

**EXAMINING BIPARTISAN LEGISLATION TO
IMPROVE THE MEDICARE PROGRAM**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
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COMMERCE
HOUSE OF REPRESENTATIVES
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¹ Ms. Grealy's full statement can be found at: <http://docs.house.gov/meetings/if/if14/20170720/106287/hhrg-115-if14-bio-grealy-20170720.pdf>.

² Dr. Moore's full statement can be found at: <http://docs.house.gov/meetings/if/if14/20170720/106287/hhrg-115-if14-bio-moorej-20170720.pdf>.

EXAMINING BIPARTISAN LEGISLATION TO IMPROVE THE MEDICARE PROGRAM

THURSDAY, JULY 20, 2017

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

The subcommittee met, pursuant to call, at 10:01 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Burgess, M.D. (chairman of the subcommittee) presiding.

Present: Representatives Guthrie, Barton, Shimkus, Murphy, Blackburn, McMorris Rodgers, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Butterfield, Matsui, Castor, Schrader, Kennedy, Eshoo, Degette, Pallone (ex officio), and Burgess.

Staff Present: Kelly Collins, Staff Assistant; Jordan Davis, Director of Policy and External Affairs; Daryll Dykes, Health Fellow; Paul Edattel, Chief Counsel, Health; Adam Fromm, Director of Outreach and Coalitions; Jay Gulshen, Legislative Clerk, Health; Drew McDowell, Executive Assistant; Alex Miller, Video Production Aide and Press Assistant; James Paluskiewicz, Professional Staff, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Policy Coordinator, Health; Evan Viau, Staff Assistant; Jeff Carroll, Minority Staff Director; Una Lee, Minority Senior Health Counsel; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; and C.J. Young, Minority Press Secretary.

Mr. BURGESS. The Subcommittee on Health will now come to order.

As a housekeeping note, there will be votes on the floor as we—probably before we conclude opening statements. The chair advises the members that we are keeping an eye on the floor, and when the votes are called, obviously, we will consider recessing at that point to reconvene immediately after votes.

Before I recognize myself for an opening statement, I also want to acknowledge the majority counsel, this is her last hearing. We are going out with a bang with 11 witnesses today. But Danielle Steele has done a good job for us, but as they say, she is going to a better place over in the other body. But thank you, Danielle, thanks for your help on the committee.

[Applause.]

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

Mr. BURGESS. I now recognize myself 5 minutes for an opening statement.

Today, we are going to be discussing 11 bipartisan policies led by members of this committee. Each of these policies exemplifies our shared commitment to strengthening the Medicare program for its current beneficiaries and improving it for future generations.

I would like to thank Representative Dingell for working with me on two of the bills that we will be considering today, H.R. 3120 and H.R. 3263. I have made it a top priority to improve the value of electronic health records for providers and patients. And I believe we have made some progress through the policies enacted in the Medicare Access and CHIP Reauthorization Act of 2015, as well as the 21st Century Cures Act of 2016. However, there is more to be done, and H.R. 3120 will continue to move us in the right direction.

Meaningful use requirements for physicians in hospitals in the Social Security Act demand that the Secretary seek to improve the use of electronic health records and health quality over time by requiring more stringent measures of meaningful use. Time has shown us that simply increasing the rigor of the standards does not improve the use of electronic health records or the quality of the healthcare delivered.

As the Secretary has mandated to continue to raise the stringency of standards over time, more and more providers would possibly fall behind. Therefore, the only clear result of increasingly stringent standards for meaningful use has been an increasing need for the Department of Health and Human Services to grant more waivers. H.R. 3120 will simply remove the mandate that meaningful use standards become more stringent over time and allow the Department to be deliberative in determining how meaningful use can improve electronic health records and the quality of care.

Over the past 5 years, the Independence at Home Demonstration program has provided Medicare beneficiaries with the unique opportunity to receive home health services that they would not otherwise have been able to access. Designed in a manner that requires home care providers to improve outcomes for patients while reducing the overall cost of care, the program continues to be a standard bearer for bipartisan collaboration in improving the delivery of care for seniors.

H.R. 3263 would both extend the program for an additional 2 years and allow providers currently participating in the program to increase the number of patients currently under management.

I want to take a moment to speak to the two discussion drafts the subcommittee will also review today. I hope both of these drafts show that the committee is open to ideas on ways to reform the Medicare program, and is willing to put in the long-term bipartisan work necessary to fully develop these important policies. For example, reforming the payment system for the mobile collection of lab samples offers an opportunity to reduce spending and protect program integrity and to move to an episodic payment. I hope the committee will see each of these bills offers a common sense improvement to the Medicare program.

There is one draft before us I hope we will not have to act on, and that is the discussion draft of another simple extender of the therapy caps exception process. Much like the sustainable growth rate formula, we have a policy inherent to the therapy cap that no one supports, and each year, we have to find offsets in the Medicare program to simply protect beneficiaries from a policy harmful to their access to treatment. Also, like the sustainable growth rate formula, this year-by-year approach is not cost effective, does not provide needed stability for providers and patients. As we did with the repeal of the sustainable growth rate formula, it is my hope that we can find a permanent policy solution for this issue. That work should start and be lead by this subcommittee. I hope members will examine these policies and provide feedback to the committee staff.

I do want to thank all of our witnesses for being here today. I look forward to hearing from each of you on how these bills we are considering can improve the Medicare program.

And I do want to recognize Mr. Bilirakis to speak on his bill.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Today we will be discussing eleven bipartisan policies led by members of this Committee. Each of these policies exemplifies our shared commitment to strengthening the Medicare program for current beneficiaries, and improving it for future generations. I would like to thank Representative Dingell for working with me on two of the bills we will be considering today-H.R. 3120, and H.R. 3263.

I have made it a top priority to improve the value of electronic health records for providers and patients, and I believe we have made great progress through policies enacted in the Medicare Access and CHIP Reauthorization Act of 2015 as well as the 21st Century Cures Act of 2016. However, there is still more to be done and H.R. 3120 will continue to move us in the right direction.

Meaningful use requirements for physicians and hospitals in the Social Security Act demand that the Secretary “seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use.” Time has shown that simply increasing the rigor of standards does not improve the use of electronic health records or the quality of health care. As the Secretary is mandated to continue to raise the stringency of standards over time, more and more providers are likely to fall behind. Therefore, the only clear result of increasingly stringent standards for meaningful use has been an increasing need for HHS to grant more hardship waivers. H.R. 3120 will simply remove the mandate that meaningful use standards become more stringent over time and allow the Department to be deliberative in determining how meaningful use can improve the use of EHRs and the quality of care.

Over the past 5 years, the Independence at Home Demonstration Program has provided Medicare beneficiaries with a unique opportunity to receive home health services that they would not otherwise be able to access. Designed in a manner that requires home care providers to improve outcomes for patients while reducing the overall cost of care, the program continues to be a standard bearer for bipartisan collaboration in improving the delivery of care for our seniors. H.R. 3263 would both extend the program for an additional 2 years, and allow for providers currently participating in the program to increase the number of patients that they manage under it.

I want to take a moment and speak to the two discussion drafts the subcommittee will also review today. I hope both show that the committee is open to ideas on ways to reform the Medicare program, and is willing to put in the long-term, bipartisan work necessary to fully develop these important policies. For example, reforming the payment system for the mobile collection of lab samples offers an opportunity to reduce spending, protect against program integrity vulnerabilities, and move to an episodic payment.

I hope the committee will see each of these bills offer commonsense improvements to the Medicare program, but there is one draft before us that I hope we will not have to act on and that is the discussion draft of another simple extender of the

therapy caps exception process. Much like the SGR we have a policy inherent to the therapy cap that no one supports and each year we must find offsets in the Medicare program to simply protect beneficiaries from a policy harmful to their access to treatment. Also, like the SGR, this year-by-year approach is not cost effective nor does it provide needed stability for providers and their patients. As we did with the SGR, it is my hope that we can find a permanent policy solution to this issue—that work should start and be led by this Committee.

I hope members will examine these policies and provide feedback to the Committee staff.

Thank you to all of our witnesses for being here today, I look forward to hearing how each of the bills we are considering can improve the Medicare program today and into the future.

Mr. BILIRAKIS. Thank you very much, Mr. Chairman. I appreciate it so much. Thank you again for holding this hearing, and I thank the panel for their testimony.

Last week, we had the largest healthcare fraud takedown in history. Four hundred twelve defendants were charged nationwide, including more than 80 cases in Florida, for Medicare fraud, totaling \$1.3 billion in losses.

Medicare is absolutely critical for seniors in my district and across the country. Not only is Medicare fraud an affront to hard-working taxpayers, it hurts the millions of seniors who rely on the program. That is why I introduced, along with my fellow Floridian, Kathy Castor, much needed legislation to strengthen penalties against those who commit fraud in the Medicare program.

The Medicare Civil and Criminal Penalties Update Act, H.R. 3245, cracks down on Medicare fraud and abuse by increasing civil and criminal fines. Some of these penalties have not been updated in over 20 years. We must ensure the Medicare program is strong and sustainable for today's and tomorrow's beneficiaries.

I yield back, Mr. Chairman. Thank you.

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

The chair now recognizes the subcommittee ranking member, Mr. Green, 5 minutes for an opening statement, please.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman. And I welcome our witnesses today.

Since 1965, Medicare has provided affordable health insurance coverage and access to the care for our Nation's seniors in most vulnerable populations. Few programs have improved the lives of Americans as significantly as Medicaid and Medicare. Fifty years ago, almost half of elderly Americans lacked health insurance, and now Medicare provides lifesaving insurance to nearly 100 percent of the adults over 65.

Today, we are examining 11 bipartisan bills that aim to improve the Medicare program, particularly Medicare Part B, which covers physician, outpatient, laboratory, and some home health services, as well as durable medical equipment.

One of the discussions we are actually considering will extend the therapy cap exceptions process. I have long supported repealing the therapy caps, which was enacted in 1997, and harm some of the most vulnerable beneficiaries. I support extending the exceptions process at the very least, but I also want to be sure that all the extenders that are included in the Medicare Access and CHIP

Reauthorization Act, MACRA, are set to expire at the end of the fiscal year or calendar year, are addressed in a timely fashion.

Another bill we are considering is H.R. 1148, the Furthering Access to Stroke Telemedicine, or FAST Act, is worthy of our support. The bill will expand Medicare reimbursement for providers for stroke telemedicine services beyond those provided in rural areas. Telemedicine, in general, holds great promise to improve patient care and lower costs, and I am pleased to be part of the bipartisan telemedicine working group. Telestroke, in particular, can be critical service to patients who need access to a stroke specialist as soon as possible after an event.

H.R. 849, the Protecting Seniors' Access to Medicare Act, will repeal the Independent Payment Advisory Board, the IPAB. While the recent Medicare Trustees' report concluded that the IPAB recommendation process wouldn't be triggered this year, it is still important that Congress move to repeal this ill-conceived board. We should not be outsourcing our responsibility to manage and oversee the Medicare program. I opposed the IPAB when it was debated during the crafting of the Affordable Care Act, and it wasn't part of our bill when we passed it in the House, and strongly support its repeal.

H.R. 3163, the Medicare Part B Home Infusion Services Temporary Transitional Payment Act, is another bill worthy of our support. It will provide temporary transitional payment for home infusion therapy under Medicare. The overpayment of the home infusion drugs was addressed in the 21st Century Cures, but the timing payment changes for drugs and services associated with their administration do not line up, potentially resulting in reduction of patient access. This bill fixes the problem by providing a temporary bridge from 2019 to 2021, so patients who need home infusion therapy don't unduly lose access to the care they need.

I also want to highlight H.R. 3271, Protecting Access to Diabetes Supplies Act. The bill would make improvements to Medicare's competitive bidding program for diabetes testing strips by strengthening patient protections and enhancing beneficiary choice. It would require CMS to enforce the requirement that suppliers provide at least 50 percent of all diabetes test supplies that are commercially available before implementing a competitive bidding program, prevent suppliers from coercing beneficiaries into changing their choice of test strips, and make it easier for patients to switch and receive different testing supplies if they want to. I have co-sponsored this legislation in the past, and I will continue to support it.

H.R. 2465, the Steve Gleason Enduring Voices Act, will permanently get rid of the durable medical equipment rental cap for speech generating devices. SGDs are exempt from the rental cap until October 1 of 2018. This bill would make the policy permanent. We should ensure beneficiaries who rely on SGDs have the access to their necessary and personalized communication technology, even if they reside in a nursing home or are hospitalized or in a hospice.

Mr. Chairman, all 11 bills are bipartisan, and will improve Medicare participating providers, and more importantly, care for our

beneficiaries. I look forward to hearing from these folks and I yield back the balance of my time.

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

The chair recognizes the chairman of the full committee, Mr. Walden of Oregon, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you. Thank you very much, Mr. Chairman. Thanks for holding this hearing.

As we have heard, we are going to look at 11 bipartisan bills today as part of reforms to Medicare Part B. Each of these have been championed by different members on this subcommittee. We care deeply about them. We look forward to your testimony.

Together, we seek to improve the care delivered to our Nation's seniors who rely on the Medicare program, whether that is by allowing them to stay in their homes and seek care through home infusion or receiving home call visits or the Independence at Home program.

We want to improve these programs. We want to improve the integrity of them. We want to look at the vulnerabilities and the current laboratory fee schedule. We want to update the criminal and civil monetary penalties associated with Medicare fraud. Fundamentally, no crook should ever be less afraid of defrauding the Medicare program or taking advantage of a beneficiary simply because the penalties haven't been updated in decades. We need to make those penalties have teeth. And when we have an extremely successful program like competitive bidding, which has saved Medicare and its beneficiaries billions of dollars, proper oversight work of our committee should not stop. I always believe in oversight. I think it is important for programs that we pass, to make sure that they are being implemented appropriately, and for programs that have been there a long time, to make sure that they are working for the people they are intended to serve.

Today, we will also seek to use the ability of providers to deliver care by allowing CMS flexibility in setting goals for meaningful use and discuss the permanent solution of the arbitrary cap on therapy services. I have heard about that from time to time. No doctor should be forced to counsel a patient to choose surgery over therapy because they might otherwise run out of therapy services.

Finally, there are times when the current Medicare rules just don't make sense. For example, Medicare would take away the ability of a beneficiary to speak when their care setting changes. A time when communication is most important. Or Medicare's current policy that pays for the debilitating impact of a stroke and the long-term care services that follow in the Medicaid program, instead of paying a trained neurologist to examine a patient, providing a telestroke consult, and potentially avoiding the cost and the disability altogether.

So I think all of these are common sense fixes. I believe my colleagues here would agree with that. It is more good work by this committee and by those of you who have brought these issues to our attention.

We will also address the Independent Payment Advisory Board. While the Medicare Trustees have given us some added time, we should not delay abolishing this expropriation of congressional authority over the Medicare program.

Finally, I want to thank Mr. Pallone and Mr. Green for their willingness to work with us on all of these efforts, and particularly, to begin the hard but necessary conversations surrounding a permanent policy on the therapy caps. Our committee has a long history of taking on these lingering problems and dealing with them by working together, and we have proven that this year, again, on a lot of different legislative fronts, and I look forward to continuing to do so.

So, again, thanks to our witnesses for being here. And with that, I know Mrs. McMorris Rodgers wanted time, if she is able to get here from her leadership meeting, but between now and then, I would yield the balance to my friend and colleague from Tennessee, Mrs. Blackburn.

Mrs. BLACKBURN. And I thank the chairman for yielding. And, Mr. Chairman, I thank you for this hearing. The topic is timely, as you can see, by the panel that is in front of us. You all look more like a football team up there ready to go to the game. And we are going to focus on a few areas.

I have 19 counties in my district, 16 of which are rural. So looking at what we do with rural access is something that is going to be very important to me. And as the chairman outlined some of the changes that are in front of us, increasing that access to rural providers is going to be important. Rescinding flawed systems that really are doing harm rather than increasing access, we will want to focus on that, and then program integrity. I think you cannot underestimate that. It is important, not only to us, but to the providers, and there are questions that we are going to have for each of you. So welcome. Many of you have been before us before, so we appreciate the continued conversation.

And, Mr. Chairman, I will yield back to the chairman.

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

The chair recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

Today, we will examine 11 bipartisan bills aimed at improving care in the Medicare program. Medicare plays a critical role in the lives of our Nation's seniors and disabled Americans, and it is so important that this committee continue to look for ways to strengthen the program and deliver the highest quality care to beneficiaries. And I commend the chairman for holding this hearing. I look forward to working with you on these measures as we move forward.

First, I want to say I am pleased that we will be discussing H.R. 1148, the FAST Act, introduced by Representatives Joyce and Griffith. When it comes to stroke, every second counts. Stroke telemedi-

cine, also known as telestroke, breaks down barriers to care, and is a valuable tool for combating our Nation's fifth leading cause of death.

The FAST Act would expand coverage of telestroke services in the Medicare program so that beneficiaries can get the right treatment at the right time, no matter where they live. I look forward to hearing from Dr. Kissela today about the impact of expanding telestroke services in the Medicare program.

Additionally, I am pleased that we have a discussion draft on extending the exceptions process and targeted manual medical review for physical therapy caps. It is long past overdue for us to have a serious discussion about a permanent policy to address these caps. In MACRA, we instructed CMS to eliminate manual medical review for all claims above the \$3,700 threshold, and instead put in place a targeted less burdensome review. I understand that this process is working quite well for both beneficiaries and providers, and I look forward to hearing from the American Physical Therapy Association today about how targeted medical review can be part of a long-term solution that both preserves access for beneficiaries and reduces the burden on providers.

I also look forward to hearing from the National Home Infusion Association about H.R. 3163. Home infusion is a critically important service that allows Medicare beneficiaries to receive infusion drugs at home, rather than other more expensive and less convenient sites of care. I support H.R. 3163, and I am glad that we have been able to work on a bipartisan basis on this important bill to ensure continued patient access to these important drugs at home.

I also look forward to hearing from our witnesses on the other six bills and the discussion draft on mobile laboratories. All of these bills aim to make meaningful changes to the Medicare program by protecting beneficiaries, reducing provider burden, improving program integrity, or delivering comprehensive primary care services to Medicare beneficiaries in their home. And I look forward to learning more about these bills and working on a bipartisan basis to advance these efforts.

And, finally, H.R. 849, introduced by Representatives Ruiz and Roe. This would repeal the Independent Payment Advisory Board, or IPAB. This is not the first time we have considered repealing IPAB. As I have said in the past, I am opposed to IPAB and would be in favor of abolishing it. However, unlike the past, I hope we can work in a bipartisan fashion to eliminate IPAB. It is my belief that Congress should not be ceding legislative authority to independent commissions like IPAB by allowing them to play more than an informational role.

The Affordable Care Act strengthened the Medicare program and put it on the path towards incentivizing value over volume. It lengthened the life of the Medicare trust fund and contributed to a lower rate of growth of Medicare expenditures. It is our job as legislators to continue this work to ensure that the program remains strong for future generations. It is not the job of an unelected commission.

So I look forward to learning more from our witnesses about all the policies up for discussion today. And unless someone else wants my time—I don't think so. I will yield back the balance of my time.

Mrs. MCMORRIS RODGERS. Would the gentleman yield?

Mr. PALLONE. Oh, you want my time? Sure.

Mrs. MCMORRIS RODGERS. Could I, please? Thank you. Thank you. A little bipartisanship going on. I promise not to say anything that offends you too much.

Thank you, Ranking Member Pallone, and everyone on the committee. In 2014, I heard from a concerned mom in my district, Gail Gleason, who told me a story about her son, Steve. Born and raised in Spokane, Washington, Steve was a college football and NFL star before being diagnosed with ALS in 2011. Gail was afraid outdated and practical Medicare payment regulations were preventing people like Steve from accessing critical technology, individualized speech generating devices. She was right.

Under the rules issued by CMS, these speech generating devices were categorized and covered under a capped rental payment. However, if an individual was admitted to a nursing home, hospital, or hospice, payment abruptly ended, leading to severe access issues. To fix this, we introduced the Steve Gleason Act in 2015, which required Medicare to cover these devices as routinely purchased medical equipment. This allowed patients to continue communicating with their doctors, their caregivers, and their loved ones using this cutting edge technology, regardless of where they were being treated. Thanks to a great deal of hard work right here in this committee, it became law later that year.

But we could only provide the relief for 2 years. The law is scheduled to sunset in 2018. This is why my legislation, which we will be discussing today, is so important. The Steve Gleason Enduring Voices Act makes the changes accomplished in the original Steve Gleason Act permanent. Without a permanent solution, the short-sided policy decisions previously made by CMS could again limit the ability of thousands of men and women living with these degenerative diseases to access their only means of communication, to tell their husbands, their wives, their children, that they love them.

The Steve Gleason Enduring Voices Act gives a permanent voice to the voiceless. And as Steve Gleason says, it ensures there are no white flags.

Thank you, and I yield back.

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

This concludes with member opening statements. The chair would like to remind members that, pursuant to committee rules, all members' opening statements will be made part of the record.

The floor is still in amendment debate, so we want to thank our witnesses for being here today, for taking time to testify before the subcommittee. Each witness will have the opportunity to give an opening statement, followed by questions from members.

