursement is contingent on the ability to accurately evaluate and continuously improve performance. Congress should prioritize a unified strategy for measuring, capturing and communicating quality in healthcare. Efforts have been underway since before the passage of HITECH to devise quality indicators that can be electronically captured in normal clinical workflow, yet organizations still must deploy sizable staffs for manual abstracting as electronically generated measures are often inaccurate and unreliable.

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[2] The 21st Century Cures Act (HR 34), 114th Congress. https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf

Currently, providers are required to report clinical quality measures (CQMs) to several public and private entities. Individual healthcare delivery organizations submit more than 20 reports across federal, state and private sector programs for various CQMs each month. Hours of work and expertise are required to comply with these reporting demands and such burdens are exacerbated by a lack of technical harmonization. Even when the same CQMs are used among different programs, they tend to require different technical specifications or values to be reported with different thresholds.

Efforts to reduce provider burden by streamlining reporting redundancies must be a priority and requiring data collection and submission on measures that do not advance patient care must cease. Access to real-time, actionable data will be critical for success in the Merit-based Incentive Payment System (MIPS) and alternative payment models (APMs). The Meaningful Measures initiative underway at the Centers for Medicare and Medicaid Services (CMS) appears to share the goal of eliminating duplicative quality measures and refocus on those that are focused on outcomes, thus reducing reporting requirements which in turn would decrease healthcare costs and allow clinicians to focus more attention on patient care.

Enabling Innovation in Healthcare Technology

A great deal of innovation is underway to develop population health tools and other new technologies that will be critical for advancing provider success in APMs. CMS must avoid a heavy-handed approach to determining what technologies providers must use. Further, the Department of Health and Human Services (HHS), more specifically CMS in coordination with ONC, should take an approach that allows innovation to continue to flourish rather than prematurely trying to certify these innovative technologies.

As the Committee monitors the implementation and administration of Medicare payment policies and programs, we urge members to ensure providers have access to technology necessary to facilitate their success in new payment models and drive care improvements for patients while ensuring CMS pursues reasonable policies that will reduce provider burden, facilitate greater care coordination, and direct the maximum amount of attention on the care delivered to patients. The Committee should instruct the Administration to consider lessons learned and incorporate provider input on how to ensure the technology clinicians need and patients want is available. A focus on improved outcomes (rather than process measures), facilitated by interoperability, will position providers for success in new payment programs while enabling the delivery of better care to patients.

Our members are enormous proponents of technology, yet, they also understand the importance of the human touch. Technical innovation must flourish but it is also important to keep in mind the importance of fostering the connection between patients and their clinicians. We therefore believe HHS must be mindful of keeping patients and caregivers connected to their providers so technology can be used to deliver better care, not detract from patient care. For instance, the Promoting Interoperability program has unwittingly incentivized clinicians to spend less time with their patients and more time in front of their computer screens. If innovations cause the distance between clinicians and their patients to grow, technology may be perceived as a barrier rather than a solution.

Artificial Intelligence

We believe that technology has great potential to help achieve better care and greater efficiencies, such as artificial intelligence (AI). Yet it is critical to balance the drive for innovation and use of technology with the need to ensure that innovators understand the downstream ethical considerations that will determine the extent of adoption by the end-users – clinicians and patients. Such considerations may not be immediately apparent to innovators. However, they are significant for both clinicians and patients and will help determine the overall success of the innovation. We recognize that this balance is often a delicate one such that innovation is not stifled, yet ethical considerations must continuously be at the forefront as technology is being developed and rolled out.

Telehealth

Providers can inject innovation in care delivery when rules and reimbursement allow them to do so. Telehealth technologies offer a multitude of benefits to patients and clinicians. Increasingly our members are leveraging telehealth and remote monitoring services in a variety of ways to meet patient care needs. CHIME and KLAS Research conducted a detailed *study* in 2017 of 104 organizations currently administering telehealth programs. Some of the key findings include:

- 59 percent of respondents identified reimbursement as the biggest factor limiting expansion of telehealth services
- 34 percent of respondents noted cost or resources as a factor limiting expansion of telehealth services
- 59 percent of respondents cited improved patient access as a benefit of telehealth
- 35 percent of respondents cited improved clinical outcomes as a benefit of telehealth

All too often, telehealth is viewed solely as a benefit to small and rural hospitals that need to connect to clinicians at larger tertiary facilities. In fact, telehealth brings value to the entire delivery system. For instance, disease monitoring services can be a less expensive, more efficient and more convenient for patients with chronic conditions to stay connected with their care team. Telehealth services can also help minimize the risk of a readmission or bring video consultations to emergency departments. We are also seeing increased use of telepsychiatric screening. We also appreciate the additional authorities granted by Congress through the Balanced Budget Act of 2018 which permits Medicare to reimburse for more telehealth services.

The Committee should also consider how to address cross-state licensure concerns, often imposing troublesome legal barriers to a physician wishing to offer telehealth services to a patient in another state. Policies should allow licensed healthcare providers to offer services to patients, using telemedicine, regardless of what state a patient resides in, notwithstanding whether the patient is within a traditional care setting or in one's home. We applaud the Department of Veterans Affairs for taking on this issue for their patient population, and support the new rule that is now in place, "*Authority of Health Care Providers to Practice Telehealth*." We hope that we can learn from this VA initiative and address cross-state care provision concerns for the broader patient population.