Today, we are going to hear from Ms. Christel Aprigliano, CEO of the Diabetes Patient Advocacy Coalition; Dr. Brett Kissela, Professor of Neurology, Chair, Department of Neurology and Rehabilitation Medicine, University of Cincinnati Gardner Neuroscience Institute, on behalf of the American Academy of Neurology; Ms. Lisa Bardach, Speech-language Pathologist, ALS of Michigan; Dr. Varner Richards, Board Chair, National Home Infusion Associa-

tion; Ms. Mary Grealy, President, Healthcare Leadership Council; Dr. Justin Moore, CEO, American Physical Therapy Association; Ms. Stacy Sanders, Federal Policy Director, Medicare Rights Center; Dr. Eric De Jonge, President-elect, American Academy of Home Care Medicine; Mr. Alan E. Morrison, Chair, Diagnostic Services Committee, National Association for the Support of Long Term Care; Dr. Deepak Kapoor, Chairman and CEO, Integrated Medical Professionals; Mr. Cletis Earle, Chairman-elect of the Board of Trustees of CHIME.

We appreciate all of you being here today. And Ms. Aprigliano, you are now recognized for 5 minutes to summarize your opening statement, please.

STATEMENTS OF CHRISTEL APRIGLIANO, CEO, DIABETES PATIENT ADVOCACY COALITION; BRETT KISSELA, PROFESSOR OF NEUROLOGY, CHAIR, DEPARTMENT OF NEUROLOGY AND REHABILITATION MEDICINE, UNIVERSITY OF CINCINNATI GARDNER NEUROSCIENCE INSTITUTION, ON BEHALF OF AMERICAN ACADEMY OF NEUROLOGY; LISA BARDACH, SPEECH-LANGUAGE PATHOLOGIST, ALS OF MICHIGAN; VARNER RICHARDS, BOARD CHAIR, NATIONAL HOME INFUSION ASSOCIATION; MARY GREALY, PRESIDENT, HEALTHCARE LEADERSHIP COUNCIL; JUSTIN MOORE, CEO, AMERICAN PHYSICAL THERAPY ASSOCIATION; STACY SANDERS, FEDERAL POLICY DIRECTOR, MEDICARE RIGHTS CENTER; K. ERIC DE JONGE, PRESIDENT-ELECT, AMERICAN ACADEMY OF HOME CARE MEDICINE (AAHCM); ALAN E. MORRISON, CHAIR, DIAGNOSTIC SERVICES COMMITTEE, NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE (NASL); DEEPAK A. KAPOOR, CHAIRMAN AND CEO, INTEGRATED MEDICAL PROFESSIONALS; AND CLETIS EARLE, CHAIRMAN-ELECT, CHIME BOARD OF TRUSTEES

STATEMENT OF CHRISTEL APRIGLIANO

Ms. APRIGLIANO. Thank you.

Good morning, Chairman Burgess, Ranking Member Green, and members of the subcommittee. My name is Christel Marchand Aprigliano, and I am speaking to you today as the CEO of the Diabetes Patient Advocacy Coalition and as a person with diabetes. I am delighted to be here today to talk with you about and urge you to enact 3271.

Today, more than 30.3 million Americans are known to have diabetes, with an estimated 84.1 million diagnosed with prediabetes. According to CDC calculations, 1 in 3 Americans will have diabetes by 2050. And we are on the cusp of a severe health crisis.

The cost of this disease's well-known debilitating complications, including heart disease, blindness, nerve damage, kidney damage, and amputations, are common among people with mismanaged diabetes, and are associated with extraordinary consumption of health services. The Medicare program bears much of this financial burden. It is also well-known that the tight blood glucose control can reduce the risk of these developing complications.

Medicare's competitive bidding program, while saving money on diabetes testing products, may be hindering the ability to achieve this important control and causing problems that lead to higher

costs elsewhere within the program. Diabetes testing supplies—blood glucose monitors, test strips, lancets, et cetera—were included in the first rounds of CBP. Before the CBP, Medicare paid between \$34 and \$38 for a box of 50 test strips. Today, Medicare pays \$8.32 for a box of 50 test strips. For beneficiaries, this remarkable savings makes it easier to afford supplies, and I applaud you for that.

But, while the lower price yields substantial immediate savings, it comes at a cost for beneficiaries and for the program elsewhere. Since implementation of the national mail order CBP in 2013, Congress has seen reports indicating that beneficiary access to diabetes testing supplies has dropped significantly.

Recent studies by the IG for the Department of Health and Human Services show that the most commonly prescribed testing systems, before implementation of the CBP, are now no longer available via mail order. Why? Under the CBP, suppliers are paid the same amount by Medicare for diabetes testing supplies, regardless of which brand they offer. Medicare is incentivizing suppliers only to offer the least costly supplies available.

I have heard from beneficiaries who report suppliers trying to switch them to a different blood glucose monitor, presumably because those systems are cheaper for the supplier. The beneficiary is switched to an unfamiliar meter and despite the antiswitching protections. These are not the meters that they have been recommended and trained on by health professionals.

When a patient, particularly an older patient, is given an unfamiliar technology, they may not be nimble enough to make the transition. They can get frustrated and stop testing. Unfortunately, on top of that, if that testing system is of inferior quality, as they too often are, the threat to regular and accurate testing is even greater. A recent study by the Diabetes Technology Society brings to light the consequences of this incentive.

The data shows that more than 60 percent of the strips furnished to beneficiaries between October and December of 2016, failed the study's accuracy standards, which are the FDA's accuracy standards. In other words, more than half the systems paid for by Medicare during the last quarter of 2016 can't be relied on to produce accurate and consistent blood glucose readings, according to the study's standard.

Insulin and oral medications are lifesaving, but they can also be harmful, even fatal when misdosed. Inaccurate blood glucose readings can cause overdoses and underdoses of insulin or oral medications, sending people to the ER and costly hospitalization stays.

If the majority of test systems furnished to beneficiaries can no longer be relied upon to produce accurate results, we are no longer on the cusp of the public health crisis we see. We are in the midst of it, and Medicare is going to bear the financial brunt.

I am not here today advocating for Congress to eliminate the CBP. Policy behind Medicare's competitive bidding program is sound, shouldn't be abandoned. I do, however, believe it can and should be improved to ensure the safety of people with diabetes.

There are a number of steps that Congress should take to address these concerns. H.R. 3271 is a step in the right direction. Congress and CMS establish beneficiary protections, like the 50

percent and antiswitching rules, to prevent the shift in product access and deterioration in product quality. Nonetheless, these protections clearly are not properly implemented and also not sufficient. H.R. 3271 would strengthen these existing patient protections and establish new ones to better protect Medicare beneficiaries.

As a person living with diabetes since 1983, I rely on access to accurate blood glucose testing systems to mitigate both short- and long-term complications. For the more than 8 million Medicare beneficiaries in my diabetes community, I respectfully urge you to enact H.R. 3271 to ensure access to these blood glucose monitoring systems.

Thank you for the honor and the opportunity to speak with you today. I am delighted to answer any of your questions.

[The prepared statement of Ms. Aprigliano follows:]



**Statement for the Record from the
Diabetes Patient Advocacy Coalition**

**House Energy and Commerce Committee
Subcommittee on Health**

**Examining Bipartisan Legislation to Improve the Medicare Program
July 20, 2017**

The Diabetes Patient Advocacy Coalition (DPAC) is pleased to submit this testimony in response to the above referenced hearing, and specifically on H.R.3271, the Protecting Access to Diabetes Supplies Act.

The DPAC is an alliance of people with diabetes, caregivers, patient advocates, health professionals, disease organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of people with diabetes. DPAC seeks to ensure the safety and quality of medications, devices, and services; and access to care for all 29 million Americans with diabetes. In light of this mission, the DPAC has a strong interest in the Medicare Competitive Bidding Program (CBP).

The DPAC believes that additional legislative action is necessary to improve the program's functioning and protect beneficiaries with diabetes. As such, the DPAC appreciates the Subcommittee's request for suggestions on how the Medicare program can be improved to protect beneficiaries and ensure that they are able to access the care that they need. We urge the Subcommittee to take swift action on the proposals discussed herein.

Diabetes

Diabetes is a complex disease that requires the active engagement of the patient and a number of health care providers. Among U.S. residents ages 65 and older, 11.2 million had diabetes in 2012.¹

Costly and debilitating complications – such as heart disease, blindness, nerve damage, kidney disease and amputations – are common among people with mismanaged diabetes. Blood glucose control can reduce the risk of developing the eye, nerve, and kidney complications of diabetes. For some people with Type 2 diabetes, blood glucose levels can be effectively managed by healthful eating and regular physical activity, but nearly 18 million of the 29 million Americans with diabetes take either or both insulin or oral medication to manage blood glucose levels.

¹ Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services; 2014.

Treatment of diabetes among people aged 18 years or older with diagnosed diabetes, United States, 2010–2012

	Number of adults using diabetes medication* (millions)	Percentage using diabetes medication (unadjusted)
Insulin only	2.9	14.0
Both insulin and oral medication	3.1	14.7
Oral medication only	11.9	56.9
Neither insulin nor oral medication	3.0	14.4

*Does not add to the total number of adults with diagnosed diabetes because of the different data sources and methods used to obtain the estimates.
Source: 2010–2012 National Health Interview Survey.

Medicare's Competitive Bidding Program

Congress established the Competitive Bidding Program (CBP) for Durable Medical Equipment and Supplies in 2003 to achieve savings and address fraud concerns. Diabetes testing supplies – blood glucose testing strips and lancets, *etc.* – were among the supplies included in the first rounds of the CBP.

Under the first round of the CBP, Medicare payment for a box of 50 diabetes test strips provided via a mail order supplier² fell from an average of \$32.47 per box to \$14.62 per box, a decrease of nearly 55 percent. Upon the implementation of the National Mail Order (NMO) Program for Diabetes Testing Supplies (DTS) in July 2013 the payment rate for diabetes strips further decreased to \$10.41 per box of 50 strips. Medicare payment under the NMO Recompete, effective July 1, 2016, fell an additional 20 percent to \$8.32 per box of 50 strips.

Beneficiary Concerns

While this consistently decreasing price-per-box of strips results in substantial savings on the amount of money spent on testing supplies by the Medicare program, it comes at a cost for beneficiaries and the Medicare program overall.

Since implementation of the NMO program for DTS in July 2013, Congress has seen reports and data indicating that beneficiary access to DTS is being significantly restricted. Recent studies by the Inspector General for the U.S. Department of Health and Human Services^{3,4,5} and the American Association of Diabetes Educators,^{6,7} for example, show a dramatic and continued shift in market availability of DTS. These studies show that the most common tests systems used by beneficiaries before implementation of the NMO program are now no longer available to beneficiaries.⁸

According to the Inspector General, in the CBP in 2009, claims were submitted for at least 75 types of diabetes test strips with two types of strips accounting for 26 percent of Medicare mail order market share. By comparison, the Inspector General study of the third quarter of 2013 (the first quarter after the

² Diabetes test strips purchased at retail locations were not subject to Round 1 of the CBP.

³ Office of Inspector General, Memorandum Report, “*Medicare Market Shares of Mail Order Diabetes Test Strips from July – September 2013*,” OEI-04-13-00680, June 13, 2014.

⁴ Office of Inspector General, Memorandum Report, “*Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program*,” OEI-04-13-00681, June 20, 2014.

⁵ Office of Inspector General, Memorandum Report, “*Medicare Market Shares of Mail Order Diabetes Test Strips*,” OEI-04-10-00130; December 2, 2010.

⁶ “*Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey*”; American Association of Diabetes Educators (November 17, 2011).

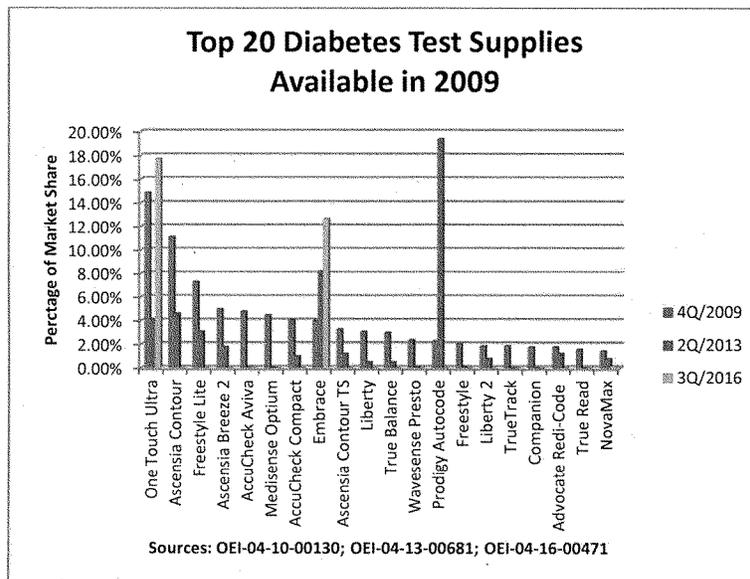
⁷ “*Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey*”; American Association of Diabetes Educators (March 2017).

⁸ *Ibid.*

national CBP was implemented) shows claims were submitted for only 43 types of diabetes test strips, with two types of strips accounting for 45 percent of the Medicare mail order market share. These numbers represent a 43 percent decrease in types of strips available to Medicare beneficiaries. This trend continues into the Inspector General's study of the third quarter of 2016 (the first quarter after the NMO recompetete was implemented; showing claims submitted for only 18 types of strips with the top two types representing 60 percent of the market place.⁹

Even more significant, the most common tests strips used by beneficiaries before implementation of the National Mail Order Competitive Bidding Program are now no longer available to beneficiaries.

Rather than preserving access to a broad array of products, the CBP has forced the market to consolidate sharply, leaving beneficiaries with fewer options. This point is illustrated in the chart below, which shows that much of the product available in the marketplace in 2009 is no longer available to Medicare beneficiaries.



The DPAC has long been concerned about the negative effect this has on beneficiary health status, morbidity and mortality, and program costs. Unfortunately, some of our concerns are now substantiated by the results of a study recently published by a group of leading endocrinologists, diabetes researchers

⁹ Office of Inspector General, "Medicare Market Shares of Mail-Order Diabetes Test Strips from July through September 2016"; OEI-04-16-00471; February 2017.

and health services researchers in Diabetes Care, the clinical, scientific journal of the American Diabetes Association.¹⁰

The article, “Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis,” published in the April 2016 edition of Diabetes Care, studied the implementation of the CBP and its impact on access to blood glucose testing supplies and beneficiary health outcomes. Specifically, the authors conducted a longitudinal, retrospective study examining four years of Medicare claims data comparing a cohort of Medicare beneficiaries with diabetes who treat their diabetes with insulin and who reside in competitive bidding areas to those who reside outside competitive bidding areas. The study found, among other things, the following:

- A significant percentage of beneficiaries in areas subject to the CBP shifted from purchasing DTS from mail order suppliers to retail pharmacies after the CBP became effective.
- A significantly higher proportion of insulin-treated Medicare beneficiaries with diabetes who were adherent with insulin therapy and adherent to testing with DTS in areas subject to the CBP substantially reduced or even stopped purchasing diabetes testing supplies after the CBP became effective compared to matched populations in areas not subject to CBP. Not only did purchase patterns change, but these beneficiaries substantially reduced, and in some cases stopped, testing blood glucose levels, even though they continued to treat their diabetes with insulin.
- The drop-off in testing among these insulin-treatment adherent beneficiaries was associated with an increase in mortality, an increase in inpatient admissions, and higher inpatient costs.

These findings highlight a number of disturbing developments. First, the CBP was intended to control costs without impacting access to services. The study indicates that, in areas where competitive bidding for DTS was implemented, the program failed to achieve the desired effects. The study found that beneficiaries in CBP areas switched to traditional retailers as a source for their DTS, moving away from the mail order suppliers subject to the CBP. Beneficiaries who were able to navigate the new system were voting with their feet. Because of differences in the business model and how consumers interact with a retail pharmacy versus a mail order supplier, retail pharmacies tend to carry more of the brands and models that beneficiaries prefer, as opposed to only carrying the least expensive models.

Second, the study shows that a significant percentage of beneficiaries in CBP markets who were adherent to insulin treatment and previously adherent to testing with DTS reduced or eliminated their purchase of testing supplies after the implementation of CBP.

Last, and most critically, the study indicates that decreasing or eliminating testing among insulin-treated beneficiaries has a negative impact on beneficiary health outcomes. The study showed that in CBP markets, insulin-treated beneficiaries who were adherent to insulin therapy and migrated from being adherent to testing with DTS to only partial or no testing with DTS after the introduction of CBP had nearly twice as many inpatient hospital admissions as did matched beneficiaries in non-CBP markets, and those admissions were nearly twice as expensive. Most disturbing, the study showed that those insulin-adherent beneficiaries in CBP markets who migrated to not purchasing or purchasing fewer testing supplies were at greater risk of death than those who did not.

¹⁰ *Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis*, Diabetes Care, Puckrein, Gary A., et al., DOI: 10.2337/dc15-1264 (Apr. 2016).

Adding to these concerns are recent findings from the Diabetes Technology Society that indicate that, of the systems available to Medicare patients, a shocking number do not produce accurate test results.¹¹ The Diabetes Technology Society recently published the results of its testing of 18 different home blood glucose monitoring systems representing those commonly used by diabetes patients during the time period 2013 to 2015, when the study protocol was developed.

The Diabetes Technology Society tested these 18 different home blood glucose monitors against ISO standards in effect when the study's protocol was developed and the latest FDA guidance (FDA 2016, "Self-Monitoring of Blood Glucose Test Systems for Over-the-Counter Use"). The study's authors found that only six of these systems produced results that were consistently accurate.

Most notable among the study's findings is that all of the products used in the Medicare NMO CBP (that had more than 0.2 percent utilization in Q4 2016) that were tested – failed. The Medicare mail-order products tested represented 90 percent of Medicare mail order product volume as of Q4 2013 and 61 percent as of Q4 2016, based upon the respective OIG Medicare mail-order surveys. The products that passed the test and received the "Seal of Approval" were not available to Medicare beneficiaries through Medicare Mail order winning suppliers as of the Q4 2016 OIG survey.

The table on the following pages shows the main results of the Diabetes Technology Society's study.

¹¹ "Blood Glucose Monitor Surveillance Program"; <https://www.diabetestechology.org/surveillance.shtml>; Klonoff, D., et al.; June 23, 2017; Last accessed July 17, 2017.

MAIN RESULTS																
Brand	Blood Glucose Monitor	Test Strip	Study 1			Study 2			Study 3			Overall				
			N	Percentage Compliant †	Pass/Fail	N	Percentage Compliant	Pass/Fail	N	Percentage Compliant	Pass/Fail	Passes out of 3 Studies	Seal of Approval ‡	Valid Trials	Compliant N	Compliant %
Bayer	Contour Next	Contour Next	98	99%	PASS	101	100%	PASS	113	100%	PASS	3	YES	312	311	100%
Roche	ACCU-CHEK AVIVA Plus	ACCU-CHEK AVIVA Plus	97	97%	PASS	101	100%	PASS	113	98%	PASS	3	YES	311	306	98%
Arkray	Walmart RelOn Confirm (Micro)	RelOn Confirm (Micro)	100	96%	PASS	114	96%	PASS	103	99%	PASS	3	YES	317	307	97%
Agamatrix	CVS Advanced Freestyle Lite	CVS Advanced Freestyle Lite	101	96%	PASS	114	96%	PASS	103	98%	PASS	3	YES	318	307	97%
Abbott	Accu-Chek SmartView	ACCU-CHEK SmartView	108	98%	PASS	106	96%	PASS	106	92%	PASS	3	YES	320	305	95%
Arkray	Walmart RelOn Prime	RelOn Prime	98	85%	FAIL	101	95%	PASS	113	96%	PASS	2	NO	312	288	92%
LifeScan	OneTouch Verio	OneTouch Verio	108	87%	FAIL	106	98%	PASS	105	91%	PASS	2	NO	319	294	92%
Prodigy	Prodigy Auto Code	Prodigy No Coding	98	86%	FAIL	101	92%	PASS	113	93%	PASS	2	NO	312	282	90%
LifeScan	OneTouch Ultra2	OneTouch Ultra	97	92%	PASS	101	84%	FAIL	113	94%	PASS	2	NO	311	280	90%
Abbott	Walmart RelOn Ultima	RelOn Ultima	107	96%	PASS	106	97%	PASS	106	75%	FAIL	2	NO	319	285	89%
Bayer	Contour Classic	Contour	108	95%	PASS	106	85%	FAIL	106	86%	FAIL	1	NO	320	284	89%
Omnis Health	Embrace	Embrace No Code	102	87%	FAIL	114	93%	PASS	103	84%	FAIL	1	NO	319	282	88%
HDI/Nipro	True Result	True Result	101	94%	PASS	114	83%	FAIL	103	86%	FAIL	1	NO	318	279	88%
HDI/Nipro	True Track	TrueTrack	102	83%	FAIL	103	80%	FAIL			FAIL*	0	NO	205	167	81%
BioSense Medical	SokusV2	SOLUS	108	56%	FAIL	106	84%	FAIL	106	89%	FAIL	0	NO	320	244	76%
Diabetic Supply of Suncoast + Philosys, Inc.	Advocate Redi-Code + Gmate Smart	Advocate	102	88%	FAIL	114	71%	FAIL	103	68%	FAIL	0	NO	319	241	76%
		Gmate	108	61%	FAIL	106	79%	FAIL	106	72%	FAIL	0	NO	320	226	71%

* No Study 3 data for HDI/Nipro TrueTrack because of test strip recall.
† Within 15% of reference value if 100 mg/dl or 15 mg/dl of reference value if ≤ 100 mg/dl.
‡ Studies 1, 2, and 3: each of the 18 blood glucose monitoring systems (BGMS) was tested at 3 different sites. Over the 3 studies each BGMS was tested once by each site. The number of compliant readings needed to pass depends on the number of trials. For 100 trials, at least 91 readings must be within 15% or 15 mg/dl of the reference value. Full methodology of the study will be published.