Remote Patient Monitoring

Providers and health systems are encouraged by the potential of remote health monitoring but are still grappling with the realities of the wide-spread integration of these devices, such as wearables, into the provision of care. Our members acknowledge the value in collecting such

additional data, not only in real-time, but policies and procedures are still nascent. We would encourage the Committee to consider the value of wearables and remote monitoring technologies and ensure reimbursement paradigms are in place to support their expanded use. We applaud CMS for beginning to reimburse for this technology which will help spur greater uptake.

Bolstering Healthcare Cybersecurity

Cybersecurity attacks are highly disruptive and can be crippling to healthcare entities, as illustrated by the WannaCry and Petya ransomware attacks in 2017. The attacks impacted more than a dozen hospitals and countless other entities spanning the globe, reaching a reported 150 countries. Healthcare is deemed a critical infrastructure by the Department of Homeland Security (DHS) and as such, patient safety and patient data should be viewed as a public good; protecting those things should be a national priority.

As payment and delivery system reforms propel us towards greater connectivity, new vulnerabilities have arisen. Without proper safeguards, the safe and secure transmission of sensitive data will continue to be a challenge and will hinder efforts to care outcomes. We must ensure the implementation of stringent privacy and security standards.

Policies are needed to help support providers secure their systems and patient data, and policies that reward good cybersecurity hygiene should be developed. Given the growth in federal policies towards increased data sharing, many of which are rooted in CMS, it is critical that cybersecurity remain at the forefront of policymaking rather than an afterthought. CHIME calls upon the Committee to address the growing nature of cybersecurity threats to patient data and ensure that security is included in any policy recommendations.

The evolving threat landscape and the persistent attacks from nation-state and professional entities seeking to cause harm to patients and health systems, demonstrate the need to revisit enforcement activity following an incident. Cybersecurity incidents have devastated even some of the nation's most well-resourced health systems. The Committee should encourage the Administration to evaluate their current enforcement discretion authority and penalty processes under HIPAA and HITECH to ensure existing policies are not unnecessarily "victimizing the victim".

The industry will benefit from the current efforts underway at CMS and the Office of the Inspector General (OIG) to examine new exceptions and safe harbors under the Stark and Anti-kickback statutes, including for cybersecurity services. Facilitating the donation of technologies and services to promote a stronger cyber posture among providers is welcomed. Congress should encourage CMS, however, to explore all possible avenues to supporting and incenting providers achieve this as cost continues to remain a barrier for many.

As the Committee monitors the implementation and administration of Medicare policies, we urge Members to ensure providers have access to technology necessary to facilitate their success in new payment models while ensuring CMS pursues reasonable policies that will reduce provider burden and facilitate greater care coordination.



Comprehensive Cancer Care Network

Hospitals
Atlanta
Chicago
Philadelphia
Phoenix
Tulsa

Outpatient Care Centers
Downtown Chicago
North Phoenix
Scottsdale

August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-NC,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Re: **Comments in Response to CMS–1720–NC, Request for Information Regarding the Physician Self-Referral Law**

Dear Administrator Verma,

We strongly support CMS's efforts to address the regulatory burden and obstacles to innovation imposed by the Stark Law and are pleased to provide comments to assist CMS in understanding how reform can remove barriers to healthcare quality and efficiency.

Cancer Treatment Centers of America, Comprehensive Cancer Care Network ("CTCA") is the only national network of cancer care hospitals (as well as clinics and physician practices) specializing in the treatment of cancer. Founded in 1988 on a personalized, patient-centered approach to cancer care, CTCA tailors a combination of cancer treatments to the needs of each individual patient. From genomic tumor assessments to state-of-the-art technologies and evidence-informed supportive therapies that target cancer-related side effects, comprehensive services are delivered by a team of cancer experts, all under one roof. As CTCA seeks to extend its patient-centered approach and meet the growing national demand for cancer care by partnering with physicians' practices and other providers, we encounter regulatory limitations that we believe unreasonably limit these arrangements. As explained more fully below, many of these limitations arise under the Stark Law and discourage or prohibit otherwise lawful and economically reasonable arrangements.

The Stark Law is ill-suited to the realities of the current healthcare marketplace – a marketplace that has undergone fundamental transformation since the Stark Law

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was first enacted in 1989. The Stark Law imposes arbitrary rules that impede development of new and innovative arrangements designed to achieve CMS's Triple Aim of improving patient care, reducing healthcare costs, and improving population health.

We recognize that CMS is constrained by the statutory language in the Stark Law, but we believe the agency has the authority to make meaningful changes to the Stark Law regulations that will better effectuate Congress's intent and align the Stark Law with the realities of the current healthcare marketplace and enforcement environment. Without these changes, the Stark Law will continue to frustrate efforts to achieve a value-based, patient-centered health care system.

1. CMS should assess the Stark Law and its implementing regulations from the perspective of the realities of the current landscape.

Enacted almost thirty years ago in the context of a healthcare delivery system that bears little resemblance to the landscape in 2018, the Stark Law has become an anachronism. In the 1990s, Medicare was a fee-for-service program that provided substantial incentives for overutilization. Today, the Medicare program has been transformed into a complex system of alternative payment models, including bundled payments and other risk-sharing arrangements. This transformation continues, with providers facing continuing pressure to embrace value-based care. In a value-based health care system, physician compensation is tied to efficiency and quality of care, not volume. As a result of the evolving payment model, physician economic self-interest aligns with the interest in eliminating unnecessary services. Indeed as explained more fully below, the Stark Law in its current form severely inhibits innovation that could otherwise accelerate the shift toward quality of care models and improved patient outcomes.

The health care enforcement landscape has also undergone substantial transformation since the time the Stark Law was first enacted. At that time, there was concern that regulators were constrained by the heightened burden of proof and expense of pursuing criminal prosecutions under the Federal Anti-Kickback Statute ("AKS"). Those limitations no longer exist as Congress has adopted civil monetary penalties to address AKS violations, requiring a lower burden of proof. The AKS has thus become a dominant force in the regulation of physician arrangements, particularly when coupled with the Federal False Claims Act ("FCA") and the growth of the relator bar.

CMS's understanding of the Stark Law and the agency's role in implementing the law's requirements must necessarily take into account these changes to the health care marketplace and the enforcement landscape.

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2. The Stark Law imposes arbitrary restrictions on permissible physician arrangements, needlessly restricting a health system's ability to enter into meaningful alignments with physicians.

Since its enactment, the Stark Law has evolved into a hopelessly complex regulatory scheme that imposes arbitrary restrictions on physician arrangements. These arbitrary restrictions inhibit the ability of health systems and physicians to develop meaningful alliances, stifling innovation in favor of a series of Hobson's choices that inevitably fall well short of achieving meaningful change.

Ultimately, what the Stark Law allows versus what it prohibits bears no meaningful relationship to the risk of overutilization, which is the fundamental policy concern the Stark Law is intended to address.

For example, the Stark Law allows a single oncology group to own capital-intensive therapeutics – such as a radiation therapy center – to which the group's physicians refer all of their patients, and to distribute to those referring physicians the profits from all the radiation therapy services furnished at the center. The Stark Law does not, however, allow multiple oncology groups to pool their capital to create a single freestanding radiation therapy center to which they refer their patients and distribute the profits out to the referring physicians. As a result, there is inefficient and duplicative deployment of capital, adding needless costs to the health care delivery system. Similarly, the Stark Law allows an oncology group to operate an infusion center and distribute the profit from infusion services out to the group's physicians who refer their patients for chemotherapy. In contrast, if a hospital joint ventures with an oncology group and, for reasons of efficiency, care coordination, and optimal clinical care, the physicians refer patients to a hospital-based infusion center, the Stark Law would prohibit the joint venture from distributing profits from those infusion services out to physicians. The Stark Law directly incentivizes physician groups to do alone what they cannot do through partnerships, discouraging collaboration in favor of siloed care.

We encourage CMS to consider the inequities that result from the web of arbitrary rules reflected in the current regulations. In particular, we encourage CMS to allow for more meaningful hospital-physician alignments, including joint ownership and shared-profit distributions for ancillary services. We believe that with appropriate safeguards, these types of arrangements can more effectively align physician and hospital economic interests with the goals of meaningful care coordination and cost containment.

Specifically, we believe CMS should consider modifications to the In-Office Ancillary Services exception and the definition of "Group Practice" to allow physician groups to enter into joint ventures for ancillary services that do not present any greater risk of program or patient abuse

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than arrangements that are currently permissible under the Stark Law. In particular, we believe that the *nature of the ancillary services* at issue and *the parties to the joint venture* are key factors in safeguarding against such risk. For example, we believe hospital-physician joint ventures for ancillary services where the ancillary services at issue are a natural extension of the physician practice's operations (e.g., a medical oncology practice joint venture for an infusion center) promote care coordination and accountability and present minimal risk. Similarly, we believe that CMS should allow physician practices to enter into joint venture arrangements where the nature of the services and the parties to the joint venture clearly demonstrate that the arrangement is intended to facilitate vertical alignment to provide coordinated care. CMS can allow these types of arrangements by modifying the In-Office Ancillary Services exception, which currently allows designated health services to be performed by a wholly-owned subsidiary of a single group practice, to extend to designated health services performed by a subsidiary that is partly-owned by a hospital.