Persons with diabetes rely on these systems to test their blood sugar levels, sometimes many times during the day. Even though a disturbing number of patients have reduced or eliminating testing altogether, testing should not be viewed as optional. Blood sugar testing helps patients maintain their health and avoid getting sick from blood sugar levels that are too low or too high. Because insulin, while life-saving for persons who manage their diabetes with this drug, can be harmful, even fatal, if mis-dosed, Medicare beneficiaries must be able to rely on accurate test systems to help manage their insulin therapy.

Immediate Action Needed

While its intentions behind the CBP are admirable, Congress could not have foreseen the scope and impact of the unintended consequences of reduced testing, increased morbidities, and lessened accuracy of the systems being made available to Medicare beneficiaries.

While Congress did include a number of beneficiary protections in the original CBP statute, these protections are not having the intended effect and continue to leave beneficiaries vulnerable to harm.

Congress has the opportunity now to take steps that address these deficiencies.

Enhance Beneficiary Protections

On July 17, 2017, Congresswoman Diana DeGette, Congressman Tom Reed and Congresswoman Susan Brooks introduced H.R. 3271, the “Protecting Access to Diabetes Supplies Act.” This bill reflects lessons learned from the first rounds of the CBP, and ensures that as CMS embarks on future rounds, beneficiaries have access to preferred and familiar test systems. These protections should be enacted as soon as possible.

1. Strengthen the 50 Percent Rule

Under the CBP, suppliers are paid the same amount by Medicare for DTS regardless of which brand of DTS they supply to a beneficiary. As such, suppliers have a powerful economic incentive to maximize profits by offering the least expensive supplies obtainable. Congress was concerned that this incentive would lead suppliers to significantly restrict the brands and models of DTS available and to no longer offer many of the test systems commonly used by beneficiaries. Under this scenario, beneficiaries might not be able to find replacement supplies for their current test systems. Congress enacted the “50 Percent Rule” to ensure that beneficiaries would continue to have access to the same test systems that they used prior to implementation of the CBP by requiring that mail order suppliers make available at least 50 percent of all types of diabetes test supplies on the market before implementation of the CBP.

Unfortunately, the manner in which CMS has implemented the 50 Percent Rule has rendered this statutory protection inadequate. CMS interpreted the statute as applying only to brands included in a supplier’s bid; not to the inventory maintained and offered by the supplier once awarded a CBP contract. Under CMS’ interpretation a supplier was able to submit a bid that included a wide range of DTS brands yet only maintain in their inventory a small subset of those brands (typically the least expensive brands).

Moreover, CMS gave suppliers 10 percent credit toward satisfying the 50 percent requirement merely for selecting “Other—Not Listed,” a catch-all designation not associated with a particular test system or product.

The Inspector General found that in 2013, after implementation of the Round 1 of the CBP program, 22 suppliers submitted claims for 43 different types of DTS.¹² This report shows a dramatic decrease in the range of brands being made available. The OIG report also showed that three types of DTS accounted for more than one-half of the total volume of DTS provided under the CBP in 2013. By comparison, the OIG found that in 2009, 7 types of DTS accounted for 52 percent of the total volume.¹³ The report highlights a dramatic shift in the mix of types of DTS available after implementation of the CBP. Indeed, the top 7

¹² *Supra.* OEI-04-13-00680.

¹³ *Supra.* OEI-04-10-00130.

types of DTS in 2009 were not even included in the 2013 findings, indicating that these popular brands were no longer being made available.

H.R. 3271 would strengthen the 50 Percent Rule by making the following changes:

- Authorizes the Secretary to terminate a supplier contract if the Secretary finds that the supplier is not offering the products listed in its bid, unless the reason for not offering such products is because the products are no longer available from the manufacturer or there is a market-wide shortage of the product;
- Requiring bidding suppliers to demonstrate an ability to obtain an inventory of strips by volume consistent with the inventory mix provided in that supplier's bid;
- Establishing and maintaining a surveillance program to ensure that suppliers comply with the 50 Percent Rule;
- Requiring CMS to use multiple sources of data, and data that measures consumption and utilization of DTS by individuals other than just those Medicare beneficiaries who purchase DTS through Medicare-participating mail order suppliers, for purposes of measuring compliance with the 50 Percent Rule; and
- Barring CMS from giving bidding suppliers additional percentage credit toward satisfying the 50 Percent Rule by selecting "Other—Not Listed."

2. Strengthen the Anti-switching Rule

CMS established the Anti-switching Rule to protect beneficiary and physician choice of glucose meters. This rule requires suppliers to furnish the test system requested by the beneficiary, and prohibits contract suppliers from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand.

CMS has likewise rendered this protection inadequate. The Inspector General reports we have discussed clearly show a significant and dramatic shift in the types of DTS made available to and purchased by Medicare beneficiaries through the CBP. Shifts as dramatic as those identified by the Inspector General are wholly inconsistent with a program that is intended to protect a Medicare beneficiary's access to their preferred type of equipment. In fact, the reports suggest that mail order suppliers may be switching beneficiaries in spite of the rule.

Beyond the clinical implications, once a beneficiary is switched, it becomes administratively difficult, if not impossible, for the beneficiary to purchase additional supplies from another supplier, like a retail pharmacy, in order to continue to use their preferred type of DTS. When a mail order supplier sends unwanted supplies to a Medicare beneficiary and submits a claim for payment for those supplies, claims for additional supplies (*e.g.*, if the beneficiary were to go to a retail pharmacy seeking preferred supplies), will be denied because the beneficiary's supply benefit has already been exhausted for that period. If the supplier continues to send supplies and submit claims, the beneficiary cannot break the cycle and is unable to "switch back" to their preferred type of DTS system.

H.R. 3271 would strengthen the Anti-switching Rule by making the following changes:

- Codifying the Anti-switching Rule;
- Allowing beneficiaries to break the claims cycle by requiring suppliers to contact and receive a refill order from the beneficiary not more than 14 days prior to dispensing a refill; and
- Requiring suppliers to verbally provide beneficiaries with an explanation of the beneficiary's rights, including the beneficiary's right to receive DTS compatible with the beneficiary's blood glucose testing system, the right not to be influenced or incentivized to switch blood glucose

testing systems, the right to obtain strips from another mail order supplier or retail pharmacy, and the right to reject unwanted DTS.

While this bill is too new to have received a Congressional Budget Office score, it is expected that this bill would impose no additional cost on the Medicare program.

This bill's predecessor, H.R. 771 was cosponsored by a bipartisan group of 28 Representatives and was endorsed by the American Association of Clinical Endocrinologists and the American Association of Diabetes Educators, among other organizations.

The DPAC strongly urges the Subcommittee to take swift and decisive action on this bill in order to assure that the Medicare CBP does not result in irreparable harm to Medicare beneficiaries with diabetes across the country.

* * * * *

Please contact Christel Marchand Aprigliano at caprigliano@diabetespac.org for additional information.

Mr. BURGESS. The chair thanks the gentlelady for your testimony.

Dr. Kissela, you are recognized for 5 minutes, please.

STATEMENT OF BRETT KISSELA

Dr. KISSELA. Chairman Burgess, Ranking Member Green, and others members of the committee, thank you for the opportunity to testify today on behalf the American Academy of Neurology about the FAST Act of 2017, the Furthering Access to Stroke Telemedicine Act.

I am a stroke neurologist. And as a neurologist, I care for many neurologic diseases, and I am very supportive of the bills that are being presented here today, many of which affect neurologic patients. But I have extra training and expertise in vascular problems of the brain, the most common of which is stroke.

I am going to focus today on ischemic stroke, which is 90 percent of all strokes, and that occurs when a blood clot blocks one of the arteries going to the brain so that the downstream tissue is not getting the blood with the oxygen that it needs to survive. And that brain tissue is, in a sense, dying, suffocating, I tell patients, if we can't do something about it. Luckily, we can do something about it.

We have very successful treatments that we can implement in a short timeframe after the stroke starts. We have the clot-busting drug, tPA, or alteplase, that can be given by a vein, and break open the blood clot and restore flow, sending people home normal who otherwise might be disabled. And we have catheter-based treatment for the largest strokes, which we have just literally learned how to use effectively in the last few years, to handle the most disabled people who would otherwise be impaired by stroke.

What we have learned over the years with our new treatments is that time is brain. Every minute counts. If we waste time and have delays, we will have worse outcomes. In fact, if we can shorten the time from stroke onset to treatment by 15 minutes, an additional 5 percent of patients will go home normal, as opposed to being disabled by their stroke. So time is brain.

Telestroke is a form of telemedicine that we use to do acute stroke evaluations, and it is a tool that saves lives and will ultimately save money by improving the outcome for our stroke patients.

I work in Cincinnati, and I will tell you about a typical night on call. We have a very unusual situation in our city where we have a stroke team that serves the entire region, 27 hospitals, that are not only in the greater metropolitan area of Cincinnati, which includes southeastern Ohio, but also parts of Indiana and northern Kentucky. And when there is a stroke at one of those hospitals, they give us a call, and we try and offer our therapy.

When I started 20 years ago, we only had phone calls. We would take the information as best we could, try and make a good decision. If it was at a local hospital, we would drive out and make a good decision by evaluating the patient, but that wasted valuable time. Now we have telestroke. We started with our outlying hospitals, and now we are doing it throughout the entire region, because this is the right thing to do. It saves time and saves brain and improves the outcome.

Ninety-four percent of all strokes happen in urban and suburban areas, not in rural areas. And therefore, we would like to provide Medicare reimbursement for telestroke to all stroke patients.

One of my stroke calls recently was a Saturday night. This is how I spend my Saturday nights. I was treating a patient who had a large stroke, a health teacher from northern Kentucky, who we were able to take his clot out and save him from a lifetime of disability, and he is teaching junior high students about stroke.

In the middle of that case, another call came in from, in fact, a 35-year-old mother of two. Her husband is an EMT, so he saves lives every day by bringing people in on the ambulance, and we were called to try and save his wife, who he knew very well was having a stroke. By telemedicine, I was able to evaluate her quickly, make the right decision, and we saved her from being paralyzed on the right and unable to speak to now being able to be fully normal, taking care of her family, and telling her children that she loves them. They also run a charity in Haiti, and they are helping poor people there. Thankfully, this woman can still do that. And that is the power of telestroke.

Telestroke will save money. It has been estimated by the American Heart and Stroke Association, that the FAST Act could save the healthcare system as much as \$1.2 billion over the next 10 years, if approved. The cost of stroke is all on the downstream time. When someone is disabled by stroke and has to live in a care facility, that is what the true expense is. Telestroke can mitigate this cost. One study of cost utility of telestroke networks estimated that by implementing across an entire region, more than \$1,400 per patient could be saved, even after accounting for the cost of implementing the network and administering additional treatments.

The standard of care of stroke has changed, and we have improved our ability to treat this devastating disease. And now we have a new tool that can help us do it faster and better and save money. I would urge that the FAST Act be approved in that we have a new standard of care, and the reimbursement model should align with that standard of care to incentivize people to set up telestroke in all parts of this country and treat all Americans with stroke.

Thank you for your attention to stroke, which is a terrible disease that I am very passionate about treating. On behalf of the American Academy of Neurology, I greatly appreciate the thought and deliberations that went into the development of this bill, as well as the opportunity to express our strong support at today's hearing. Thank you.

[The prepared statement of Dr. Kissela follows:]

WRITTEN STATEMENT OF DR. BRETT KISSELA, MD, MS, FAAN, FAHA
Professor and Chair of Neurology and Rehabilitation Medicine at the University of Cincinnati
School of Medicine; Member of the American Academy of Neurology Board of Directors

Before the

House Committee on Energy and Commerce

On Examining Bipartisan Legislation to Improve the Medicare Program

Thursday, July 20, 2017

Chairman Burgess, Ranking Member Green, and other Members of the Committee, thank you for the opportunity to testify on behalf of the American Academy of Neurology at today's hearing about the FAST Act of 2017 ("Furthering Access to Stroke Telemedicine Act of 2017"; H.R. 1148).

There have been great advances in acute stroke treatment in the past two decades. We have gained the "clot-busting" drug Alteplase (tPA or tissue plasminogen activator) and also catheter-based clot-removal devices—both of which can reverse an acute stroke within the first few hours. We also have learned that time to treatment is one of the most important predictors of ultimate post-stroke outcome. Telemedicine ("telestroke") is a tool that significantly improves the speed and quality of evaluating the acute stroke patient. This legislation, if enacted, would allow Medicare beneficiaries with acute stroke to receive the most efficient and effective care, which will save lives and reduce the number of those who survive with costly post-stroke disability. The American Academy of Neurology is pleased to offer our support for this legislation.

Stroke is a major public health problem that takes an enormous toll on families and on our nation. It is our nation's No. 5 cause of death and a leading cause of serious, long-term disability.¹ Stroke is a disease that is more common in the elderly, and despite some success in reducing the incidence of stroke, the absolute number of strokes is increasing as our US population ages. A report by the American Heart Association has projected that the number of people living with stroke will increase from 7.5 million Americans in 2015, to 11.2 million in 2035, a 50 percent increase over the next 20 years. This report also estimates that the medical costs of stroke in the U.S. will more than double, from \$37 billion in 2015, to \$94 billion in 2035.² There are substantial costs required for the acute hospital care of stroke, but the majority of cost derives from years of post-stroke care when a survivor is disabled. MedPAC has reported that stroke is the leading Medicare diagnosis for inpatient rehabilitation stays,³ and is a leading diagnosis requiring nursing home care. Unfortunately, stroke is also becoming increasingly

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more common in the young.⁴ Strokes in younger people are less likely fatal, and thus lead to more potential years of disability and productive work life lost, with substantial lifetime cost to our health system. One way to reduce post-stroke disability across the lifespan is improve access to telestroke care, which in turn will improve post-stroke outcomes.

Time Is Brain

In the treatment of stroke, we often say that "time is brain." The majority of strokes (90%) are ischemic strokes, arising when a blood vessel to the brain is blocked by a blood clot. With every minute that a stroke goes untreated, brain cells and connections between them are irreversibly injured. The brain tissue is "suffocating" from a lack of blood flow with oxygen, and once the cells are dead they cannot grow back. As described above, we now have proven treatments available to remove the blood clots and restore blood flow to the affected areas including tPA and catheter-based clot-removal devices. When patients are appropriately selected, these treatments are highly effective. To maximize benefit to patients, the treatments must be administered as quickly as possible after the onset of stroke symptoms start. Similar to lessons learned in treating acute heart attacks, every minute counts. Research has shown that stroke patients who get treated with tPA within 60 minutes of hospital arrival do significantly better than those treated more slowly. It has been shown that for every 15 minute reduction in treatment time, 5.1 percent more patients recover well enough that they can return directly home from the hospital.⁵ Ischemic stroke patients who are treated with the clot-busting drug within 90 minutes of symptoms starting are nearly three times more likely to recover with little or no disability.⁶ Similarly, more than 90 percent of patients treated with a clot retrieval device within 150 minutes of stroke onset recover with little or no disability.⁷

To receive one of the proven acute stroke treatments, patients must arrive at the hospital within the first few hours after stroke onset. Ideally, they would present to a hospital certified as a stroke center but many patients live too far from such a center to arrive within the time window. Ideally the acute stroke patient would also be seen by a stroke expert such as a vascular neurologist, but there is a shortage of these experts relative to the number of strokes. As such, it is unfortunate that very few stroke patients receive acute treatment. Research originating from the University of Cincinnati has shown that only about 3.4 to 5.2 percent of patients receive the clot-busting medication.⁸ Among Medicare-eligible patient discharges, the national average tPA treatment rate is only 2.4 percent.⁹ Even fewer patients are treated with clot retriever devices; only 1 in 5 stroke patients are managed and discharged from hospitals that neither give tPA nor perform thrombectomy.¹⁰ Telestroke remedies several of the problems

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listed above, in that the expertise of stroke experts at stroke centers can “go to the patient” and thus increase the percentage of stroke patients who receive acute stroke treatment and also reduce the time it takes to get the treatment started.

Telestroke: A New Standard of Care

The first step in acute stroke care is rapid and accurate diagnosis, because a variety of conditions can mimic acute ischemic stroke and 10% of stroke patients have hemorrhagic stroke and for these patients tPA is dangerous. For hospitals that do not have vascular neurologists available, the only option historically (prior to telestroke) was telephone-based triage.

In Cincinnati, our University of Cincinnati-based stroke team has provided acute stroke care to all hospitals in the region since the late 1980's. This is a unique situation that is not found in most US cities. We accomplished this prior to telemedicine by telephone-based triage, and then physically driving to each hospital in the metropolitan area where we believed there was a potential acute stroke patient who could be treated. This system did allow stroke expertise to all patients in the metropolitan area but was inefficient, as valuable time was wasted with telephone communication and then driving. Often we would drive a substantial distance only to find that the patient had a stroke mimic and was not eligible. For outlying hospitals (outside the main metropolitan area), we could only do telephone triage and had to make treatment decisions based upon limited information.

Telemedicine provides a means to immediately assess a patient and most rapidly implement appropriate treatment to patients that need it. We began telestroke for outlying hospitals several years ago because we felt it necessary to have the ability to visually assess the patient in order to make medically appropriate decisions. As more and more data have emerged about how even short delays can lessen the chance of good outcome, we felt it necessary to begin telestroke even for urban and suburban hospitals within the last two years. Rather than spending valuable minutes on the phone and then as much as 40 minutes driving (the distance from my house to the most distant hospital in the region is 35 miles), we can see the patient via telestroke within seconds and make a fully informed decision within minutes.

Multiple studies have shown that telemedicine has improved the percentage of patients who receive recommended acute stroke treatment. One study of four urban hospitals in Illinois with low tPA treatment rates found that their utilization of tPA increased by two to six times after telestroke was implemented.¹¹ In our regional network of 27 hospitals, we have seen a substantial increase in the number of acute stroke patients treated—almost a four-fold increase

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from 2006 to 2016. While there are other reasons for the increase, such as an expanded time window and new technologies, there is no doubt expanded telestroke presence has played an important role in increasing regional access to acute stroke treatment.

Importantly, the outcomes for stroke patients cared for in hospitals with telemedicine support are comparable to those achieved in other stroke centers and have surpassed those achieved by general hospitals without telemedicine support or stroke units.¹² In our Cincinnati network, our average door-to-needle time in 2016 was 55 minutes across the entire network. By comparison, the national goal is 60 minutes, and at the University of Cincinnati Medical Center (which is a Joint Commission Certified Comprehensive Stroke Center) our door-to-needle time was 45 minutes. These data represent a substantial improvement over prior years, and demonstrate that telestroke allows the highest quality care to be practiced remotely.

Despite these proven benefits of telestroke, Medicare's coverage for it is woefully outdated. The current Medicare policy of limiting coverage for telehealth services to those patients originating in only rural areas has hampered the development of widespread telestroke coverage. Approximately 94 percent of strokes occur in urban or suburban settings. It has been estimated from 2014 data that approximately 522,000 Medicare beneficiaries 65 and older who have a new stroke would be eligible for a telestroke consultation. This estimate includes individuals in rural areas that do not meet the current and fairly narrow definition of "rural" for Medicare payment of telestroke services.

Finally, as new treatments become available, an increasing number of patients might be eligible for stroke care. In our Cincinnati region, the number of calls to the stroke team has risen exponentially such that we fielded 4341 calls in 2016. In our old model, driving to even a small proportion of those cases thought to be eligible would be overwhelming. Telemedicine allows efficient deployment of our efforts to those we are sure will qualify for treatment, and thus provides greater overall coverage of our entire region.

Therefore, the most significant step Congress could take would be to allow Medicare to reimburse for telestroke evaluations for patients regardless of their location, as the FAST Act would do.

Telestroke Saves Time, Which Improves Outcomes and thus Saves Money

Telestroke not only improves access to acute stroke care, but also will result in healthcare cost savings by reducing chronic disability that requires expensive and ongoing medical care. Several studies have conclusively shown that the use of tPA for acute ischemic stroke is cost-effective. The definitive tPA study published in the *New England Journal of*

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Medicine showed that stroke patients receiving tPA were at least 30 percent more likely to have minimal or no disability at three months, compared to patients who did not receive this treatment. These patients also had shorter hospital stays and were more frequently discharged to their homes rather than to more costly nursing homes.¹³ Another study found that the average cost savings when administering tPA was \$4,255 in 1996 dollars per treated patient, largely as a result of decreased utilization of nursing home and rehabilitation care by the patient.¹⁴ The most recent study on this topic found that treatment with tPA resulted in \$25,000 lifetime cost savings per patient.¹⁵ Similar data are available from recent series of catheter-based treatment for large strokes. Finally, a study aimed at evaluating the cost utility of telestroke networks estimated net savings of \$1,436 per patient, even after accounting for the costs of implementing the telestroke network and administering tPA.¹⁶

The American Heart Association has estimated that the FAST Act could save the Medicare and Medicaid programs as much as \$1.2 billion over 10 years, even after the costs of providing more telestroke evaluations and more tPA treatments are factored in. In its analysis of the FAST Act, the Congressional Budget Office did not allocate the full amount of savings to the federal Medicare and Medicaid programs since some of the savings that results from reducing the need for nursing home care accrues to state rather than federal government. Even if this is correct, acute stroke medicine is evolving to optimize access to the best care that produces the best outcomes. Adjusting the reimbursement model to match the new standard of care is surely cost-effective and is the right thing to do for patients.

This change in Medicare law is long overdue. A growing number of lawmakers and organizations have endorsed telestroke care and the FAST Act of 2017. For example, H.R. 1148 currently has 122 bipartisan cosponsors. In addition to the American Academy of Neurology and the American Heart/Stroke Association, organizations such as AARP, the American Hospital Association, the American Medical Association, American Association of Neurological Surgeons and the National Coalition for Health Care have also expressed their support for lifting Medicare's current restrictions on telestroke coverage. Finally, the Medicare Payment Advisory Commission, in its June 2016 report to Congress, found telestroke to be one of the most beneficial and cost-effective applications of telehealth and suggested that policymakers may want to expand Medicare coverage of telestroke to urban settings,¹⁷ as the FAST Act would do.

In conclusion, acute stroke care has progressed tremendously in the last 20 years. Telestroke is supported by a wealth of evidence and is a common-sense, cost-effective step

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that the Committee can take to improve post-stroke outcomes. I am convinced that expanding the use of telestroke will greatly increase the utilization of effective acute stroke treatments, reduce stroke-related disability for many Americans, and save the health care system money. As such, I urge the House Committee on Energy and Commerce to act favorably on the FAST Act. Thank you for your attention to stroke, which is a terrible disease that I am passionate about treating. On behalf of the American Academy of Neurology, we greatly appreciate the thought and deliberations that went into the development of this bill and for the opportunity to express our strong support at today's hearing.

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Mr. BURGESS. Thank you, Doctor. Thank you for your testimony.
Ms. Bardach, you are recognized for 5 minutes for your opening statement, please.

STATEMENT OF LISA BARDACH

Ms. BARDACH. Imagine that you have suffered a severe stroke or that you are living with ALS. You have been robbed of your ability to speak and write. You no longer have control over your body. You are completely aware of your surroundings and you understand everything that is happening to you. Your son comes home from high school and announces that he has just been elected class president. You are so proud, but you cannot tell him this. Later that evening, as your wife helps you get ready for bed, you want to tell her how much you love her. You want to tell her how proud you are of the children that you have raised, but you cannot do this.

Communication devices help people talk. This is how individuals participate in the myriad of communication opportunities that arise every day.

My name is Lisa Bardach, and I am the speech-language pathologist at ALS of Michigan. I am also the owner of a private practice called Communicating Solutions, in Michigan, that provides evaluation and treatment for people who need communication devices. And I am here on behalf of Team Gleason as well. But mostly, I am here on behalf of everybody in the United States who needs a communication device in order to be able to speak.

People who are unable to communicate verbally use communication devices, also known as speech generating devices, or SGDs. These are electronic means of communication, and a person uses them to speak by accessing stored messages or by creating new utterances using pictures, words, text, spelling, or any combination thereof. I am here to ask you to support the Steve Gleason Enduring Voices Act of 2017, H.R. 2465.

Steve Gleason, a former NFL player who is living with ALS, has provided a tremendous amount of support and inspiration for people across the country. But ALS only represents a small percentage of people who need communication devices. Individuals with multiple sclerosis, Parkinson's disease, stroke, cerebral palsy, traumatic brain injury, autism, and quite a number of other conditions require communication devices.

Communication devices have been a covered benefit under Medicare since 2001. The Steve Gleason Enduring Voices Act of 2017 permanently reinstates communication devices into the payment category that they were originally determined under the national coverage decision in 2001. And it also ensures that users will have access to the necessary and personalized communication technology, regardless of their setting. So if they have to leave their home to go to a nursing home or a hospice or a hospital, they can take their technology with them.

In 2001, CMS put these devices under the category of frequently purchased, meaning Medicare paid one lump sum and the beneficiary owned the device, and, therefore, if he or she changed residences, that communication technology could go with him. In 2014, these devices were placed in the category as capped rental. Make no mistake about it, Medicare still covered these devices, but the

payment was amortized over 13 months in the rental period, and, therefore, if at any point during that rental period the beneficiary had to change residences, they couldn't take their technology with them because Medicare stopped paying for it. This resulted in patients delaying necessary and critical services. It resulted in them being afraid that they would have to relinquish their devices at the most vulnerable time in their lives. It resulted in people dying without being able to tell the people around them that they loved them.

I would like to share with you the words of Diane, who is a stroke survivor. She had a brain stem stroke at age 22. She says: I am writing this to you with the help of my mother who is writing down words I want to say from nodding my head to the alphabet. This is very time consuming and tedious for both of us. It seems like forever that my device has been in repair, and I am miserable without it.

Deanna is a person living with ALS. She came to me for a communication device in late 2014 when capped rental was in place. She was deathly afraid that she would lose the device if she got it funded under Medicare. Team Gleason purchased that device and amount for her. She continues to use it to this day. She wrote to me last night: I have complete peace of mind, as does my husband, that if I were to be hospitalized, my device would remain active. I can be fully independent in conveying my thoughts and desired actions in what may be my most critical time.

Losing a voice under capped rental has an impact that is absolutely incalculable. No one knows if or when their situation will change. The only way to keep a personally configured communication device with the individual who needs it at all times is upfront purchase. While the consequences of capped rental were unintended, they were deadly.

I would like to end by sharing a note that I received from the family of one ALS patient 1 week after she died. It said: Dear Lisa, Debbie's last words were spoken on the ALS eye gazer, communication device, 2 hours before she passed. Love you all. That included you and the ALS staff, I am sure. Thanks.

Please help ensure that patients who cannot speak have unrestricted access to the communication devices they require and pass the Steve Gleason Enduring Voices Act of 2017.

[The prepared statement of Ms. Bardach follows:]

I write this testimony in support of the Steve Gleason Enduring Voices Act of 2017, a bill to revise the Steve Gleason Act of 2015. I write in support of individuals across the country who are unable to communicate via natural speech and must instead rely on Speech Generating Devices (SGDs), an electronic means of communication used by individuals with debilitating conditions such as ALS, MS, Parkinson's Disease, Locked-In Syndrome, cerebral palsy, aphasia, and others. Imagine for a moment, that you have suffered a severe stroke, or that you are living with ALS. It has robbed you of your ability to speak and to write. You cannot control the movements of your body. You are completely aware of and understand the things that are happening around you. Your child comes home from school and tells you he has been elected class president. You are so incredibly proud, yet you cannot tell him. You would dearly love to give him advice, but you cannot. Later that night, as your wife helps you get ready for bed, you want to tell her what she means to you, tell you how much you love her. But you cannot. This is what communication devices allow individuals to do – participate in the various communication opportunities that arise on a daily basis.

The Steve Gleason Act of 2015 removed SGDs from the category of capped rental and reinstated them in the category of frequently purchased equipment. Simply put, it ensured that beneficiaries would have access to their necessary and personalized communication technology, even in the event of residence in nursing home, hospital, or hospice. The Steve Gleason Enduring Voices Act of 2017 will remove the sunset date, protecting extremely vulnerable Medicare beneficiaries from ever having to relinquish their only means of communication.

Communication devices have been a covered benefit under Medicare since 2001. Putting them in the category of rental equipment does **not** change this. What it **does** change is the ability of those most vulnerable to continue to use their technology. If an SGD is a frequently purchased device, Medicare pays the manufacturer in one lump sum. The beneficiary then owns the device and can take it with her, even if she must move out of her home and into a hospice, hospital, or nursing facility, or begins to receive hospice services at home. While communication is always important, it is uniquely crucial

when circumstances, providers, and caregivers change. Under capped rental, instead of Medicare making a payment in one lump sum to the manufacturer, payment is made in 13 monthly increments. Therefore, the beneficiary does not own the device until the 13 months have passed. So if the device is not paid for and the beneficiary must change residence (sometimes even briefly), Medicare no longer pays for the device and the user cannot communicate.

Communication devices are uniquely configured to individual patients. Not everyone wants to say the same thing. One person's end of life wishes are not the same as another's. Some people have such limited movement that uniquely customized physical access such as eye gaze is required. Individuals may have hundreds of phrases stored to facilitate quick and meaningful communication. Current technology allows an individual to use message banking, a process where a user with an acquired condition can store messages in his own voice and then customize those messages to be available in his SGD. Nursing homes, hospitals, and hospices are unable to provide a uniquely configured substitute SGD when one has been taken away.

The impact of losing a voice under capped rental is incalculable. No one ever knows if/when their situation will change. The only way to keep a personally configured communication device with the individual who needs it at all times is up-front purchase. There was a 6-month period in 2014 when capped rental was in place. This resulted in people delaying critical care because they feared loss of their communication device. People died without being able to say goodbye to their loved ones. While unintended, these consequences were and would be devastating.

I'd like to end by sharing a note I received from the family of an ALS patient one week after she passed away. It said: *Dear Lisa, Debbie's last words were spoken on the ALS eye gazer [communication device] 2 hrs before she passed. "Love you all". That included you and the ALS staff I'm sure. Thanks.*

Please help ensure that patients who cannot speak have unrestricted access to the communication

devices they require and pass the Steve Gleason Enduring Voices Act of 2017.

Lisa G. Bardach, MS CCC-SLP

ALS of Michigan, Inc.

President and CEO, Communicating Solutions, LLC

Summary

- Individuals who are unable to communicate verbally using natural speech can do so using Speech Generating Devices (SGDs), also known as communication devices.
- These devices are an electronic means of communication, allowing the individual to access stored messages and also to generate novel messages using text, words, pictures, or any combination thereof.
- SGDs have been a Medicare covered benefit since 2001.
- The Steve Gleason Enduring Voices Act permanently retains communication devices in the payment category determined by the original National Coverage Decision.
- This permanent legislation is necessary because of a 2015 CMS rules change that on the surface wouldn't have seemed devastating, but when implemented caused people to have their "voices" taken away when they were most vulnerable.
- Although the Act is named for Steve Gleason, a former NFL player who has ALS, the disease is only a small percentage of the conditions whose patients benefit from the acquisition of communication devices.

Testimonials (appendix)

My name is Diane Georgoudakis, and I am writing this to you with the help of my mother who is writing down words I want to say from nodding my head to the alphabet. This is very time consuming and tedious for both of us. Normally, I would use my speech generating device, but it has been in for repair for quite some time now. It seems like forever being that I use it on a daily basis. I am very miserable without it since I have been using a device for 10 plus years now.

Stroke is a brain attack and one of the leading causes of long term disability.

Without my device, I am unable to express my thoughts or join in conversation with others in the same room; and/or do activities on my own that help keep my brain stimulated.

I do so much with my device; it is my access to the outside world. For instance, I belong to an on-line stroke support group where I have made many friends. We all give each other advice, support, and encouragement. I keep in touch with family and other friends via e-mail, and social media. My sister and her family live out of state, and my sister sends me pictures on the internet of my growing niece and nephew who are particularly important to me.

I also shop on-line giving me the independence to pick out my own clothing, and any other items I might need. I was very independent before my stroke, so this helps.

Being 22 when I had my stroke was such an overall shock to the system, that any independence helps a great deal.

I like to keep up on the latest research and breakthroughs and tell my doctors if need be.

I do this with the help of my speech generating device by preparing a message beforehand.

I also like to research political candidates and keep up with current events. I belong to an on-line association where I am able to e-mail senators, heads of corporations, etc, and make my voice heard.

As you can see, I do many things with the internet capability on my speech generating device.

That being said, do keep in mind that I, not Medicare, pay for my own cost of having internet accessibility. Please take into consideration that others need this capability as well!

Thank you for taking the time to read this.

Sincerely

Diane Georgoudakis

CS, wife of a person with ALS, describing her husband's end of life experience. *"He was having a great deal of difficulty breathing and simply could not get comfortable in his hospital bed or wheelchair. We decided to go with in-hospital hospice since his pain management was not well controlled. In hospice, he regularly used his [eye gaze-accessible] SGD to tell us what he wanted and what he didn't want. I am so grateful that he was able to use it extensively during the last few days of his life. I don't know what we would have done without it."*

Mr. BURGESS. The chair thanks the gentlelady for her testimony. Dr. Richards, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF VARNER RICHARDS

Dr. RICHARDS. Subcommittee Chair Burgess, Subcommittee Ranking Member Green, and members of the subcommittee, thank you for inviting me to share the National Home Infusion Association's, which I will refer to as NHIA in the further part of my discussion, insights on H.R. 3163, the Medicare Part B Home Infusion Services Temporary Transitional Payment Act.

My name is Varner Richards, and I serve as the chair of the NHIA board of directors. NHIA is a trade association that represents providers of home infusion therapy and other companies that supply and otherwise support the delivery of infusion therapy in a patient's home. I am also the owner and CEO of Intramed Plus, Inc., a home infusion provider in the State of South Carolina. We provide services statewide to patients in South Carolina and border counties of North Carolina from three home infusion pharmacies in Columbia, Greenville, and in Charleston. I am also a clinician. I have been directly involved with providing infusion services for patients in their homes for over 30 years.

Home infusion is basically defined as a medication being infused through a needle or catheter in a patient in their home setting. It is usually prescribed for patients where their conditions cannot be treated effectively by oral medications. Typically, the infusion therapy means the drug is administered intravenously, but can also be subcutaneously for certain therapies, which is an infusion under the skin.

Under Medicare Part B DME home infusion coverage, there is a limited number of drugs which cover a very small patient population. This small population, even though these patients suffer from life-threatening illnesses, which include cancer, cancer-related pain, viral, fungal infections, immune deficiency, and end stage congestive heart failure. For our discussions today, I am focused on the Medicare Part B DME infusion coverage. Medicare Part B provides coverage under the durable medical equipment benefit for a limited set of home infusion therapies.

Before the passage of 21st Century Cures Act, the program specifically covered drug, pump, and supplies. There was no coverage for home infusion professional services. The available drug margin subsidizes payments for some of the home infusion professional services. With the passage of the 21st Century Cures Act, the Medicare B coverage had two important changes.

First, the drug reimbursement methodology, which changes in the average sales price to align with drug payment with the way physicians receive—offices were currently reimbursed. This eliminated any drug margin to subsidize clinical services, and it became effective January 1, 2017.

Secondly, a professional clinical service fee was added to cover the clinical services for these patients' therapies, and that was excellent. The difficulty was scheduled to take effect in 2021. We applaud the committee with this addition of this important profes-

sional fee to ensure these patients received effective care in their own home.

The gap of 4 years between these two implementation dates of these provisions needed to be addressed in order to preserve access to these medications for home infusion patients until 2021. Last year, members of this committee pledged to resolve this issue this year.

We thank the committee for your commitments to work on this gap transition issue, and that is why we are here today. The Medicare Part B Home Infusion Services Temporary Transitional Payment Act, H.R. 3163, was introduced on July 6, and provisions from this bill was included in H.R. 3178, which was recently marked up by the Ways and Means Committee. NHIA knows that the legislation marked up by the Ways and Means Committee included technical corrections to H.R. 3163, and that this committee supports those technical corrections as does NHIA.

The bill will allow the most vulnerable of patients to continue to have access to lifesaving home infusion therapy. This legislation will create a temporary transitional payment beginning January 1, 2019, the professional services related to part B, DME infusion drugs. NHIA supports H.R. 3163 and urges passage of the bill.

While we are discussing part B home infusion drugs, I would be remiss if I did not note that most infusion drugs are covered by Medicare part D. Medicare part D reimburses providers for drug and drug only. It does not cover the specialized infusion-related services and equipment and supplies. NHIA has and continues to seek and fix this issue as part of the Medicare Home Infusion Site of Care Act. Congressman Eliot Engel has been a long-time champion of this legislation, as you know, with Congressman Pat Tiberi of the Ways and Means Committee.

Thanks to the committee and your staff for the hard work to get this legislation prepared for the consideration today. NHIA knows that the legislation is very technical in nature, and we commend all who are involved in this effort.

Thank you for your time today, and please accept NHIA's support, the home infusion community's support, my company's personal support, and all Medicare beneficiaries who benefit from this in support of H.R. 3163. Thank you.

[The prepared statement of Dr. Richards follows:]



Testimony of Varner Richards, PharmD

Chief Executive Officer

Intramed Plus, Inc.

Chairman, Board of Directors

National Home Infusion Association

Examining Bipartisan Legislation to Improve the Medicare Program

Before the

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

July 20, 2017

Key Points

- The National Home Infusion Association supports passage of the *Medicare Part B Home Infusion Services Temporary Transitional Payment Act (HR 3163)*.
- The home infusion therapy services temporary transition payment is of vital importance to Medicare beneficiaries that require infusion therapy at home.
- The legislation will allow providers of infusion therapy at home to continue servicing Medicare beneficiaries that suffer from life threatening illnesses that include:
 - Viral and/or fungal infections;
 - Cancer and cancer-related pain therapy;
 - Immune deficiency; and
 - Heart failure.

National Home Infusion Association Testimony

Introduction

Subcommittee Chairman Burgess, Subcommittee Ranking Member Green, and members of the Subcommittee, thank you for inviting me to share the National Home Infusion Association's (NHIA) insights on HR 3163, *Medicare Part B Home Infusion Services Temporary Transitional Payment Act*.

My name is Varner Richards and I serve as the chair of the NHIA board of directors. NHIA is a trade association that represents providers of home infusion therapy and other companies that supply and otherwise support the delivery of infusion therapy in the home.

I am also the Owner & CEO of Intramed Plus, Inc, a home infusion provider in South Carolina. We service to patients in South Carolina and border counties of North Carolina from three home infusion pharmacies located in Columbia; Greenville; and Charleston, SC. I am also a clinician who has been directly involved with providing infusion services to patients in their homes for over 30 years.

Infusion Therapy at Home

Infusion therapy involves the administration of medication through a needle or catheter. It is prescribed for patients whose condition is so severe that they cannot be treated effectively by oral medications. Typically, "infusion therapy" means that a drug is administered intravenously, but the term may also refer to situations where drugs are provided through other non-oral routes, such as the subcutaneous (under the skin) route when the infusion lasts longer than 15 minutes.

Diseases which require infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain, dehydration, and gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system. Other conditions treated with infusion therapies include cancers, congestive heart failure, Crohn's Disease, hemophilia, hepatitis, immune deficiencies, multiple sclerosis and rheumatoid arthritis.

Several specialized services are necessary for the delivery of home infusion. Home infusion services that are performed by pharmacists and nurses include:

- Preparation and dispensing of sterile intravenous drugs;
- Intravenous drug administration;
- Comprehensive assessment that considers the patient's complete medication history, current physical and mental status, lab reports, cognitive and psychosocial status, family/caregiver support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications;
- Disease state management for highly complex chronic illnesses focused on reducing hospital admission, avoiding unnecessary emergency room visits, and improving patient quality of life;
- Care coordination with key stakeholders involved in patient care such as primary care physicians, specialists, home health, and ancillary services;
- Drug interaction monitoring and identification of potential drug, dose or drug-catheter incompatibilities;

- Admission procedures that include patient education of medical equipment, supply use, medication administration, medication storage and handling, emergency procedures, vascular access device management, proper storage and disposal of hazardous waste, as well as the recognition and reporting of adverse drug reactions;
- Care planning that considers actual or potential drug or equipment-related problems, therapy monitoring with specific patient centered goals, and coordination of activities with other providers such as home health agencies and physicians;
- Comprehensive patient monitoring and reassessment to ensure a positive response to treatment, proactively address potential complications, and improve patient compliance;
- Laboratory analysis and subsequent therapy change recommendations to other members of the patient's care team to adjust medication orders if necessary;
- Maintenance of appropriate physical facilities for storage, preparation, dispensing, and quality control of all infusion medications, supplies and equipment; and
- Quality assurance programs that include collection of clinical outcomes data, patient perception data, trending and analysis of these and other key performance indicators focused on maintaining a highly reliable healthcare organization.

Notably, patients treated at home with infusion therapy instead of in a facility are at a reduced risk of acquiring health care acquired infections (HAI). HAIs are a crucial safety consideration since many of these patients are at high risk of infection due to their disease process, age, and/or compromised immune system.

Commercial insurers, Medicaid programs, and many Medicare Advantage health plans (Medicare Part C) currently recognize that infusion therapy delivered at home is a cost-effective, low risk, and clinically-effective treatment option. Those programs provide comprehensive coverage of this therapy. Private sector coverage of home infusion has existed since the 1980s.

Home Infusion Medicare Coverage

The Medicare fee-for-service program provides piecemeal coverage for home infusion. Medicare Part B provides coverage under the durable medical equipment (DME) benefit for a limited number of infusion drugs that are administered using a mechanical or electronic external infusion pump. Because of the reliance on DME, the number of drugs that are covered under this benefit is limited to a small number of therapies for specific populations, such as: patients with fungal and viral infections, cancer and cancer related pain, immune deficiency and heart failure.

While we are focusing on Medicare Part B infusion coverage, I must note that most infusion drugs are covered as part of the Medicare Part D benefit. Medicare Part D reimburses providers for the drugs and a retail-based dispensing fee, which falls short of covering the costs associated with the safe provision of home infusion drugs. Importantly, Medicare Part D does not cover the specialized infusion-related services, equipment and supplies, and it is for this reason that most Medicare beneficiaries do not have access to infusion drugs in the home, despite the fact the drugs are covered in that setting. NHIA is seeking to fix this issue as part of the *Medicare Home Infusion Site of Care Act*, which was introduced by Representative Engel of this subcommittee and House Ways and Means Subcommittee on Health Chairman Tiberi in the 114th Congress.