3. **CMS should address ambiguities in the existing regulations by adopting bright line rules for the core substantive requirements regarding fair market value, takes into account, and commercial reasonableness.**

The Stark Law imposes a substantial regulatory burden on hospitals and physicians, which ultimately has the effect of driving increased costs for the entire healthcare system. Among the key drivers of this burden is the lack of objectivity and clarity in the three core requirements that are included in virtually every compensation exception: fair market value, takes into account, and commercial reasonableness. We believe that adopting clear, bright line rules surrounding these requirements will introduce much needed certainty and, ultimately, alleviate the regulatory burden and associated administrative costs. We note that "bright line" rules were exactly what the Stark Law was supposed to provide, in the words of Congressman Pete Stark himself:

> "What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the arrangements that are prohibited. If the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law. The Ethics in Patient Referrals Act provides this bright line rule."[1]

We also believe that the ambiguities in these standards are the principle obstacle to development of new value-based payment models. Clarity and certainty surrounding these standards will thus directly serve CMS's goal of promoting innovation. While we support potential new exceptions that are specifically targeted at alternative payment models, we do not believe such exceptions can adequately address the existing Stark Law obstacles without CMS directly addressing the

[1] 135 CONG. REC. H240-01 (daily ed. Feb 9, 1989)(statement of Rep. Stark).

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need for bright line rules surrounding *fair market value, takes into account,* and *commercial reasonableness*.

These three concepts have also become needlessly and incorrectly conflated. We encourage CMS to return them to their intended meaning, where fair market value is a question of the *amount* of compensation under an arrangement, takes into account is a question of the *nature* of the compensation under arrangement, and commercial reasonableness is a question of the *rationale* for the arrangement.

(a) Fair Market Value

We recommend that CMS adopt a clear, objective standard for fair market value and establish a presumption that arrangements are fair market value unless proven otherwise.

Fair market value should be defined in a clear, straightforward manner as the range of values that two hypothetical parties, negotiating in good faith, would agree upon as the price, which is exactly how fair market value is understood in every other sector of our economy. Under the current Stark framework, fair market value is defined as the result of bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for the other party. Whether the parties are in a position to generate business for each other should not be part of the equation, and is not mentioned in the statutory text. The concept of fair market value is that the open marketplace determines value. Introducing consideration of what a particular party or person might have been thinking at the time of a transaction introduces a subjectivity to the assessment that creates uncertainty and adds unnecessary complexity. The parties to a transaction may enter into that transaction for any number of reasons. Fair market value is not intended to police the rationale for a transaction; it is intended to ensure the actual economic value is within an acceptable range as determined by the marketplace.

CMS should establish that an arrangement is presumed to be fair market value unless proven otherwise. Under the current Stark Law framework, because fair market value is an element of the exception, the burden rests entirely on the entity – in our case, the hospital – to demonstrate that an arrangement is fair market value. The courts have characterized it as an affirmative defense. As a result, qui tam relators have been able to bring baseless claims of excessive compensation in FCA actions and survive motions to dismiss, forcing hospitals to choose between massive legal expenses to pursue discovery and prove their compensation arrangements are compliant or entering into a settlement to end the matter – paying what amounts to nothing more than a ransom payment.

The current framework, which presumes that compensation is *not* fair market value, also reflects an outdated view of hospital-physician arrangements. At the time of the Stark Law's enactment,

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providers and physicians operated as separate and distinct components in the marketplace. Today, the lines between these components have been all but erased in favor of alignments that promote accountability and coordination across the full continuum of care. A regulatory posture that disfavors these types of arrangements is an anachronism that counterproductively creates a substantial regulatory burden on providers.

(b) Takes Into Account

The concept of "takes into account" has become a catch-all, potentially ensnaring any compensation where a party considered the potential referrals that may result from an arrangement. We encourage CMS to instead adopt a bright line rule that makes clear that compensation that does not fluctuate with a physician's referrals does not take into account the volume or value of his or her referrals. CMS can establish this type of rule through a deeming provision, similar to the other deeming provisions currently set forth at 42 C.F.R. § 411.354(d). Such an approach would offer much needed certainty to providers in developing their compensation models without creating any risk of program abuse. To the extent the non-fluctuating compensation is actually excessive, that would still be addressed under the fair market value requirement. If the non-compensation terms of the arrangement inappropriately favored the physician, this could be addressed under the commercial reasonableness requirement. The concept of "takes into account" would be rightfully limited to an inquiry into the form of the compensation.

We are also aware that, notwithstanding CMS's repeated statements that all physicians may be paid a productivity bonus based on their personally performed services, other government agencies have continued to advance a theory that such bonuses impermissibly take into account the volume or value of a physician's referrals when they generate a corresponding facility fee. We believe this "correlation" theory is directly at odds with the plain meaning of the existing Stark Law regulations, and we believe CMS has been clear in its view. Nonetheless, providers are being forced to defend against this legal theory, and it has gained the apparent support of at least one court[2]. We therefore encourage CMS to adopt clear regulatory language that a bonus based on personally performed services that generate a corresponding facility fee does not result in compensation that "takes into account" the volume or value of referrals. We believe this can be accomplished in a number of ways, including through the deeming provision at 42 C.F.R. § 411.354(d) suggested above.

[2] *See United States ex rel. Drakeford v. Tuomey (Tuomey II)*, 792 F.3d 364, 379-380 (4th Cir. 2015).

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Cancer Treatment Centers of America

Comprehensive Cancer Care Network

(c) Commercial Reasonableness

We believe that the question of "commercial reasonableness" should be understood as an inquiry into whether the items or services being purchased are useful in the purchaser's business and purchased on terms and conditions typical of similar arrangements between similarly situated parties. The concept should be limited to the noneconomic aspects of the arrangement. The amount and nature of the payments are properly and separately addressed under the fair market value and takes into account requirements.