Prior to passage of the *21st Century Cures Act* in December 2016 there were three components of home infusion that were reimbursable under the Part B DME program – the drug, the pump and other supplies associated with the infusion. Clinical services associated with these infusions were not explicitly covered by Medicare. However, the infusion drugs were being reimbursed at 95% of 2003 Average Wholesale Pricing (AWP) levels. The reimbursement of the drugs at this level essentially subsidized the costs associated with clinical services necessary for the infusions.

NHIA and the home infusion community have long advocated that Part B DME infusion drugs should be reimbursed by a more market driven calculation. The community supports an explicit payment for home infusion clinical services that are required to ensure effective patient care. The *21st Century Cures Act* contained two provisions that significantly affect the home infusion community. First, a provision contained in Section 5012 and scheduled to take effect in 2021, established a reimbursement for the professional services associated with Part B DME infusion drugs. NHIA thanks the committee for including this provision in the bill.

A second provision contained in Section 5004(a) changed the payment structure for infusion drugs under the Medicare Part B DME benefit from the AWP metric to an Average Sales Price (ASP) payment methodology to better align the drug payment with the way physician offices are currently reimbursed. Home infusion providers were not expressly opposed to this change as long as a payment for the services could be addressed.

The gap in the *Cures Act* between the implementation date for establishment of ASP reimbursement (2017) and the date established for a home infusion services payment (2021) needed to be addressed. Members of this committee last year committed to work on the issue in 2017. We thank the committee for your commitment to work on this issue and that is why we are here today.

The Medicare Part B Home Infusion Services Temporary Transitional Payment Act

The Medicare Part B Home Infusion Services Temporary Transitional Payment Act (HR 3163) will allow the most vulnerable of patients to have access to life-saving home infusion therapy. This legislation would create a temporary transitional payment beginning January 1, 2019, for services related to Part B DME infusion drugs.

Specifically, HR 3163 will create a temporary payment for home infusion services associated with Part B infusion drugs, which will allow Medicare beneficiaries to continue to access therapy in the home until the permanent services payment that was created in the *Cures Act* is implemented in 2021. NHIA supports HR 3163 and urges passage of the bill. Providing this temporary and transitional payment will allow the home infusion community to continue to service the most fragile patients until the Centers for Medicare & Medicaid Services (CMS) finalizes the services payment included in the *Cures Act*.

Conclusion

NHIA thanks the committee and its staff for their hard work in getting this legislation prepared for consideration today. NHIA knows that this legislation is very technical in nature and we commend all who were involved in this effort.

Thank you for your time today and please accept NHIA's support of HR 3163.

Mr. BURGESS. The chair thanks the gentleman.

Ms. Grealy, you are recognized for 5 minutes, please, for an opening statement.

STATEMENT OF MARY GREALY

Ms. GREALY. Chairman Burgess, Ranking Member Green, members of the committee, thank you for the opportunity to testify this morning.

I am speaking today on behalf of the members of the Healthcare Leadership Council, comprised of chief executives of innovative companies representing every sector of American healthcare.

One of HLC's foremost priorities is the attainment of a strong, sustainable, and patient-centered Medicare. And so we applaud the committee for your focus on bipartisan solutions to improve the program. We believe an initial and critical step in making Medicare stronger is to remove an entity that threatens to seriously weaken it.

The Independent Payment Advisory Board, or IPAB, was created with the ostensible purpose of controlling Medicare spending. But it does so in a way that does not improve the health of Medicare beneficiaries. It does not add value to the Medicare program, and does not respect the prerogative of the elected members of the legislative branch to set Medicare policy.

The Medicare Trustees report released last week, as we all know, did not project Medicare spending levels that triggered IPAB into action this year. We are fortunate that that has not yet occurred. Even though neither President Obama nor President Trump has nominated members to the board, the Secretary of Health and Human Services still has the legal responsibility to initiate the process. That would almost certainly lead to arbitrary cuts in what Medicare pays for healthcare services.

Now, when that process inevitably occurs with its resulting cuts to Medicare, we know that the gap between what private insurance pays physicians to treat patients and what Medicare pays will continue to widen. And this will lead to a future in which an expanding Medicare beneficiary population will have much greater difficulty finding a physician. Even today, two of my personal physicians in Maryland have posted notices in their waiting rooms saying that they are no longer taking new Medicare patients. IPAB, if implemented, will worsen this access problem.

Nearly 800 organizations representing patients, healthcare providers, seniors, employers, veterans, Americans with disabilities, and others, are asking Congress to do away with the Independent Payment Advisory Board before harm is done to Medicare beneficiaries. Fortunately, there is bipartisan legislation pending before Congress to do just that.

H.R. 849, the Protecting Seniors' Access to Medicare Act, sponsored by Representatives Phil Roe and Raul Ruiz, is being cosponsored by a majority of the House. It should also be noted that similar legislation has been introduced in the Senate, and that a majority of that body has cosponsored one or more of the repeal bills and resolutions that are under consideration.

But I want to call your attention to the joint resolution, H.J. Res. 51, which Congressmen Roe and Ruiz have also introduced. There

is an unusual provision in the IPAB authorizing legislation that allows both Houses of Congress to enact a joint resolution by August 15, 2017, which would eliminate the IPAB threat once and for all. This joint resolution would be fast tracked with no amendments and no filibuster allowed in the Senate. We strongly urge lawmakers to take advantage of this one-time opportunity that was written in to the original law.

Steps do, of course, need to be taken to make Medicare a more value-focused program, to be a more effective combatant against rising rates of chronic disease, to save money in the long run by helping beneficiaries become healthier and lessen their need for hospitalizations and emergency room visits.

Today you are considering bipartisan legislation that will do just that. IPAB with its rapid and indiscriminate approach to healthcare spending cuts will not.

We also believe very strongly that Medicare decision-making should be in the hands of the public's elected representatives. It does not matter if a future Independent Payment Advisory Board is filled with imminently qualified appointees. It also does not matter if, in lieu of a board, that power rests with a Democratic or Republican HHS Secretary. What does matter and what should be opposed is the idea of moving Medicare policy making farther away from the millions of Americans who will feel the impact of these changes.

Congress has shown repeatedly, and most recently through the MACRA legislation from this committee, that it will act in a bipartisan fashion to improve healthcare for Medicare beneficiaries. And it is with Congress that this authority should remain.

Thank you again for this 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 Bipartisan Legislation to Improve the Medicare Program

July 20, 2017

Chairman Burgess, Ranking Member Green, members of the committee. Thank you for the opportunity to testify this morning.

I'm speaking today on behalf of the members of the Healthcare Leadership Council, comprised of chief executives of innovative companies from every sector of American healthcare. One of HLC's foremost priorities is the attainment of a strong, sustainable, and patient-centered Medicare, and so we applaud this committee for your focus on bipartisan solutions to improve the program.

We believe an initial, and critical, step in making Medicare stronger is to remove an entity that threatens to weaken it. The Independent Payment Advisory Board, or IPAB, was created with the ostensible purpose of controlling Medicare spending, but it does so in a way that does not improve the health of beneficiaries, does not add value to the Medicare program, and does not respect the prerogative of the elected members of the legislative branch to set Medicare policy.

The Medicare Trustees report released last week, as we all know, did not project spending levels that triggered IPAB into action this year. We're fortunate that has not yet occurred. Even though neither President Obama nor President Trump has named members to the board, the Secretary of Health and Human Services still has the legal responsibility to initiate the process that would almost certainly lead to arbitrary cuts in what Medicare pays for healthcare services.

When that process does inevitably occur, it is projected that the gap between what private insurance pays physicians to treat patients and what Medicare pays will continue to widen, leading to a future in which an expanding beneficiary population will have greater difficulty finding a physician. Even today, two of my personal physicians have posted notices in their waiting rooms saying they are no longer taking new Medicare patients. IPAB, if implemented, will worsen this access problem.

This is actually made quite clear by the statute creating IPAB. Any notion that IPAB could be a catalyst in promoting productive healthcare reforms is undermined by the provisions in the law stating that IPAB must achieve scoreable savings – sufficient to reach statutory budget targets – within a one-year timeframe. Given this restriction, IPAB is most likely to focus on short-term savings in the form of payment cuts to

healthcare providers. The Congressional Budget Office, in fact, reached that very conclusion and projected that IPAB will reach savings through changes in payment rates or methodologies affecting non-exempt providers.

Nearly 800 organizations representing patients, healthcare providers, seniors, employers, veterans, Americans with disabilities and others are asking Congress to do away with the Independent Payment Advisory Board before harm is done to Medicare beneficiaries. Besides my own Healthcare Leadership Council, two of the organizations here at the witness table – the American Academy of Neurology and the American Physical Therapy Association – are among this group and I want to thank Dr. Kissela and Dr. Moore for their leadership on this issue. Fortunately, there is bipartisan legislation pending before Congress to do exactly what these hundreds of organizations are requesting.

H.R. 849, the Protecting Seniors Access to Medicare Act, sponsored by Representatives Phil Roe and Raul Ruiz, is being cosponsored by a majority of the House. It should also be noted that similar legislation has been introduced in the Senate, and a majority of that body has cosponsored one or more of the repeal bills and resolutions under consideration.

But I want to call your attention to the joint resolution, H.J. Res 51, which Congressmen Roe and Ruiz have also introduced. There is an unusual element in the IPAB authorizing legislation that allows both houses of Congress to enact a joint resolution by August 15, 2017 which will eliminate the IPAB threat once and for all. This joint resolution would be fast-tracked with no amendments and no filibuster in the Senate. We strongly urge lawmakers to take advantage of this one-time opportunity that was written into the law.

Steps do, of course, need to be taken to make Medicare a more value-focused program, to be a more effective combatant against rising rates of chronic disease, to save money in the long run by helping beneficiaries become healthier and lessen their need for hospitalizations and emergency room visits. You are considering bipartisan legislative measures today that will do that. IPAB, with its indiscriminate approach to healthcare spending cuts, will not.

We also believe very strongly that Medicare decisionmaking should be in the hands of the public's elected representatives. It does not matter if a future Independent Payment Advisory Board is filled with eminently-qualified appointees. It does not matter, in lieu of a board, if that power rests with a Democratic or Republican HHS Secretary. What does matter, and what should be opposed, is the idea of moving Medicare policymaking farther away from the millions of Americans who will feel the impact of these changes. Congress has shown repeatedly – most recently through the MACRA legislation – that it will act in a bipartisan fashion to improve healthcare for Medicare beneficiaries and it is with Congress that this authority should remain.

With this testimony, I am also providing a copy of the letter from nearly 800 organizations to Congress urging IPAB repeal, a comprehensive fact sheet on the issue, a paper discussing "myths and facts" regarding IPAB, and a number of recent news stories on the subject. I thank you again for this opportunity to testify and look forward to responding to your questions.

July 5, 2017

Dear Member of Congress:

The undersigned organizations – representing Medicare beneficiaries and patients, all sectors of the healthcare industry as well as employers and other purchasers of health care – believe strongly that the Medicare program must protect patient access to quality healthcare. The Independent Payment Advisory Board (IPAB), a provision of the Patient Protection and Affordable Care Act (PPACA), not only poses a threat to that access but also, once activated, will shift healthcare costs to consumers in the private sector and infringe upon the decisionmaking responsibilities and prerogatives of the Congress. We request your support to repeal IPAB.

IPAB, as constructed under PPACA, is a board comprised of Presidential appointees who will be charged with making recommendations to cut Medicare expenditures if spending growth reaches an arbitrary level. Once the Secretary of Health and Human Services (HHS) implements an IPAB recommendation, that action is not subject to administrative or judicial review. As constructed, IPAB is granted unprecedented powers – even the ability to change laws previously enacted by Congress – with virtually no oversight.

The potential impact of this board causes deep concern among our organizations and the millions of Americans we represent. IPAB proponents suggest that the board will be an asset in developing needed healthcare delivery reforms. That goal, however, is not realistically achievable. The law requires IPAB to achieve scoreable savings within a one-year time period. Thus, instead of pursuing long-term reforms that may not achieve immediate savings, IPAB is more likely to consider short-term savings in the form of payment cuts for healthcare providers. This was, in fact, the conclusion of the Congressional Budget Office, which stated that IPAB is most likely to focus on payment rates or methodologies for services provided by non-exempt providers.

This would be devastating for patients, affecting access to care and innovative therapies. Already, the number of physicians unable to accept new Medicare patients due to low reimbursement rates has been increasing over the past several years. IPAB-generated payment reductions would only increase the access difficulties faced by too many Medicare beneficiaries. Furthermore, payment reductions to Medicare providers will almost certainly result in a shifting of health costs to employers and consumers in the private sector.

Under IPAB's provisions, the responsibility for enacting healthcare system changes of this magnitude would be transferred from the legislative branch to the executive. More specifically, an unelected board without adequate oversight or accountability would be taking actions historically reserved for the public's elected representatives in the U.S. House and Senate. This is an unacceptable decisionmaking process for a program that millions of our nation's seniors and individuals with disabilities rely upon.

Moreover, if IPAB does not act within the law's required timeframe or if IPAB members are not appointed by the President or confirmed by the Senate, the law transfers IPAB's responsibilities solely to the HHS Secretary. This places an enormous degree of power in the hands of one unelected individual.

We strongly support bringing greater cost-efficiency to the Medicare program. We also advocate continuing efforts to improve the quality of care delivered to Medicare beneficiaries. The Independent Payment Advisory Board will achieve neither of these objectives and will only

weaken, not strengthen, a program critical to the health and well-being of current and future beneficiaries. We urge Congress to eliminate the IPAB provision.

Sincerely,

1 in 9: The Long Island Breast Cancer Action Coalition
60 Plus Alabama
60 Plus Association
AARP North Carolina
A Partnership of Diabetics
Abbott
Actelion Pharmaceuticals
Action CF
ADAP Advocacy Association (aaa+)
AdvaMed - the Advanced Medical Technology Association
Advocacy Council of ACAA
Advocates for Responsible Care (ARxC)
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Community Research Initiative of America
AIDS CT
AIDS Foundation of Chicago
AIDS Outreach Montana
AIDS Resource Center Ohio
AIDS Response Seacoast
AIDS Services for the Monadnock Region
Alabama ACEP
Alabama Association of Ambulatory Surgery Centers
Alabama Council of Community Mental Health Boards
Alabama Hospital Association
Alabama Lifespan Respite Resource Network
Alabama Podiatric Medical Association
Alabama Society for Clinical Social Work
Alabama Society for the Rheumatic Diseases
Alaska Behavioral Health Association
Alaska ACEP
Alaska Rheumatology Alliance
Alaska State Medical Association
Alliance for Patient Access
Alliance of Specialty Medicine
Alzheimer's & Dementia Alliance of Wisconsin
Alzheimer's Arkansas
Alzheimer's Association - Capital of Texas Chapter
Alzheimer's Texas
American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Physical Medicine & Rehabilitation
American Association for Hand Surgery
American Association for Pediatric Ophthalmology and Strabismus
American Association of Clinical Endocrinologists
American Association of Clinical Urologists
American Association of Hip and Knee Surgeons

American Association of Neurological Surgeons
American Association of Oral and Maxillofacial Surgeons
American Association of Orthopaedic Surgeons
American Autoimmune Related Diseases Association
American Behcet's Disease Association
American College of Allergy, Asthma & Immunology
American College of Cardiology
American College of Emergency Physicians (ACEP)
American College of Mohs Surgery
American College of Osteopathic Family Physicians
American College of Osteopathic Surgeons
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians & Gynecologists
American Congress of Obstetricians & Gynecologists, Oklahoma Chapter
American Gastroenterological Association
American Glaucoma Society
American Kidney Fund
American Liver Foundation
American Liver Foundation Pacific Coast Division
American Medical Association
American Military Society
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Osteopathic College of Rheumatology
American Physical Therapy Association
American Podiatric Medical Association
American Shoulder and Elbow Surgeons
American Society for Dermatologic Surgery Association
American Society for Mohs Surgery
American Society for Surgery of the Hand
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Ophthalmic Administrators
American Society of Ophthalmic Plastic and Reconstructive Surgery
American Society of Plastic Surgeons
American Spinal Injury Association
American Urological Association
American Uveitis Society
AmisourceBergen
Amgen
AMN Healthcare
Arizona Bioindustry Association (AZBio)
Arizona College of Emergency Physicians
Arizona Radiological Society
Arizona United Rheumatology Alliance
Arizona Urological Society
Arkansas Chapter ACEP
Arkansas Medical Society
Arkansas Ophthalmological Society
Arkansas Orthopaedic Society
Arkansas Podiatric Medical Association

Arkansas Rheumatology Association
Arthritis Foundation
Arthritis Foundation South Central Region
Arthroscopy Association of North America
Ascension
Association of University Professors in Ophthalmology
Asthma and Allergy Foundation of America
Asthma and Allergy Foundation of America, New England Chapter
Atrius Health
Austin Radiological Association
BEACON - Biomedical Engineering Alliance & Consortium
Better Medicare Alliance
Bingham County Senior Center
Bio Nebraska Life Sciences Association
BioBuzz Workforce Foundation
Biocom
BioFlorida
BIOForward
BioHouston
BioKansas
BioNJ
BioNorthTX
BioOhio
Bioscience Association of West Virginia
Biotechnology Industry Organization (BIO)
BioUtah
Birmingham Neurosurgery and Spine Group, PC
Brain Injury Alliance of Oregon
Brain Injury Association of Nebraska
California Academy of Eye Physicians and Surgeons
California ACEP
California Asian Pacific Chamber of Commerce
California Association of Health Facilities
California Association of Neurological Surgeons, Inc
California Chronic Care Coalition
California Health Collaborative
California Hepatitis C Task Force
California Life Sciences Association - CLSA
California Medical Association
California Orthopaedic Association
California Podiatric Medical Association
California Rheumatology Alliance
California Senior Advocates League
California Society for Cardiac Rehabilitation
California Urological Association
Cambridge Chamber of Commerce
Campbell Clinic
Caregiver Action Network
Center for Health Care Services
Center for Healthcare Innovation
Center of Health Engagement
Central Coast Medical Society
Central Florida Behavioral Health Network
Centro de mi Salud
Cervical Spine Research Society
Charleston Parkinson's Support Group

Chattanooga-Hamilton County Medical Society
 Chemed Corporation
 Citrus Council NKFF
 City of New Orleans
 Cleveland Clinic
 CNY HIV Care Network
 COAAA
 Coalition of Asian-American IPA
 Coalition of State Rheumatology Organizations (CSRO)
 Colon Cancer Alliance
 Colorado BioScience Association
 Colorado Cross-Disability Coalition
 Colorado Gerontological Society
 Colorado Medical Society
 Colorado Podiatric Medical Association
 Colorado Radiological Society
 Colorado Rheumatology Association
 Colorado Society of Eye Physicians & Surgeons
 Colorado's Insurance Consultant, LLC
 Communicating for America, Inc.
 Community Access National Network (CANN)
 Community Health Action Network
 Community Health Charities of Nebraska
 Community Liver Alliance
 Community Oncology Alliance
 Congress of Neurological Surgeons
 Connecticut Orthopaedic Society
 Connecticut Podiatric Medical Association
 Council for Affordable Health Coverage
 Council of State Neurosurgical Societies
 CPEM, Inc
 Crohn's & Colitis Foundation of America, Georgia Chapter
 CSRA Area Agency on Aging
 Delaware Academy of Ophthalmology
 Delaware Ecumenical Council on Children and Families
 Delaware HIV Consortium
 Dia de la Mujer Latina
 Easter Seals
 Easter Seals Central and Southeast Ohio Inc.
 Easter Seals Central Texas
 Easter Seals Iowa
 Easter Seals Massachusetts
 Easter Seals Nebraska
 Easter Seals North Georgia
 Easter Seals of Southeastern PA
 Eastern Orthopaedic Association
 EDSers United Foundation
 Eisai Inc.
 Eli Lilly and Company
 ELLAS
 Emergency Department Practice Management Association
 Enchantment Healthcare
 Endometriosis Association
 Enterprise Family Healthcare
 Epilepsy Association of the Big Bend
 Epilepsy Foundation of Greater Chicago

Epilepsy Foundation of Greater Southern Illinois
 Epilepsy Foundation of Hawaii
 Epilepsy Foundation of San Diego County
 Epilepsy Foundation of Western Wisconsin
 Familia Unida Living with MS
 FCEP Florida College of Emergency Physicians
 Federation of American Hospitals
 Federation of Families for Children's Mental Health ~ CO Chapter
 First Step House
 Fleet Reserve Association
 Florida Allergy, Asthma & Immunology Society
 Florida Neurosurgical Society
 Florida Orthopaedic Society
 Florida Osteopathic Medical Association
 Florida Partners in Crisis
 Florida Podiatric Medical Association
 Florida Society of Dermatology and Dermatologic Surgery
 Florida Society of Rheumatology
 Florida State Hispanic Chamber of Commerce
 Friends of Our Lady of Good Counsel
 Geaux Group
 Georgia Bio
 Georgia College of Emergency Physicians
 Georgia Commission on Women
 Georgia Neurosurgical Society
 Georgia Orthopaedic Society
 Georgia Osteoporosis Initiative
 Georgia Podiatric Medical Association
 Georgia Society of Clinical Oncology
 Georgia Society of Dermatology and Dermatological Surgery
 Georgia Society of Ophthalmology
 Georgia Society of Rheumatology
 Georgia Women's Institute
 Global Genes
 Global Healthy Living Foundation
 Global Liver Institute
 Granite State Taxpayers
 Greater North Dakota Chamber
 Greater Providence Chamber of Commerce
 H.E.A.L.S of the South (Hepatitis Education, Awareness and Liver Support)
 Hawaii ACEP
 Hawaii Independent Physicians Association
 Hawaii Medical Association
 Hawaii Podiatric Medical Association
 Health Agents for America, Inc. (HAFA)
 Healthcare Innovation Exchange
 HealthCare Institute of New Jersey (HINJ)
 Healthcare Leadership Council
 HealthHIV
 Healthy African American Families
 Hispanic CREO
 Home Care Association of Washington
 Hopkins County Memorial Hospital
 ICAN, International Cancer Advocacy Network
 Idaho Association of Nurse Anesthetists
 Idaho Medical Association