4. Preemption of State Laws

The proliferation of so called "mini Stark" laws among the states should be addressed in manner to eliminate conflicts between these state statutes and the Stark Law (as reformed based on the suggestions above). The existence of multiple and often conflicting state rules has the natural effect of limiting the development of a national market in healthcare services, reducing choices for consumers and raising the cost of healthcare. We recognize that preemption of such laws may be a more proper subject for action by Congress rather than agency regulation. We include this suggestion here, however, to urge CMS to consider supporting legislation to achieve this end.

Respectfully Submitted,



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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

On

"Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

September 13, 2018
1:15 p.m.

2322 Rayburn House Office Building

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Burgess, Ranking Member Green, and the members of the Subcommittee on Health for your leadership in exploring ways to improve access to quality healthcare services in the Medicare program. The chain pharmacy community welcomes the opportunity to partner with lawmakers and other stakeholders in examining ways to improve access to better care through innovative, value-based care in the Medicare program.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. For more information, visit www.NACDS.org.

As the Subcommittee examines innovative approaches to improve health care quality and lower costs through value-based program designs, NACDS urges the Subcommittee to consider how community pharmacies can assist in achieving these important health system goals.

Access, quality, cost, and efficiency in healthcare are critical. This is especially important as many beneficiaries suffer from multiple chronic conditions and require coordinated care by a team of professionals. Significant consideration should be given to policies and initiatives that improve healthcare capacity and strengthen community partnerships. Retail pharmacies are often the most readily accessible healthcare provider. Research shows that nearly all Americans (89%) live within five miles of a retail pharmacy. To expand on the need for including pharmacy as a valued member of the health care team, we direct you to the attached letter NACDS recently submitted to the Health Care Innovation Caucus detailing the role retail pharmacies can play in innovative value-based programs.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

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Statement to The
U.S. House Energy and Commerce Committee, Subcommittee on Health
Hearing on "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare"

September 13, 2018

Thank you for the opportunity to provide Medtronic's views regarding barriers to value-based care in Medicare.

Today, health systems across the country, including Medicare, are driving greater accountability for improved outcomes and reduced costs through new healthcare payment and delivery approaches that pay for value instead of volume. Medtronic's mission similarly guides us to deliver technology innovations that enable providers to manage chronic disease and improve patient outcomes – alleviating pain, restoring health and extending life. We believe fundamentally in the importance of shifting to payment models that include shared alignment and accountability with our healthcare system partners for the patient outcomes achieved in the use of our services and technology.

To realize the promise of value-based healthcare, Medtronic has formed partnerships with healthcare stakeholders and developed comprehensive technology and service solutions to address inefficiencies in healthcare delivery and foster value creation. We have a deep understanding of how cutting-edge technology can drive better clinical outcomes. We also know from experience that many technologies will not realize their full potential if they are simply placed into the care setting in a vacuum without the proper support services and training to fully leverage their capabilities in the clinical environment.

Medtronic's partnerships with providers, payers and healthcare systems include services and solutions to assist in optimizing the care pathway, coordinating care along that pathway, tracking outcomes, and sharing accountability for the results. Our capabilities in behavioral economics, reimbursement policy, data analytics, and care coordination allow us to meaningfully contribute to the optimized use of our technology to enable less invasive procedures, faster recovery times, fewer complications, and reduced utilization of clinical resources.

Value-based arrangements provide for the sharing of direct accountability for healthcare costs and patient outcomes between two or more healthcare entities and include the following characteristics:

- Targeted and meaningful outcomes must be identified in advance, with relevant metrics approved by stakeholders;
- Relevant costs of care must be known and agreed upon by stakeholders; and
- Payment by and between stakeholders is based or contingent on meeting the clinically meaningful outcomes and economic value created by the products, services and/or solutions provided.

Medtronic has established a process when considering and developing potential value-based arrangements to ensure rigor and discipline around the targeted disease or condition, identification of the appropriate patient

cohort, establishment and tracking of meaningful clinical and economic outcomes, and creation of payment models. This process helps ensure that:

- Relevant clinical and economic outcomes are related to the underlying disease or condition;
- Patient cohorts can be well-defined so best practice care pathways may be developed to reduce costs and improve outcomes;
- Outcome measures are well-defined, meaningful to patients, achievable in a defined timeframe, and agreed upon by key stakeholders;
- Outcome measures can be accurately collected through claims data, existing registries, Electronic Health Records (EHR), or other low-cost mechanisms; and
- The offering delivers measurable value – improved outcomes to patients and other benefits to the healthcare system through lower cost of care and/or other efficiencies or shared accountability.

One example of a Medtronic value-based arrangement is the Medtronic TYRX™ Risk-Share Program. The TYRX™ Antibacterial Envelope is the first commercially available implantable medical device designed to stabilize Cardiac Implantable Electronic Devices (CIEDs) and may help reduce the risk of infection. It is essentially an absorbable antibacterial envelope in which the CIED is housed when implanted into a patient.

The TYRX™ Risk-Share Program was designed to address a clear healthcare problem. Today, infections occur in 1-4 percent of all CIED implants, costing an average of $46,000-$87,000 per patient. The mortality rate of such infections is significant – ~50 percent at three years. Clinical studies have demonstrated that TYRX™ may help reduce CIED infections by 70-100 percent.

Under the TYRX™ Risk-Share Program, Medtronic will provide a rebate to participating facilities if a CIED infection occurs when a TYRX™ Envelope is used. In other words, the program incorporates accountability, such that failure to meet its clinical objectives – avoidance of CIED infection – results in Medtronic sharing the risk associated with this clinical outcome.

A second example is an innovative value-based relationship between Medtronic and UnitedHealthcare focused on delivering patient-centered solutions that improve health outcomes while reducing healthcare costs related to diabetes treatment and management.

In 2016, UnitedHealthcare and Medtronic announced an expanded relationship that gave UnitedHealthcare members with diabetes access to advanced insulin pump technologies and comprehensive support services offered by Medtronic. The partnership includes a value-based component, tying a portion of our payment from UnitedHealthCare to improved patient HbA1C levels and total cost of care.

Medtronic and UnitedHealthcare recently announced first year results stemming from the agreement. An analysis of over 6,000 UnitedHealthcare members with diabetes on Medtronic MiniMed™ 630G and previous generation insulin pumps demonstrated 27 percent fewer preventable hospital admissions compared to plan participants who are on multiple daily injections of insulin.

While Medtronic and other medical technology companies have launched a number of value-based arrangements similar to those summarized above, the existing healthcare fraud and abuse laws generally limit our ability to more robustly share risk for achieving "value" in our offerings, i.e., the improvements in patient outcomes in relation to the cost, within Medicare.

The Anti-Kickback Statute, the physician self-referral law – known as the Stark Law – and related fraud and abuse regulations were designed for a fee-for-service healthcare system to target behaviors that inappropriately increased utilization and costs. Unfortunately, the narrow interpretation and historical application of these laws stand at odds with the goals and objectives of a value-based healthcare system and prohibit full implementation of value-based programs.

The outdated fraud and abuse regulatory landscape combined with the government's historical enforcement approach creates a chilling effect for new models and partnerships, encumbering our nation's progress to achieve value-based care. Simply put, participants who can bring new and innovative ideas and relationships to the healthcare delivery system are reluctant to take on the risk of violating these outdated laws.

Medtronic believes that maintaining but modernizing these laws is critical to advancing the promise of value-based healthcare. We applaud the recent Requests for Information issued by CMS and the HHS Office of the Inspector General on the Stark Law and Anti-Kickback Statute that recognize this challenge, as well.

Specifically, the Anti-Kickback Statute was intended to protect against fraud and abuse by limiting certain types of financial arrangements and related incentives among healthcare parties, keeping them financially separated. Yet, under value-based payment arrangements, the goals are the opposite; parties are encouraged to be financially aligned to create incentives to encourage better coordination of care and other behaviors that improve outcomes and efficiencies. However, the law's existing safe harbors have not kept pace with how healthcare is delivered today and provide very limited protections for innovative value-based arrangements.

Today, much of the legal analysis for value-based arrangements depends on a somewhat subjective facts and circumstances analysis as opposed to a more objective, predictable and consistent value-based safe harbor application. For example, current law presents a significant challenge to arrangements that bundle devices and services, such as post-surgery or post-discharge remote monitoring services, which can help prevent unnecessary and costly rehospitalizations, or help catch health issues before they become serious and costly.

The Anti-Kickback Statute has very narrow technical requirements that must be met for a proposed arrangement to fit squarely within the law's existing discount safe harbor. The provision of such typically non-reimbursable services alongside the sale of a reimbursable product in a risk-sharing arrangement raises complex questions under the discount safe harbor requirements for bundling products and/or services, which require that all the items in the bundle be reimbursed by the "same methodology."

There is no meaningful consensus among the health law bar as to what "same methodology" means, which stifles true development and implementation of value-based healthcare programs. Absent clear safe harbor protection, the analysis depends on a facts and circumstance review, which as noted above may be highly subjective and inconsistent and lead a manufacturer or other stakeholder to decide that the risk of criminal prosecution is not worth the effort to offer innovative value-based programs.

Additionally, the services could be reviewed under the Anti-Kickback Statute's services safe harbor which requires, among other things, that the services be priced and charged at "Fair Market Value." The challenge with this is that because the healthcare market is so new to these types of value-based services and products programs, it is hard to find comparable offerings to serve as benchmarks for pricing. The risk of the services being priced at an amount that is arguably not consistent with a Fair Market Value also causes many manufacturers and other stakeholders to avoid potential legal exposure and decline to innovate in this important area.

To address these and similar challenges slowing the shift to value-based healthcare, we urge Congress to support consideration of new Anti-Kickback Statute and Stark Law value-based arrangement exceptions and/or safe harbor protections that provide appropriate opportunities for collaborative arrangements between and among all healthcare stakeholders, including providers, payers, therapy manufacturers, healthcare services and solutions providers and others, while maintaining protections for patients and the healthcare system.