Idaho Orthopaedic Association
 Idaho Orthopaedic Society
 Idaho Osteopathic Physicians Association
 Idaho Podiatric Medical Association
 Idaho State Dental Association
 Illinois Biotechnology Innovation Organization
 Illinois College of Emergency Physicians
 Illinois Manufacturers' Association
 Illinois Neurological Institute
 Illinois Podiatric Medical Association
 Illinois Society of Eye Physicians & Surgeons
 Illinois State Ambulance Association
 Illinois State Medical Society
 INACEP
 Independent Medical Providers Action Council
 Indiana Academy of Ophthalmology
 Indiana Health Industry Forum
 Indiana Medical Device Manufacturers Council
 Indiana Neurosurgical State Society
 Indiana Podiatric Medical Association
 Indiana State Medical Association
 Indiana University Health, Inc.
 Infectious Diseases Society of America
 Insight Human Services
 Integral Rheumatology and Immunology Specialists (IRIS)
 International Foundation for Autoimmune Arthritis
 International Institute of Human Empowerment
 International Society for the Advancement of Spine Surgery
 ION Solutions
 Iowa Academy of Ophthalmology
 Iowa ACEP
 Iowa Biotechnology Association
 Iowa Orthopaedic Society
 Iowa Osteopathic Medical Association
 Iowa Podiatric Medical Society
 Iowa State Grange
 J. Robert Gladden Orthopaedic Society
 JobKeeper Alliance
 Johnson & Johnson
 Julian CNA Training School
 Kansas Association of Osteopathic Medicine
 Kansas Orthopaedic Society
 Kansas Podiatric Medical Association
 Kansas Rheumatology Alliance
 Kansas Society of Eye Physicians & Surgeons
 Kansas Urological Association
 Kendall Square Association
 Kentuckiana Rheumatology Alliance
 Kentucky Academy of Eye Physicians and Surgeons
 Kentucky ACEP
 Kentucky Chamber of Commerce
 Kentucky Life Sciences Council
 Kentucky Medical Association
 Kentucky Psychiatric Medical Association
 Kidney Cancer Association
 Kidney Care Partners

Latin American Chamber of Commerce
 Latino Commission on AIDS
 Latino Diabetes Association
 Licensed Professional Counselors Association
 Life Science Tennessee
 Life Sciences Greenhouse of Central PA
 Life Sciences Pennsylvania
 Limb Lengthening and Reconstruction Society
 Louisiana Alumni, Sigma Kappa GNO
 Louisiana Association of Neurological Surgeons
 Louisiana Liberty 64
 Louisiana Lifespan Respite Coalition
 Louisiana Orthopaedic Association
 Louisiana Podiatric Medical Association
 Louisiana Womens' Network
 Lower New York Chapter, The American Association of Clinical Endocrinologists
 Lupus Alliance of Long Island/Queens
 Lupus Alliance of Upstate New York
 Lupus and Allied Diseases Association
 Lupus Foundation New England
 Lupus Foundation of America
 Lupus Foundation of America, DC/MD/VA Chapter
 Lupus Foundation of Arkansas, Inc.
 Lupus Foundation of Colorado
 Lupus Foundation of Florida, Inc.
 Lupus Foundation of Northern California
 Lupus Foundation of PA
 Lupus Foundation of Southern California
 Lupus LA
 Lupus Society of Illinois
 MA Health Council
 MACEP - Massachusetts College of Emergency Physicians
 Maine ACEP
 Malecare Cancer Support
 Mallinckrodt Pharmaceuticals
 Manufacture Alabama
 Maryland Chapter American College of Emergency Physicians
 Maryland Orthopaedic Association
 Maryland Society of Eye Physicians and Surgeons
 Massachusetts Association for Mental Health, Inc.
 Massachusetts, Maine, and New Hampshire Rheumatology Association
 Massachusetts Medical Device Industry Council (MassMEDIC)
 Massachusetts Medical Society
 Massachusetts Orthopaedic Association
 Massachusetts Society of Eye Physicians and Surgeons
 MassBio
 Maxim Healthcare Services
 Maxima Home Health LLC
 Meals on Wheels North Carolina
 MedChi, The Maryland State Medical Society
 Medical Alley
 Medical Association of Georgia
 Medical Association of the State of Alabama
 Medical Device Manufacturers Association (MDMA)
 Medical News
 Medical Oncology Association of Southern California

Medical Society of New Jersey
 Medical Society of the State of New York
 Medical University of South Carolina (MUSC)
 MedTech Association
 MemorialCare Health System
 Mended Hearts
 Men's Health Network
 Mental Health America of Montana
 Mental Health Systems
 Merck
 Metropolitan Milwaukee Association of Commerce
 Michigan Association of Neurological Surgeons
 Michigan Association of Osteopathic Family Physicians
 Michigan Biosciences Industry Association - MichBio
 Michigan Chamber of Commerce
 Michigan College of Emergency Physicians
 Michigan Lupus Foundation
 Michigan Orthopaedic Society
 Michigan Osteopathic Association
 Michigan Rheumatism Society
 Michigan Society of Eye Physicians and Surgeons
 Minnesota Academy of Ophthalmology
 Minnesota Chapter ACEP
 Minnesota Medical Association
 Minnesota Neurosurgical Society
 Minnesota Orthopaedic Society
 Minnesota State Grange
 Mississippi Academy of Eye Physicians and Surgeons
 Mississippi Osteopathic Medical Association
 Mississippi Society of Eye Physicians and Surgeons
 Mississippi State Medical Association
 Missouri Ambulance Association
 Missouri Association of Rural Health Clinics
 Missouri Biotechnology Association
 Missouri Chamber of Commerce and Industry
 Missouri Hospital Association
 Missouri State Medical Association
 Missouri Urological Society
 MoCEP - Missouri College of Emergency Physicians
 Montana ACEP
 Montana BioScience Alliance
 Montana Chamber of Commerce
 Montana Medical Association
 Montana Orthopedic Society
 Multiple Sclerosis Resources of Central New York, Inc.
 Musculoskeletal Tumor Society
 NAMI - Sheridan
 NAMI Alabama
 NAMI Anchorage
 NAMI Buffalo & Erie County
 NAMI Clackamas
 NAMI Florida
 NAMI Greater Des Moines
 NAMI Hernando
 NAMI Illinois
 NAMI Indiana

NAMI Iowa
 NAMI Kansas
 NAMI Knox Licking County Ohio
 NAMI Lewis County
 NAMI Maine
 NAMI Maryland
 NAMI Mass
 NAMI Minnesota
 NAMI Montana
 NAMI Nebraska
 NAMI Nevada
 NAMI New Mexico
 NAMI North Carolina
 NAMI North Dakota
 NAMI Northern Nevada
 NAMI Ohio
 NAMI Rochester
 NAMI Sioux Falls
 NAMI Skagit
 NAMI Stark County
 NAMI Upper Valley Idaho
 NAMI Virginia
 NAMI Washington
 NAMI York County
 NASW Texas Chapter
 National Alliance on Mental Illness
 National Alliance on Mental Illness of Central Suffolk
 National Alliance on Mental Illness of Park County, WY
 National Association for Home Care & Hospice
 National Association for Uniformed Services
 National Association of Hepatitis Task Forces
 National Association of Manufacturers
 National Association of Nutrition and Aging Services Programs (NANASP)
 National Association of Social Workers - NC Chapter
 National Association of Social Workers - Virginia Chapter
 National Association of Spine Specialists
 National Center for Policy Analysis
 National Coalition for LGBT Health
 National Council for Behavioral Health
 National Council of Asian Pacific Islander Physicians
 National Fibromyalgia & Chronic Pain Association
 National Grange
 National Hispanic Medical Association
 National Minority Quality Forum
 National Psoriasis Foundation
 National Retail Federation
 National Rural Health Association
 National Spasmodic Torticollis Association
 NCCEP North Carolina College of Emergency Physicians
 NC State Grange
 Nebraska Medical Association
 Nebraska Rural Health Association
 Nebraska State Grange
 Nebraska Taxpayers for Freedom
 Neuro Network Partners
 Neurofibromatosis, Inc. Mid-Atlantic

Neurosurgical Society of Kentucky
 Nevada Academy of Ophthalmology
 Nevada Chapter ACEP
 Nevada Health Care Association
 Nevada Orthopaedic Society
 New England Biotech Association
 New Jersey Academy of Ophthalmology
 New Jersey Association of Mental Health and Addiction Agencies, Inc.
 New Jersey Chapter ACEP
 New Jersey Mayors Committee on Life Science
 New Jersey Orthopaedic Society
 New Jersey Rheumatology Association
 New Mexico Biotechnology & Biomedical Association (NMBio)
 New Mexico Association of Nurse Anesthetists
 New Mexico Chapter ACEP
 New Mexico Health Care Association
 New Mexico Podiatric Medical Association
 New York ACEP
 New York Regional Society of Plastic Surgeons
 New York State Neurological Society
 New York State Ophthalmological Society
 New York State Rheumatology Society
 New York State Society of Orthopaedic Surgeons, Inc.
 New York State Society of Plastic Surgeons, Inc.
 New York State Urological Society
 NHACEP
 North American Neuro-Ophthalmology Society
 North Carolina Alliance for Retired Americans
 North Carolina Biosciences Organization
 North Carolina Chamber
 North Carolina Foot & Ankle Society
 North Carolina Psychological Association
 North Carolina Rheumatology Association
 North Carolina Society of Eye Physicians and Surgeons
 North Dakota Chapter ACEP
 North Dakota Medical Association
 North Dakota Podiatric Medical Association
 North Dakota Society of Eye Physicians and Surgeons
 North Macon Family Healthcare Associates
 Northeast Kidney Foundation
 Northern Utah Coalition, Inc.
 Novartis Pharmaceuticals Corporation
 Occasional Riot
 Ogden Branch of the NAACP
 Ohio ACEP
 Ohio Association of County Behavioral Health Authorities
 Ohio Association of Medical Equipment Services
 Ohio Association of Rheumatology
 Ohio Chamber of Commerce
 Ohio Council for Home Care and Hospice
 Ohio Foot and Ankle Medical Association
 Ohio Jewish Communities
 Ohio Orthopaedic Society
 Ohio Osteopathic Association
 Ohio State Grange
 Ohio Veterans United

OKBio
 Oklahoma Academy of Ophthalmology
 Oklahoma ACEP
 Oklahoma Association of Nurse Anesthetists
 Oklahoma Osteopathic Association
 Oklahoma Podiatric Medical Association, Inc.
 Oklahoma Society of Anesthesiologists
 Oklahoma Society of Oral and Maxillofacial Surgeons
 Oklahoma State Medical Association
 ONEgeneration
 Oregon Academy of Ophthalmology
 Oregon Chapter of American College of Emergency Physicians
 Oregon Medical Association
 Oregon Neurosurgical Society
 Oregon Podiatric Medical Association
 Oregon Rheumatology Alliance
 Oregon Urological Society
 Orthopaedic Research Society
 Orthopaedic Society of Oklahoma
 Orthopaedic Trauma Association
 Osteopathic Physicians & Surgeons of California
 Pacific Northwest Chapter of TRIO
 PA Prostate Cancer Coalition
 Partnership to Fight Chronic Disease
 PCa Blue Inc.
 Pediatric Orthopaedic Society of North America
 Pennsylvania Chamber of Business and Industry
 Pennsylvania College of Emergency Physicians
 Pennsylvania Neurosurgical Society
 Pennsylvania State Grange
 Perennial Services Network
 Pfizer
 Pharmaceutical Care Management Association
 Philadelphia Rheumatism Society
 PhRMA
 Plaza Community Services
 Premier healthcare alliance
 Prescription Assistance Network of Stark County, Inc.
 Prevent Blindness Iowa
 Prevent Blindness, Ohio Affiliate
 Progressive Democrats of Central New Mexico
 Progressive Leaders of Louisiana
 Prostate Health Education Network
 Radiology Associates of Macon
 Rainy Day Patriots
 Respiratory Health Association
 RetireSafe
 Rheumatism Society of the District of Columbia
 Rheumatology Alliance of Louisiana
 Rheumatology Association of Iowa
 Rheumatology Association of Minnesota and the Dakotas
 Rheumatology Association of Nevada
 Rheumatology Society of North Texas
 Rhode Island Chapter ACEP
 Rhode Island Medical Society
 Rhode Island Society of Eye Physicians and Surgeons

Rhode Island Tech Collective
 Rio Grande Valley Diabetes Association
 RIPMA
 Rocky Mountain Stroke Center
 RTI Surgical Inc.
 Rush To Live
 SAGE Utah
 Saint Agnes Healthcare
 Salud U.S.A.
 Sandhills Adult Day Health Center, Inc.
 San Diego County Podiatric Medical Association
 Sanofi US
 SC Podiatric Medical Association (SCPMA)
 Scoliosis Research Society
 Sea Island Pediatrics
 Senior Connections, The Capital Area Agency on Aging
 Seniors Golden Hammer
 Seniors Hospitality Center / Bonners Ferry Senior Center
 Sickle Cell Disease Association of Florida
 Sjögren's and Lupus Foundation of Hawaii
 Sjogren's Syndrome Foundation
 Small Business & Entrepreneurship Council
 Smile Community Action Partnership
 Society of Academic Urologists
 Society for Cardiovascular Angiography and Interventions
 Society for Vascular Surgery
 Society of Military Orthopaedic Surgeons
 Society of Urologic Oncology
 Solidarity Project Advocacy Center
 South Carolina BIO
 South Carolina Hospital Association
 South Carolina Medical Association
 South Carolina Medical Group Management Association (SCMGMA)
 South Carolina Nurses Association
 South Carolina Orthopaedic Association
 South Carolina Rheumatism Society
 South Carolina Society of Ophthalmology
 South Carolina Urological Association
 South Dakota Biotech
 South Dakota State Medical Association
 South Dakota State Orthopaedic Society
 South Florida Cancer Association
 Southern Orthopaedic Association
 State Chamber of Oklahoma
 State of Texas Association of Rheumatologists
 State of Texas Kidney Foundation
 Statewide Independent Living Council of Hawaii
 StopAfib.org
 Suicide Awareness Voices of Education
 Sunovion Pharmaceuticals Inc.
 Survivors Cancer Action Network
 Takeda Pharmaceuticals, USA Inc.
 TCEP Texas College of Emergency Physicians
 Tech Council of Maryland
 Tennessee Association of Long Term Care Physicians
 Tennessee Geriatrics Society

Tennessee Hemophilia and Bleeding Disorders Foundation
 Tennessee Medical Association
 Tennessee Orthopaedic Society
 Tennessee Rheumatology Society
 Texas Association for Home Care and Hospice
 Texas Association of Business
 Texas Association of Neurological Surgeons
 Texas BioAlliance
 Texas Health Resources
 Texas Healthcare and Bioscience Institute
 Texas Life-Sciences Collaboration Center
 Texas Medical Association
 Texas Neurological Society
 Texas Nurse Practitioners
 Texas Orthopaedic Association
 Texas Osteopathic Medical Association
 Texas Pain Society
 Texas Radiological Society
 Texas State Grange
 The AIDS Institute
 The Arc in Hawaii
 The Arc of Anchorage
 The Benefits Consultancy
 The Jewish Federations of North America
 The Macula Society
 The Marilyn Fagan Ovarian Cancer Patient Advocacy Program (ICAN-Hawaii)
 The Meeting Group, Inc.
 The Michael J. Fox Foundation for Parkinson's Research
 The National Association of Catholic Nurses - U.S.A.
 The National Catholic Bioethics Center
 The New England Council
 The New Mexico Association for Home and Hospice Care
 The Retina Society
 The Surgery Center of Huntsville
 The US Oncology Network
 The Vision Care Center
 The Wall Las Memorias Project
 Twin Falls Senior Center
 U.S. Chamber of Commerce
 U.S. Pain Foundation
 Union Pacific Railroad Employees Health Systems
 Urban Pain Institute
 Utah Advocates
 Utah Medical Association
 Utah Podiatric Medical Association
 Utah Pride Center
 Utah State Orthopedic Society
 Utah Support Advocates for Recovery Awareness
 Vermont Medical Society
 Vermont State Association of Osteopathic Physicians & Surgeons, Inc.
 Veterans Health Council
 Vietnam Veterans of America
 Vietnamese Social Services of Minnesota
 Virginia Bio
 Virginia Chamber of Commerce
 Virginia Hispanic Chamber of Commerce

Virginia Podiatric Medical Association
Virginia Society of Eye Physicians and surgeons
Visiting Nurse Association
Visiting Nurse Association of Ohio
VITAS Healthcare
Vizient, Inc.
Washington ACEP
Washington Biotechnology & Biomedical Association
Washington Rheumatology Alliance
Washington Rural Health Association
Washington State Medical Association
Washington State Orthopaedic Association
Washington State Podiatric Medical Association
Washington State Prostate Cancer Coalition
Washington State Urology Society
Wellness and Education Community Action Health Network
Wellness Station
West Virginia Academy of Eye Physicians & Surgeons
West Virginia Academy of Otolaryngology - Head and Neck Surgery, Inc.
West Virginia Orthopaedic Society
West Virginia State Rheumatology Society
Western Orthopaedic Association
Western Section of the American Urological Association
Wisconsin Academy of Nutrition and Dietetics
Wisconsin Academy of Ophthalmology
Wisconsin Association of Osteopathic Physicians & Surgeons (WAOPS)
Wisconsin Hospital Association
Wisconsin Manufacturers & Commerce
Wisconsin Medical Society
Wisconsin Rheumatology Association
Wisconsin State Grange
Wound Care Clinic - ESU
WPMA - Wisconsin Podiatric Medical Association
Wyoming Chapter American College Emergency Physicians
Wyoming Epilepsy Association
Wyoming Medical Society
Wyoming Ophthalmological Society
ZERO - The End of Prostate Cancer

[Ms. Grealy's full statement can be found at: <http://docs.house.gov/meetings/if/if14/20170720/106287/hhrg-115-if14-bio-grealy-20170720.pdf>.]

Mr. BURGESS. The chair thanks the gentlelady for her testimony. Dr. Moore, you are recognized for 5 minutes, please, for an opening statement.

STATEMENT OF JUSTIN MOORE

Dr. MOORE. Chairman Burgess, Ranking Member Green, and members of the Health Subcommittee, my name is Justin Moore, CEO of the American Physical Therapy Association. On behalf of the American Occupational Therapy Association, the American Speech-Language-Hearing Association, and APTA, thank you for this opportunity to provide testimony on bipartisan legislation to strengthen and improve the Medicare program.

Today, I will outline our shared perspective on the exceptions process to the therapy caps set to expire at the end of this year.

Without action, Medicare will impose financial limitations on outpatient physical therapy and speech-language pathology and occupational therapy services under Medicare Part B. These therapy caps create an arbitrary barrier for Americans who are in need of rehabilitation services.

For 20 years, Congress and this committee have provided relief to this barrier through moratoriums and, more recently, the exceptions process, which is currently under consideration for yet another extension.

Today, we ask Congress to finally address this issue by repealing the therapy caps once and for all. We would like to thank Representatives Blackburn and Matsui from this committee, Representatives Paulson and Kind, for championing the repeal of therapy cap legislation by introducing H.R. 807, which currently has 177 cosponsors in the House.

This pattern of yearly extensions, without a permanent solution, creates uncertainty for beneficiaries and providers, threatens access to care, and is not in the best interest of patients, providers, or the Medicare program. We recognize and appreciate that there is a cost to any permanent fix. However, the price of solving this problem will only continue to rise. With the money spent on these temporary patches over the past 2 decades, we could easily have paid for a more permanent solution.

ASHA, APTA, and AOTA have been effective partners with Congress, this committee, and CMS on this policy over the past 20 years. We have made significant reforms to preserve the integrity of the Medicare program, while simultaneously preserving access for beneficiaries. We believe it is time for Congress to finally repeal the therapy caps and replace them with a thoughtful medical review process that is more targeted, ensures that care is delivered to vulnerable patients, streamlines the ability of providers to deliver that care, and ensures the long-term viability of the Medicare program. Such a policy should build upon the lessons learned, the multiple reports, and the data gathered through the current exceptions process, as well as the current and previous medical review programs.

Representatives from the three therapy groups have been in discussions with this committee about ideas for a permanent solution. Data shows that the \$3,700 threshold and current medical review process is providing appropriate oversight of therapy spending, and

could be improved and incorporated into a permanent solution to ensure the continuum of care and decrease administrative burdens. This policy per form, coupled with a pathway for therapy providers to be part of value-based models, will better align therapy services with the transition of Medicare to performance-based models.