Related, fraud and abuse waivers granted by the Centers for Medicare and Medicaid Services (CMS) and the Health and Humans Services Office of the Inspector General (OIG) for federal value-based healthcare programs such as through the Center for Medicare and Medicaid Innovation (CMMI) have generally been limited to provider entities. This appears to envision a healthcare system that is absent of any meaningful participation by non-provider entities to the enablement of clinical services that can help drive improvements in outcomes and efficiencies in patient care.

This means that some entities, including medical technology companies like Medtronic, are not able to fully avail themselves of the same protections that are available to traditional healthcare providers. This perspective makes sense historically, in a fee-for-service only system; however, as the healthcare industry continues to evolve toward value-based care, we need to account for the various entities that must collaborate to coordinate patient care, including under CMMI and other federal value-based programs.

To address this challenge, we urge the Congress to work with CMS and the OIG to extend federal value-based healthcare program waivers to more comprehensively allow for non-provider, manufacturer participation and risk-sharing in CMMI pilots, Medicare Alternative Payment Models (APMs), such as the Bundled Payments for Care Improvement-Advanced (BPCI-Advanced) program, and other initiatives.

In the case of both new exceptions/safe harbors and waivers, the incorporation of the concepts of shared financial risk and accountability, such that failure to meet pre-defined and -determined clinical and/or economic outcomes and objectives would force parties to incur financial exposure for missing those goals, would serve as a critical disincentive for overutilization and protection of both patients and federal healthcare dollars.

We appreciate this opportunity to provide insight into the role of medical technology companies like Medtronic in the delivery of value-based healthcare. We hope it is helpful in illustrating the need for Congress to modernize both the Anti-Kickback Statute and Stark Law through enactment of new value-based arrangement safe harbors, and the extension of federal healthcare program fraud and abuse waivers, in order to advance the collaborations needed to achieve the ultimate goals of value-based healthcare – improved patient outcomes at lower cost.

Thank you, again, and we welcome the opportunity to continue to work with you on this important issue.



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Examining Barriers to Expanding Innovative Value-Based Care in Medicare

Statement for the Hearing Record
submitted by

American Society for Gastrointestinal Endoscopy

to the
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

September 13, 2018

The American Society for Gastrointestinal Endoscopy (ASGE) and it's 14,000 members thank the Subcommittee for its interest in understanding the barriers to physician participation in innovative value-based payment and delivery models in Medicare. We appreciate the opportunity to submit the following statement for the hearing record highlighting two areas that we believe are impeding physician movement toward value-based care, as well as more coordinated care that has the potential to improve patient quality of care and outcomes and reduce health care spending: 1) the lack of Advanced Alternative Payment Model (APM) opportunities for physician specialists; and 2) Stark Law restrictions.

Improving the Availability of Advanced APMs

Most Medicare providers, physician specialists in particular, are disadvantaged by the lack of choice within the Quality Payment Program (QPP) by not having Advanced APMs available to them. Immediate and bold steps are needed to improve Advanced APM opportunities for physician specialists, including acting on the recommendations of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), as established by the Medicare and CHIP Reauthorization Act. The physician stakeholder community held out great hope that the PTAC and its process for reviewing and commenting on proposed physician-focused payment models (PFPMs) put forth by individuals and other stakeholder entities would create greater APM opportunities for specialty physicians and an alternative to the Merit-based Incentive Payment System (MIPS). Yet, the lack of progress is disappointing.

At a hearing on APMs held by this Subcommittee on Nov. 8, 2017, Jeffrey Bailet, MD, chair of the PTAC, stated that there has been "tremendous" interest by the physician specialty community in the PTAC process and that the PTAC is reviewing a number of specialty PFPMs. Unfortunately, the

Centers for Medicare and Medicaid Services (CMS) has yet to implement a single APM recommended by PTAC, including Project Sonar which was recommended for limited testing. Project Sonar is a physician-focused APM that is designed to improve care for patients with Inflammatory Bowel Disease (IBD).

Removing Stark Law Barriers

While conversations with CMS regarding Project Sonar continue, gastroenterologists are seeking to implement the model with commercial payers. This chronic care management model, with a prospective payment (per member per month payment) and retrospective reconciliation based on an expected target price, encourages care coordination and patient engagement. Under an optimal scenario, participating gastroenterologists would be encouraged to either internalize or arrange contract terms involving gainsharing with a Designated Health Services (DHS) entity for providing advanced imaging and with a hospital for complex outpatient procedures that can't be performed in the ambulatory surgery center and for inpatient care.

As a next phase, in which physicians take on greater risk for the care and management of IBD patients, a gastroenterology practice, for optimal care management, may involve the use of tests — some of which are not uniformly covered now by payers — but allow for treatment decisions that ultimately improve outcomes and yield cost savings. These complex patients also have nutritional needs and often psychologic and psychosocial issues that would benefit from the involvement of dietitians, social workers and psychologists. The involvement of any of these components may require independent contracting and could involve shared savings or other non-traditional payment arrangements. Stark laws and regulations, however, serve as a barrier to the creation of these types of arrangements.