To that end, we respectfully propose three principles for a permanent fix. First, ensuring patient access. Any permanent cap policy should, at its core, ensure patient access to outpatient therapy services without unnecessary delays. The fundamental flaw in the therapy caps is that it is a barrier that does not take into account the individual needs of the patient.

Principle two is a targeted approach to oversight of outpatient therapy spending. We support a mechanism to ensure appropriate delivery and utilization of outpatient therapy services. This can include targeted medical review of therapy providers whose claims exceed the \$3,700 threshold and who have been identified based on specific criteria for additional review. However, such oversight should include protections for patients and ensure care is not delayed. Blanket mechanisms, such as the original therapy cap, or broad application of prior authorization, are not effective, restrict access, and interrupt the continuum of care.

Principle three is the alignment with value-based and performance-based models. We believe therapy services provided in a qualified alternative payment model should be exempt. Providers that participate in APMs would already be subject to quality and outcome requirements, as well as shared risk for the cost of care. In addition, therapy providers are not currently part of the MIPS program, but we anticipate being added to that program in 2019. A permanent fix is critical to effectively bringing therapy providers into value-based programs.

In closing, the therapy community stands ready to work with this committee to finally, after 20 years of extensions and moratoriums, repeal the therapy cap and find a permanent fix. Thank you for your time.

[The prepared statement of Dr. Moore follows:]

Testimony before the United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on “Examining Bipartisan Legislation to Improve the Medicare
Program”

July 20, 2017

Statement of Justin Moore, PT, DPT
Chief Executive Officer, American Physical Therapy Association

On behalf of
The American Occupational Therapy Association (AOTA)
The American Physical Therapy Association (APTA)
The American Speech-Language-Hearing Association (ASHA)

Chairman Burgess, Ranking Member Green, and Members of the Health Subcommittee of the House Committee on Energy and Commerce:

My name is Justin Moore, and I am the CEO of the American Physical Therapy Association. On behalf of the American Occupational Therapy Association (AOTA), the American Speech-Language-Hearing Association (ASHA), and the American Physical Therapy Association (APTA), I thank you for the opportunity to provide testimony on bipartisan legislation to strengthen and improve the Medicare program. Today I will share with you our perspective on a particular policy—the exceptions process to the limitations on therapy services under Medicare Part B, which is set to expire on December 31, 2017.

The therapy caps, and the current exceptions process to them, impact a wide spectrum of patients needing rehabilitation services. In particular, the therapy caps have a disproportionate impact on older, more chronically ill beneficiaries from underserved areas, such as rural and urban population centers. Advocacy work to protect access to therapy services for these patients and consumers has resulted in almost 30 patient and professional organizations coming together with the common objective to repeal the therapy caps once and for all. I want to thank Representatives Erik Paulsen, Ron Kind, Marsha Blackburn, and Doris Matsui for championing repeal of the therapy caps by introducing H.R. 807, which currently has 177 cosponsors in the House. Companion legislation has been introduced in the Senate by Senators Ben Cardin, Dean Heller, Susan Collins, and Bob Casey. This legislation has the bipartisan support of 26 senators as of today.

Since 1997, we have worked to ensure that this arbitrary limitation on outpatient rehabilitation

services does not impede access to necessary and covered care for Medicare beneficiaries. Congress has acted 16 times to prevent this policy from negatively impacting seniors and individuals with disabilities. Today, we ask that Congress fully address this longstanding concern by repealing the therapy caps and replacing them with a thoughtful medical review policy that will protect the integrity of Medicare while ensuring timely access to care. While we appreciate the committee's focus on the issue of the therapy caps, we urge the committee to avoid extending the exceptions process again, and instead pursue a permanent fix to the therapy cap.

While the current exceptions process has provided temporary mitigation for beneficiaries against the negative impact of the therapy caps, it is not a long-term solution.

We believe it is time for Congress to fully repeal the therapy caps and replace the temporary exceptions process with a permanent fix that is more targeted, ensures that care is delivered to vulnerable patients, streamlines the ability of providers to deliver needed care, and ensures the long-term viability of the Medicare program.

Background of the Outpatient Therapy Caps

As part of the Balanced Budget Act (BBA) of 1997, Congress authorized \$1,500 therapy caps on the majority of outpatient therapy services furnished under Medicare Part B: in private practice settings, physician offices, skilled nursing facilities (Part B), comprehensive outpatient rehabilitation facilities, home health agencies (Part B), and rehabilitation agencies. At the time, Congress exempted outpatient hospital settings from the therapy cap.

Due to a quirk in statutory language, it was determined that 2 caps would exist: 1 on physical therapy and speech-language pathology combined and 1 on occupational therapy services. The therapy caps authorized in the BBA were designed to be a temporary measure until the Centers for Medicare and Medicaid Services (CMS) provided an alternative payment methodology for therapy services for Congress' consideration. The authorizing language from BBA also provided for inflationary growth beginning in 2002 for the financial limit. Today the therapy cap is \$1,980 per beneficiary per year for physical therapy and speech-language language pathology services, and \$1,980 per beneficiary per year for occupational therapy, with a clinically based exceptions process.

The therapy caps originally went into effect on January 1, 1999, but were not enforced due to limitations in implementing them at the agency and local contractor level. On November 19, 1999, Congress passed the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999, which placed a 2-year moratorium on the \$1,500 cap for 2000 and 2001. Congress passed legislation again in 2000 as part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) to extend the moratorium on the therapy caps through 2002. In 2003, CMS delayed enforcement of the therapy cap from January 1, 2003, through September 1, 2003. The therapy cap was in place from September 1, 2003, until Congress passed the Medicare Modernization Act on December 8, 2003, that extended the moratorium on the therapy cap through December 31, 2005. In other words: In the first 6 years of the therapy cap, Congress passed moratoriums on this policy 3 times, and the caps were in effect for just under 100 days.

The therapy caps again went into effect temporarily on January 1, 2006, but were quickly addressed in the Deficit Reduction Act passed by Congress on February 1, 2006, by creation of the initial exceptions process. Originally, CMS implemented a 2-tier approach of an automatic exceptions process for certain diagnoses likely to exceed the therapy cap and a manual process for clinicians to provide justification of medically necessary care above the arbitrary financial limitation of the therapy cap. Due to the difficulty in reviewing all claims submitted under the manual process, the exceptions process was modified to allow for the use of a code-based modifier to signify that therapy services above the financial limit are medically necessary and appropriate.

The Middle Class Tax Relief and Job Creations Act of 2012 implemented a manual medical review (MMR) process that began in October 2012. This process initially required a MMR of all claims over the \$3,700 threshold, prior to the services being provided. Later these reviews were handled as prepayment reviews by Medicare Administrative Contractors (MACs), and then CMS used Recovery Audit Contractors (RACs) to do prepayment reviews of claims in 12 states and postpayment reviews of claims in the other 38.

In addition to RACs being inappropriate contractors to review services that have never been paid for, the entire process of review was poorly administered and never implemented in a way that did not create a burden for providers. This was particularly true of the preapproval process (similar to the issues experienced with preapproval in 2006). The MMR process was put on hold in 2014 and 2015 due to contract issues.

In 2015 the Medicare Access and CHIP Reauthorization Act put into place a *targeted* MMR process, based on set criteria. From the perspective of the 3 therapy groups, this process has worked without undue burden or delaying care for beneficiaries. The current extension of the therapy cap exceptions process expires on December 31, 2017.

The Impact

It has been estimated that almost 70% of Medicare beneficiaries have more than 1 chronic condition that may require outpatient therapy. For a patient with multiple chronic conditions, therapy services are critical to preserving or regaining function following an impairment or a major medical condition such as stroke. Medicare beneficiaries requiring extensive or multiple therapies most likely will quickly exceed the therapy cap benefit. Although the exceptions process is in place to provide a pathway to care for these individuals, the current process is only guaranteed through the end of this year.

The combined cap of physical therapy and speech-language pathology is also problematic, as these are distinct clinical services that occur at different times in the continuum of care. They address related but separate areas of impairment. A patient with a stroke might receive extensive physical therapy to regain mobility, but then the cap will limit their ability to obtain services to improve swallowing or speaking. This example of giving the patient a choice between walking and talking is an oft-cited example of the complicating factors and poor policy of the therapy cap.

Additionally, services under Medicare are required to be medically necessary, and providers must meet the required regulations to demonstrate this requirement. The therapy cap places an arbitrary stopping point to therapy regardless of the medical necessity of the services. A patient has a demonstrated need for care, and yet a policy overrides their ability to receive that care. This runs contrary to the overall policies of Medicare related to ensuring quality patient outcomes.

Congress has long known that allowing the therapy caps to go into effect would have a profound impact on patient care; that is clear from the repeated delays and extensions of the exceptions process. But the pattern of yearly extensions without a permanent solution is not in the best interest of patients, providers, or the Medicare program, as it creates uncertainty for beneficiaries and providers. We recognize and appreciate the cost of a permanent fix and appreciate Congress' work to ensure that hard caps on therapy services do not go into effect. However, the cost of a permanent fix will only continue to rise as more beneficiaries come into the Medicare system. Additionally, it appears that new models of care are discharging patients from inpatient settings earlier, and relying more and more on outpatient settings for the provision of therapy services. While these models may save the entire Medicare system money, they are shifting services from Part A to Part B. Should this pattern continue, the cost of repealing the therapy caps down the road will only increase, and so too will the negative impact on patients and outcomes. The 20 years of exceptions process extensions now has cost more than that of a permanent fix, so we urge Congress to move forward toward a solution this year, which would avoid a future of additional costly extensions.

ASHA, APTA, and AOTA believe simply extending the exceptions process yet again is not in the best interest for sustaining the long-term fiscal health of Medicare, nor does it meet the growing needs for cost-effective rehabilitation services under Medicare. The time has come to enact a replacement policy that is a permanent fix. Such a policy should build upon the lessons learned and data gathered through the current exceptions process, and current and previous medical review programs.

Current Exceptions Process and Medical Review

With the passage of MACRA, the exceptions process to the therapy caps is currently in effect. Under this system, providers may request an exception on a beneficiary's behalf when their treatment exceeds the cap—\$1,980 in 2017—and the services are determined to be medically necessary. To indicate this medical necessity, the therapy provider or practitioner is required to add a KX modifier to the claim for each applicable service. By using the KX modifier, the provider attests both that (a) the services are reasonable and necessary, and (b) there is documentation of medical necessity in the beneficiary's medical record.

A second layer to the current therapy caps exceptions process is a targeted review of claims once a beneficiary's incurred expenses reaches a threshold of \$3,700. Each beneficiary's incurred expenses apply toward the threshold in the same manner as it applies to the therapy caps. There's 1 threshold for combined PT and SLP services and another threshold for OT services.

This current medical review process allows CMS to do a targeted review of claims that exceed the \$3,700 threshold rather than a review *every* claim above the threshold, as was required when

the exceptions process was first implemented in 2006 and when medical review was first implemented in 2012. Targeted medical review focuses more on providers with aberrant billing patterns when compared with their peers, or that have a high amount of hours or minutes of therapy delivered to patients in a single day. This review occurs after therapy services have been provided.

Lessons Learned That Inform a Replacement Proposal

AOTA commissioned a report from the Moran Company to look at patterns in therapy utilization that might inform policy for a permanent fix. This report compared therapy utilization in 2011 (the year before medical review was implemented at the \$3,700 threshold) with 2015 (when the refined review process was first implemented). The data demonstrate 2 key findings:

First, the average per-beneficiary, Part B therapy spending *decreased* by 8% across all therapy types between 2011 and 2015. This compares with an *increase* of 8% in overall beneficiary Part B spending. This demonstrates that the current process of reviewing targeted claims over the \$3,700 threshold is working. Between 2011 and 2015 the proportion of overall spending above the \$3,700 threshold fell from 31% to 20% of total Medicare therapy spending for physical therapy and speech language pathology, and from 35% to 27% of occupational therapy spending. This decrease in total Medicare therapy spending on services above the threshold is the result of both a decrease in the number of beneficiaries receiving services over the threshold and a decrease in the average cost per beneficiary over the threshold. (Moran analysis Tables 3 and 4 attached).

Second, this data demonstrates that while there has been a decrease in spending above the threshold, services are still being provided and approved by the current review process. The current \$3,700 threshold and medical review process appear to be having the intended effect of controlling potentially unnecessary utilization, as seen by a decrease in per-beneficiary spending and number of beneficiaries in this category, but still maintaining a pathway for patients to receive all medically necessary services.

Representatives from the 3 therapy professional organizations have been in discussion with both Energy and Commerce Committee and Ways and Means Committee staff, as well as with Senate Finance Committee staff, about ideas for a permanent therapy cap policy. We believe that the \$3,700 threshold and current medical review process is providing appropriate oversight of therapy spending, and could be incorporated and improved in a permanent fix to ensure continuity of care, increased efficiencies, and decreased administrative burden.

One possible policy for a permanent fix could include a 3-step process of oversight of therapy claims. The first step would be to utilize the current \$3,700 threshold as a trigger for *postpayment* medical review of claims submitted by providers who meet certain criteria. Additional oversight mechanisms could be utilized for providers on postpayment medical review who are identified as meeting additional factors; in other words, providers who are not “succeeding” under postpayment review. This oversight coupled with a pathway for therapy providers to be part of alternative payment models and other performance-based models will better align therapy services with the transition of Medicare to a value-based system.

To that end, and based on our experience with previous policies, we respectfully propose the following principles:

1) Ensuring patient access

Any permanent therapy cap policy should—at its core—ensure patient access to outpatient therapy services. The fundamental flaw with the policy of the therapy cap is that it is a broad barrier to care that does not take into account the individual needs of the patient. Additionally, any new policy should ensure that care is not disrupted for long periods of time. In the past, when CMS has been asked to do a broad review of a large number of claims, they have been unable to efficiently implement the policy, resulting in delayed care for patients and high administrative burden for providers. Not only is delayed care bad for the patient, but it could lead to higher costs to the program, as the beneficiary's progress may regress if care is disrupted.

2) Targeted approach to oversight of outpatient therapy spending

We support a mechanism to ensure appropriate delivery and utilization of outpatient therapy services. This could include targeted reviews of therapy providers whose claims exceed certain thresholds and have been identified based on specific factors. Additional scrutiny could be given to providers who continue to have claims rejected under the review process. However, any additional scrutiny, whether through postpayment review or preauthorization, should include protections for patients and ensure that care is not delayed (see principle #1). This process would be similar to the current \$3,700 threshold and postpayment medical review process. Blanket mechanisms, such as the current therapy caps or broad application of prior authorization across the patient spectrum, are not effective. They restrict patient access, do not take into account

medical severity, interrupt the continuity of care, and cannot realistically be implemented by CMS.

3) Alignment with value-based and performance-based models

We believe that therapy services provided in a qualifying Alternative Payment Model (APM) should be exempt from any permanent outpatient therapy policy. Providers who participate in APMs would already be subject to quality and outcome requirements, as well as a shared risk for the cost of care, that would ensure efficient provision of services. In addition, while therapy providers are not currently part of the MIPS program, we anticipate that these providers will be added to the program in 2019. The MIPS program provides performance-based penalties and payment adjustments to providers. Under MIPS, the therapy caps and ongoing short-term fixes could impede the ability of providers to maximize outcomes, decrease costs, and improve performance. A permanent fix is essential in order for therapy providers to effectively participate in MIPS.

Conclusion

In closing, ASHA, AOTA, and APTA, along with other members of the community opposing the therapy cap, stand ready to work with the Committee to finally, after 20 years of extensions and moratoria, to repeal the therapy cap, find a permanent fix that ensures patients' access, improves the care delivered to those patients, streamlines the ability of providers to deliver that care, and ensures the long-term viability of the Medicare program. Thank you.

[Dr. Moore's full statement can be found at: <http://docs.house.gov/meetings/if/if14/20170720/106287/hhrg-115-if14-bio-moorej-20170720.pdf>.]

Mr. BURGESS. The chair thanks the gentleman for his testimony. Ms. Sanders, you are recognized for 5 minutes for your opening statement, please.

STATEMENT OF STACY SANDERS

Ms. SANDERS. Chairman Burgess, Ranking Member Green, and distinguished members of the Subcommittee on Health, thank you for the invitation to testify. We applaud the committee for identifying bipartisan opportunities to improve Medicare.

The Medicare Rights Center is a national nonprofit consumer service organization that works to ensure affordable access to healthcare for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Since 1989, we have been helping people with Medicare understand their rights, navigate their benefits, and secure the quality healthcare they deserve.

Medicare Rights answers nearly 20,000 questions on its national helpline every year, and nearly 3 million Americans turn to our on-line tool Medicare Interactive. This free Medicare encyclopedia explains basic Medicare concepts and rules written to a fifth grade reading level. We regularly work with congressional offices as well who call us for assistance on constituent casework, and we welcome the opportunity to serve as a resource to the committee and beneficiaries nationwide.

My testimony focuses on our support for the Medicare Civil and Criminal Penalties Update Act of 2017, H.R. 3245. Fraud not only harms the Medicare program and the American taxpayer, but can have a very real impact on the lives of individual beneficiaries. In order to deter fraud and abuse, this bill would increase the civil monetary penalties, fines, and sentences allowable for specific types of Medicare fraud, such as the submission of false claims and the acceptance of financial inducements.

Let me expand on why Medicare fraud is deeply problematic. For people with Medicare, fraud and abuse can lead to exploitation in the form of increased costs, including overcharging for services or even paying for care that was never delivered. Seniors and people with disabilities may also be harmed if they receive unnecessary services or if needed care is withheld. Fraud and abuse also lead to increased and inappropriate spending of taxpayer dollars.

It is critically important that Congress prioritize policies to prevent and deter fraud and abuse. Existing oversight and enforcement initiatives have proven successful. Over the last 3 years, the Office of Inspector General and its partners recovered more than \$6.10 for every dollar dedicated to healthcare fraud investigations. Of course, these or any enhanced recovery efforts must be implemented carefully so as not to inadvertently curb access to care should providers come to fear retribution for minor billing errors or honest mistakes.

A continued and enhanced commitment to fraud prevention and recovery can help ensure that people with Medicare are not over-billed or otherwise harmed and that taxpayer dollars are spent responsibly.

Many of the administrative sanctions increased by this bill were established in 1981, and last revised in 1996, leading us to believe

that these penalties are due for an update. And in 2011, the Office of Inspector General cautioned Congress that perpetrators of fraud may regard existing penalties as nothing more than the cost of doing business.

It is important to remember that there is a beneficiary-facing component to preventing Medicare fraud and mitigating the harms of abuse.

The federally funded state health insurance assistance programs, known as the SCHIAPs, and senior Medicare patrols work together in every state and U.S. territory to educate people with Medicare about how to protect themselves from fraud, to help them navigate cost-sharing challenges and billing errors, and to assist people with reporting suspected fraud and abuse.

We urge Congress to support these essential programs and secure their funding. Further, when fraud is uncovered, it is legislation like that introduced by Congressman Bilirakis and Congresswoman Castor, H.R. 3245, that is needed to ensure that those defrauding Medicare are appropriately penalized.

We look forward to working with the committee on this legislation and other bipartisan policies to improve the day-to-day experiences of people with Medicare and to strengthen the program now and into the future. Thank you.

[The prepared statement of Ms. Sanders follows:]



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Testimony of Stacy Sanders
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Prepared for the
United States House of Representatives
Energy & Commerce Committee, Subcommittee on Health

“Examining Bipartisan Legislation to Improve the Medicare Program”

July 20, 2017

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Introduction:

Chairman Burgess, Ranking Member Green, and distinguished members of the Subcommittee on Health, thank you for the opportunity to testify on bipartisan legislation to improve the Medicare program. I am Stacy Sanders, Federal Policy Director of the Medicare Rights Center (Medicare Rights). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

Medicare Rights answers nearly 20,000 questions on our national helpline each year, serving older adults, people with disabilities, and those that help them, including family caregivers, social workers, attorneys, and other professionals. Through our educational initiatives, we touch the lives of nearly three million Americans who are seeking an unbiased and trusted Medicare source, whether online or through in-person trainings.

Our commentary draws directly from nearly 30 years of experience serving older adults and people with disabilities who rely on Medicare for basic health security. Problems presented by callers to the Medicare Rights helpline are varied and complex. Year after year, the most common questions heard on the helpline concern three themes: affording basic health care costs, appealing denials of coverage, and enrolling in Medicare. In all of these areas, among others, we see that people with Medicare would benefit from more support.¹

We applaud the Committee for identifying bipartisan opportunities to improve Medicare for today's beneficiaries and for future generations. We strongly believe that members of Congress should work in a transparent and constructive manner to improve the day-to-day experiences of people with Medicare and to strengthen the program now and into the future.