The federal physician self-referral law, or "Stark Act," is a labyrinth of exceptions, rules and regulations. Physician practices interested in innovative payment and delivery arrangements that have the potential to improve patient care and reduce costs are deterred by the mere threat of violating the Stark Law and the incredible cost of lawyers and consultants to ensure compliance.

Stark laws and regulations should not inhibit the creation of these types of arrangements, which, to work and achieve cost savings and higher quality, requires hospitals, physicians and all parties involved to enter into alternative payment arrangements.

ASGE believes the most straightforward approach to reduce confusion and anxiety associated with compliance of the Stark Law and to consequently encourage physician participation in innovative payment and care delivery design is for CMS to create a single, comprehensive waiver to the Stark Law for participants in any Medicare APM that can reasonably be expected to meet the "triple aim" of improved individual beneficiary quality of care; improved quality of care for patient populations; and lower growth of health care expenditures. A waiver should also be extended to physicians and entities providing DHS that participate in Other Payer APMs, as distribution of shared savings, incentive payments, and the provision of infrastructure necessary to earn non-Medicare bonuses also raise concerns under the Stark Law.

Creation of a waiver for physicians and other providers who participate in Medicare and Other Payer APMs will ensure that those APM entities and participants can utilize financial incentives, including the distribution of shared savings, that are otherwise prohibited under the Stark Law but are necessary for care coordination and for APMs to meet their intended goals.

ASGE endorses the "Medicare Care Coordination Improvement Act of 2017" (H.R. 4206) authored by Rep. Larry Bucshon and Rep. Raul Ruiz which would remove the "value or volume" prohibition of the Stark Law. This protection would apply to practices that are developing or operating an APM, including, Advanced APMs, APMs approved by the PTAC, MIPS APMs and other APMs.

The key impediment to APMs is that these types of arrangements inevitably link payments to the volume or value of physician referrals. Many of the Stark exceptions require that any compensation involved be calculated in a manner that does not take into account the volume or value of referrals between parties.

As noted in the models described above, physician groups may decide to enter into independent contractor arrangements. Under current Stark regulations, the agreement must satisfy either the Stark "personal services" or "fair market value" safe harbor. Those safe harbors require that compensation must be set in advance, consistent with fair market value and not determined in a manner that takes into account the volume and value of referrals or other business generated by the referring physician. These restrictions impede better management of a physician's referral patterns, utilization of ancillary services, and collaboration with high-quality or cost-efficient partners. As examples, for hospitals to work with medical staff members to improve quality and lower costs for specialty care, a traditional hourly "fair market" fee for work will not capture the complexity of teams of various practitioners working together on quality improvement projects and pathways to address episodes of care. Within APMs, there may be a variety of capitation and subcapitation for specialty case rates, incentive withhold pools, gainsharing or quality bonus payments. These will frequently be tied to volume and require agreements to refer within the "network" of providers within the APM.

Enactment of H.R. 4206 would constitute an important and necessary step to removing barriers to innovative value-based care and better care coordination.

Making Advanced APMs a Viable Pathway for Physicians

We believe Congress made a very prudent decision when it gave, as part of the Bipartisan Budget Act of 2018, CMS three additional years of flexibility for the implementation of MIPS. Another area that we suggest would benefit from congressional intervention is to modify the threshold for eligible clinicians to earn the status of Qualifying APM Participant. To become a Qualifying APM Participant, a clinician must meet a specific Medicare payment or patient count threshold, which may not be easily attainable depending on a practice's mix of services. For example, gastroenterologists may be interested in participating in CMS' new Bundled Payments for Care Improvement Advanced model, which is an Advanced APM, but because all the gastroenterology-related bundles are inpatient bundles, gastroenterologists are unlikely to meet either the required revenue or patient count thresholds. Only Advanced APM participants that meet the thresholds qualify for the APM bonus payment and a guaranteed exemption from MIPS.

To encourage development and participation in Advanced APMs, ASGE supports and encourages Congress to act on the proposal in the President's Fiscal Year 2019 Budget that would allow clinicians to receive a five percent bonus on physician fee schedule revenue received through the APMs in which they participate regardless of whether they meet or exceed the payment or patient thresholds. As explained in budget documents, this change would reward clinicians along a continuum for their participation in Advanced APMs without imposing arbitrary participation thresholds. Removing the thresholds would also simplify the QPP.

Conclusion

The ASGE asks the Subcommittee to support physicians as they transition to new value-based payment models by fostering early opportunities for success and eliminating barriers that impede advancement toward new payment and delivery designs. Congress can support physicians during this transition by:

- encouraging CMS to adopt the recommendations of the Physician Technical Advisory Committee;
- removing Stark law barriers to APM development and physician participation by passage of the Medicare Care Coordination Improvement Act of 2017 (H.R. 4206); and
- removing reference of payment or patient count thresholds from the definition of a Qualifying APM Participant at Section 1833(z)(2) of MACRA.

For questions or more information, contact Lakitia Mayo, ASGE Senior Director, Health Policy and Education (lmayo@asge.org or 630-570-5641) or Camille Bonta, ASGE consultant (cbonta@summithealthconsulting.com or 202-320-3658).