Combating Medicare Fraud and Exploitation:

The focus of our testimony concerns Medicare fraud and abuse, and particularly the *Medicare Civil and Criminal Penalties Update Act of 2017* (H.R. 3245). This bipartisan legislation was introduced by Congressman

¹ Sutton, C., Bennett, R., Sanders, S., and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2012 Call Data from the Medicare Rights Center's National Helpline," Medicare Rights Center (January 2014), available at: <http://www.medicarerights.org/policy/priorities/2012-medicare-trends/>; Morales, S., Bennett, R., and S. Sanders, "Medicare Trends and Recommendations: An Analysis of 2013 Call Data from the Medicare Rights Center's National Helpline," Medicare Rights Center (March 2015), available at: <https://www.medicarerights.org/pdf/2013-helpline-trends-report.pdf>; Morales, S., Schwarz, C. and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2014 Call Data from the Medicare Rights Center's National Helpline," Medicare Rights Center (January 2016), available at: <https://www.medicarerights.org/pdf/2014-helpline-trends-report.pdf>; Morales, S., Riccardi, F., Carter, J., and S. Sanders, "Medicare Trends and Recommendations: An Analysis of 2015 Call Data from the Medicare Rights Center's National Helpline," Medicare Rights Center (March 2017), available at: <https://www.medicarerights.org/pdf/2015-helpline-trends-report.pdf>

Bilirakis and Congresswoman Castor to address penalties for fraud in the Medicare system. Examples of health care fraud include, “billing for services not rendered...making duplicative claims, unbundling packaged services or items, providing excessive or medically unnecessary services, and issuing kickbacks.”²

Medicare fraud is deeply problematic from two key perspectives—both beneficiary and taxpayer. For people with Medicare, fraud and abuse can lead to exploitation in the form of increased costs, including overcharging for services received or even paying for care that was never delivered. Beneficiaries may also be harmed if they receive unnecessary services, like inappropriate screenings, or if needed care is withheld, such as when a provider accepts a financial inducement to limit care.³ Fraud and abuse also lead to increased and inappropriate spending of taxpayer dollars.

Over the last year, 6,000 visitors accessed Medicare Rights’ free educational content, through the online learning tool Medicare Interactive (www.medicareinteractive.org), on the subject of health care fraud.⁴ Further, Medicare Rights regularly fields calls regarding billing inquiries, the 4th most common trend on the helpline in 2015.⁵ Often times, these cases involve situations where a beneficiary cannot afford excessive cost-sharing or where the beneficiary suspects he or she was overcharged for services received.

For example, one caller reached out to Medicare Rights about a charge for an outpatient procedure that she could not afford to pay. After communicating with the beneficiary and health care provider, Medicare Rights determined that the physician charged the beneficiary cost-sharing over and above the Medicare-approved amount. Medicare Rights is not positioned to assess whether such cases involve a simple billing error versus a fraudulent claim. But when such cases arise, we typically refer our clients to the Senior Medicare Patrol (SMP) or the Office of the Inspector General (OIG).

It is critically important that Congress prioritize policies to prevent and deter the many forms of Medicare fraud and abuse. Existing oversight and enforcement initiatives to combat fraud in federal health programs—including investigative task forces, data sharing and analytics, civil monetary penalties and fines, criminal prosecution, and more—have proven successful. Over the last three years, the U.S. Department of Health and Human Services (HHS) OIG and its partners recovered more than \$6.10 for every \$1.00 dedicated to health care fraud

² See Congressional Budget Office (CBO), “How Initiatives to Reduce Fraud in Federal Health Care Programs Affect the Budget,” p 3 (October 2014), available at: <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/49460-ProgramIntegrity.pdf>.

³ See *Ibid.*, pg. 5; K.D., Lind, “Reduce Waste, Fraud, and Abuse in Health Care,” AARP (July 2009), available at: http://www.aarp.org/health/health-care-reform/info-09-2009/fs158_fraud.html.

⁴ See Medicare Interactive, “Medicare Fraud and Abuse,” Medicare Rights Center (2017), available at: <https://www.medicareinteractive.org/get-answers/medicare-fraud-and-abuse>.

⁵ Based on internal analysis of helpline calls; includes almost 1,500 questions.

and abuse investigations.⁶ Importantly, these or any enhanced recovery efforts must be implemented carefully so as not to inadvertently curb beneficiary access to care should health care providers come to fear retribution for minor billing errors or honest mistakes.

A continued and enhanced commitment to fraud prevention and recovery can help ensure that people with Medicare are not over-billed or otherwise harmed and that taxpayer dollars are spent efficiently and responsibly. For these reasons, Medicare Rights supports H.R. 3245. This legislation would increase the amount of civil monetary penalties, criminal fines, and sentences allowable for specific instances of Medicare fraud, such as the submission of false claims, acceptance of financial inducements, and willful violation of the terms of assignment, among others.

These administrative sanctions were established in 1981 and last revised in 1996, leading us to believe that these penalties are due for an update. Adding further support for this, in 2011, the OIG testified before Congress that:

The perpetrators of these [health care fraud] schemes range from street criminals, who believe it is safer and more profitable to steal from Medicare than to traffic in illegal drugs, to Fortune 500 companies that pay kickbacks to physicians in return for referrals... We are concerned that providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business.⁷

In addition to efforts like those advanced through H.R. 3542, there is a beneficiary-facing component to preventing Medicare fraud and mitigating the harms of abuse. The federally-funded State Health Insurance Assistance Programs (SHIPs) and SMPs work in concert—in every state and U.S. territory—to educate people with Medicare about how to protect themselves from fraud; to help beneficiaries navigate cost-sharing challenges and billing errors; and to assist beneficiaries with reporting suspected fraud and abuse. As we have learned through the Medicare Rights helpline, potential cases of fraud typically present to SHIPs when a beneficiary is unable to pay a bill. The SHIPs then report cases of suspected fraud to Medicare, often working alongside SMP partners.

As the only on-the-ground resource for people with Medicare, the SHIP and SMP network also plays a vital role in identifying trends and common types of potential fraud and abuse. For example, we recently learned from our SMP and SHIP colleagues to be on the lookout for cases involving stolen Medicare numbers used to submit claims for Durable Medicare Equipment (DME). SHIP counselors are coming across cases where beneficiaries

⁶ Office of the Inspector General (OIG), “2016 National Health Care Fraud Takedown” (2017), available at: https://oig.hhs.gov/newsroom/media-materials/2016/2016HealthCareTakedown_FactSheetv2_508.pdf.

⁷ See Congressional Budget Office (CBO), “How Initiatives to Reduce Fraud in Federal Health Care Programs Affect the Budget,” p 14 (October 2014), available at: <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/49460-ProgramIntegrity.pdf>.

are denied DME, because records indicate they obtained that same DME in the past five years. In reality, however, the beneficiaries' Medicare numbers were fraudulently used to bill Medicare for the DME.

Thus, SHIPs and SMPs are vitally important to education and outreach about Medicare fraud and abuse as well as its identification and prevention. And SHIPs fulfill many other essential roles, providing one-on-one, in-depth, and personalized counseling on coverage options, appeal rights, low-income assistance programs, and more.⁸ We urge members of Congress to reject attempts to defund the SHIP program. Further, when SHIPs and SMPs identify fraud, it is legislation like H.R. 3245 that is needed to ensure that those defrauding the program are appropriately penalized.

Other Matters before the Committee Supported by Medicare Rights:

- **Eliminating and replacing the therapy caps:** Medicare Rights strongly supports eliminating the Medicare therapy caps for physical, speech, and outpatient therapies. “These arbitrary caps are aimed at federal cost savings rather than providing clinically appropriate service. Further, these caps disproportionately affect the most vulnerable Medicare beneficiaries who require ongoing therapy services,” says the Leadership Council of Aging Organizations, a national coalition representing the interests of older Americans, of which Medicare Rights is a member.⁹

In the absence of full repeal of the caps, Medicare Rights supports an extension of the existing exceptions process, as reflected in the discussion draft made available for today’s hearing. We urge the Committee to work towards a bipartisan, permanent solution that will allow people with Medicare to reliably access medically-necessary therapy services.

- **Preserving access to speech-generating devices:** Medicare Rights joins over 60 national and state organizations as well as qualified professionals in support of the *Steve Gleason Enduring Voices Act of 2017* (H.R. 2465).¹⁰ This legislation will ensure that Medicare coverage for speech generating devices (SGD) and related accessories will continue beyond the current law’s sunset date of October 1, 2018.

⁸ See National Council on Aging (NCOA), “Funding for Medicare State Health Insurance Assistance Programs” (2016), available at: <https://www.ncoa.org/resources/ship-funding-issue-brief-2016/>

⁹ Leadership Council of Aging Organizations (LCAO), “Medicare Therapy Cap Exceptions Process Should be Made Permanent” (August 2013), available at: <http://www.lcao.org/files/2013/09/FINAL-LCAO-Therapy-Caps-Exceptions-IB.pdf>

¹⁰ Letter to Congressman Kevin Brady and Senator Orrin Hatch in support of the Steve Gleason Enduring Voices Act of 2017 (April 28, 2017), on file with the Medicare Rights Center.

These unique devices are personally tailored and for many individuals they are the only means of communication available to them. The Committee should advance this legislation to secure access to these essential devices, even when a Medicare beneficiary must reside in a nursing home, hospital, or hospice for an extended period of time.

- **Extending the Independence at Home demonstration:** Medicare Rights is a strong believer in the Independence At Home (IAH) demonstration program, and supports legislation (S. 464) to make the program permanent. If not made permanent, we urge the Committee to advance legislation to extend the program, as reflected in the bill included for today's hearing.

The IAH model uses interdisciplinary teams to coordinate all medical and social services in eligible patients' homes, providing high quality clinical care and excellent patient experience while reducing total Medicare costs. Over the last five years, this innovative program has provided home-based primary care services to over 10,000 older adults and people with disabilities living with chronic, complex conditions.

Medicare Rights welcomes the opportunity to review other bipartisan bills under consideration by the Committee at today's hearing. We applaud members of the Committee for identifying bipartisan opportunities to limit Medicare fraud and abuse, preserve access to needed therapies and devices, and continue a promising care model for the most vulnerable people with Medicare. Thank you for the opportunity to testify.

Mr. BURGESS. The chair thanks the gentlelady. The chair notes that a vote has been called on the floor. We are going to hear from Dr. De Jonge, and then we will recess for the final three witnesses and then be back for witness questions.

Dr. De Jonge, you are recognized for 5 minutes, please.

STATEMENT OF DR. K. ERIC DE JONGE

Dr. DE JONGE. Thank you. I am a geriatrician here in D.C., and I have been making house calls for 25 years. My team and I recently had the privileged of making house calls to a 113-year-old woman, who is one of the oldest people in the United States. Home-based primary care, supported by the Independence at Home Medicare program, allowed her to remain at home until the final day of her life.

Thank you, Chairman Burgess, and Ranking Member Green, and the members of the committee for inviting me to talk about the Independence at Home. On behalf of the American Academy of Home Care Medicine, we offer full support for the 2-year extension of the IAH Medicare demo, which otherwise expires on September 30.

Thanks to Representatives Burgess and Dingell, and also Representatives Roskam and Thompson for introducing the bill.

Today, I am going to do three things. I am going to discuss why home-based primary care and the IAH model works, review the IAH demo results, and highlight the value of the 2-year extension.

First, why does the IAH model work? For seriously ill elders and their families, it supports 24/7 mobile, medical, and social services in the home until the last day of life. That allows life with dignity and skilled care in the home throughout the lifespan.

One of my patients is a Mrs. B. She was a 72-year-old woman, who presented for care in 2010 with liver and heart failure. In the last 2 years before that, she had been in the hospital for admissions 10 times. In the next 5 years, she received over 200 medical and social work house calls, hundreds of phone calls to family caregivers, mobile x-rays, IV treatment, medication delivery, blood tests in the home, and a lifesaving procedure for a GI bleed in the ICU at the hospital. In those 5 years, she had a total in 5 years of three admissions to the hospital and spent over 99 percent of her days at home.

Second, it works for providers and health systems. House calls build trust. It leads to more accurate diagnosis and better treatment that the patient and family want, better outcomes for patients and families, which is really satisfying for providers. Health systems get to serve highest cost populations in a preferred and lower cost setting, and they actually get paid for better results.

Our IAH consortium in mid-Atlantic with Penn, Virginia Commonwealth, and MedStar Health have received shared savings payments that have allowed us to grow our programs.

The VA is a national leader in home-based primary care and has also proven the high ratings of patient satisfaction and total cost reduction over 10 percent per year in their 40-year home-based primary care program. Providers in many other states are ready to participate in the IAH model.

Finally, from Medicare, the IAH model has three big results. One, it provides better service to most of the frail and sick elders in our communities and their families. It has a wonderful side effect of substantial total cost savings, because you are caring for people in their home and not calling 911 and ending up in the high-cost setting. And third, practices are held accountable. They have six major quality metrics they have to meet. They have incentives to actually reduce total cost. So you have to create and be innovative and figure out what can I do in the home setting that will be better care but also keep them at home, and then they receive shared savings payments if they are successful.

There is also an accountable self-culling measure, where you remain in the program only if you meet the quality metrics and you produce savings.

Some of the results of IAH over the last 5 years, we have served 11,000 patients and families nationwide so far; we serve patients who have serious chronic illnesses, at least two; they are physically disabled, and they have been in the hospital the past year and have had skilled home health or rehab, so they have high cost there proven.

In year one of the IAH program, 9 of 17 sites exceeded 5 percent in savings and received payments back for an average of \$3,000 per patient per year in savings. And in year two, 7 of 15 sites received that 5 percent savings and received on average of \$1,000 per patient. The total savings for IAH was \$32 million in 2 years, about 50 percent of which was paid to providers to support the programs.

So the American Academy of Home Care Medicine supports the IAH extension for three major reasons: it will support the 15 current sites that can maintain the highest level of care and continue to save Medicare money; it will send a message to patients and providers all around the U.S. that this model is a success and can go to rural, urban, and suburban areas; and it will be a chance to apply lessons learned from the 5 years of the demo in the next 2 years.

So over 100 years ago when my patient was born, house calls were pretty routine. We can go back to that future and help keep Medicare solvent, and H.R. 3263 keeps us on that path. So I thank you for your attention, and I am glad to take questions.

[The prepared statement of Mr. De Jonge follows:]



Independence at Home (IAH): HR 3263

Value of Home-Based Primary Care for Frail Elders and Medicare

Testimony of K. Eric De Jonge, M.D.

President-Elect, American Academy of Home Care Medicine (www.aahcm.org)

Before the House Energy and Commerce Committee, Health Subcommittee

July, 20, 2017

I am Dr. Eric De Jonge, a Geriatrician at MedStar Health in D.C. I have made House Calls for 25 years and serve as President-Elect of the American Academy of Home Care Medicine (AAHCM).

Thank you, Chairman Burgess, Ranking Member Green, and members of the Health subcommittee for inviting me to testify. I am here to give the Academy's full support to H.R. 3263, a 2-year extension of the Independence at Home (IAH) Medicare demonstration. Thank you, Representatives Burgess and Dingell, for introducing this important legislation, along with your colleagues Representatives Roskam and Thompson.

For the last five years, my team and I have participated in the IAH demonstration, which has tested a model of Home-Based Primary care for Medicare patients who have multiple chronic conditions and disability. The IAH model uses interdisciplinary teams of medical and social service professionals to care for patients in their homes, delivering high quality clinical care, excellent patient experience, and significantly lower costs for the Medicare program.

Today, I will...

- Discuss why Home-Based Primary Care and the IAH Model Work
- Review 5 years of IAH Demonstration Results, and
- Highlight the Value of a 2-year IAH Extension

IAH works for patients, caregivers, providers, health systems, and Medicare

For seriously ill elders, providing 24/7 medical and social services at home allows them to live a life with dignity and respect, where they want to be...at home. It brings peace of mind to family caregivers by coordinating all needed health services, prepares patients and families for managing serious illness, and supports them until the last day of life. IAH practices can deliver many services available in an urgent care center or hospital room – portable diagnostic, therapeutic, and monitoring technologies that allow the patient to stay at home, rather than come to the hospital. These services include urgent medical visits, blood tests, X-rays, EKGs, IV medications, oxygen, social work, and caregiver education. In sum, ill elders and families gain access to skilled primary care, maximize their time at home, call 911 less often, and are admitted less often to the hospital.

For providers and health systems, the practice of house calls is an old idea, improved with modern technology. By visiting the home, we build close relationships and trust with patients and families, leading to more accurate diagnosis and more effective treatment. We serve as the “quarterback” of a mobile team, coordinating medical care and social services that are often as important as medical treatment. For health systems, the IAH model offers a way to ensure that high-need and high-cost elders receive care in a more desired and appropriate setting, at a lower cost. This allows health systems to qualify for value-based revenues such as shared savings and prospective payments. IAH practices are measured on cost savings and – of equal importance – on the quality of care we provide. IAH providers only receive a full share of savings if they meet 6 major quality metrics for patient care. For example, at MedStar Health, we serve as part of an IAH consortium with Virginia Commonwealth University and University of Pennsylvania. With the help of shared savings payments, MedStar funded a new House Call team in Baltimore, enabling us to serve more elders and families, and generate more cost savings.

For Medicare, home-based primary care brings multiple rewards— these include enhancing quality of service for our nation’s most ill elders and their families while achieving the important side effect of cost savings for Medicare. With mobile teams of Physicians, Nurse Practitioners or Physician Assistants, and Social Workers, we can address routine and urgent issues and manage nearly all needed care in the home. The IAH payment incentives reduce costs by requiring that program participants produce savings in order to remain in the program. This self-culling feature is an important part of the IAH demonstration that delivers high quality care and costs savings to the system. IAH also encourages innovation in telehealth services. For example, some IAH sites have implemented tele-video after-hours or used specially-trained paramedics to keep patients at home and out of the hospital.

IAH Demonstration Results

The IAH Medicare demonstration has enrolled over 11,000 Medicare patients since 2012 and is due to expire on September 30, 2017, just a few months away. IAH practices serve the 5% of Medicare patients with severe chronic illness and disability who are the most complex and costly patients. The Congressional Budget Office found that these 5% of patients represent nearly HALF of all Medicare costs. Each IAH patient, on average, costs Medicare \$40,000-\$50,000 a year.

Who are the IAH patients? The IAH demonstration strict eligibility criteria require patients have:

- Two or more permanent chronic illnesses;
- A serious disability—patient must need assistance with 2 or more “Activities of Daily Living” such as bathing or dressing; and
- Had a Hospital Admission and Post-Acute Rehabilitation or Skilled Care event in the past year.

In Year ONE of IAH, there were 17 IAH sites and in Year TWO, there were 15 sites (two practices left the demonstration). Providers only received savings if they exceeded 5% in Medicare cost reduction. In Year ONE, 9 of 17 IAH sites demonstrated total Medicare cost savings above the 5% threshold and received shared savings payments. The average savings was \$3,070/ patient year. In Year TWO, 7 of 15 sites showed cost reductions over the 5% threshold and received shared savings payments, with an average savings of \$1,010/ patient year. It is important to note that CMS retains the first 5% of savings and a portion of additional savings after the first 5%. The total Medicare cost savings for Years ONE and TWO of IAH was \$32 million, with half of those savings distributed back to IAH providers for financial support of their practices.

In our Mid-Atlantic IAH Consortium, with our colleagues from VCU and Penn, we met all 6 of 6 major quality metrics and achieved total Medicare costs reductions of 20% in Year 1 and 12% in Year TWO. The range of our savings was \$6,000-\$12,000 per patient-year.

H.R. 3263: Two-Year Extension of IAH Demonstration

H.R. 3263 extends the IAH demonstration for an additional two years and expands the number of beneficiaries from 10,000 to 15,000. For the above reasons and more stated below, we offer our strong support for the legislation.

- H.R. 3263 helps the 15 IAH current sites continue the care they are providing and promotes the use of a value-based, shared savings payment model.
- H.R. 3263 gives IAH practices and all U.S. home based primary care providers the security of knowing this model will continue to be a priority for Congress.
- H.R. 3263 provides an opportunity to apply key lessons learned during the first 5 years of the demonstration, giving us an important chance in the next two years to make common sense adjustments to the model so that it continues to improve over time.

For example, the IAH demonstration could:

- Use more telehealth tools to enhance care and further reduce costs,
- Enhance the timeliness and reliability of payments to support practice sustainability, and
- Optimize the accuracy of the savings methodology.

In time, this IAH extension will provide a national platform and the needed data to expand home-based primary care to elders and providers in ALL states, and generate even greater Medicare cost savings.

Thank You.

Resources and Evidence Base

www.AAHCM.org – The American Academy of Home Care Medicine is a professional organization of over 1200 physicians, nurse practitioners, physician assistants, social workers, and others working in the field of home care medicine. Academy member promotes the Art, Science, and Practice of Home Care Medicine.

IAH Year 1 and 2 Results from CMS: (www.cms.gov)

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-06-18.html>

<https://innovation.cms.gov/Files/x/iah-yroneresults.pdf>

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-08-09.html>

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19.html>

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T Edes et al. Better Access, Quality, and Cost for Clinically Complex Veterans with Home-Based Primary Care. *J Americ Geri Soc.* 62:1954-61. Oct. 2014
<http://onlinelibrary.wiley.com/doi/10.1111/jgs.13030/full>

Recent Media Coverage – Future of Home Care Medicine

http://www.commonwealthfund.org/publications/newsletters/ealerts/2017/jun/home-based-primary-care?view=newsletter_email&email_web=true&omnicid=EALERT1222972&mid=mh@cmwf.org

<http://www.usnews.com/news/articles/2016-08-31/get-set-for-the-modern-house-call>

<http://www.hfma.org/Content.aspx?id=51244>

https://www.brookings.edu/wp-content/uploads/2016/06/Rauch_LateLifeCare.pdf

Mr. BURGESS. The chair thanks the gentleman.

Just prior to recessing, if the gentleman from Oklahoma would be interested in introducing his staffer that he had at the dais with him.

Mr. MULLIN. I have the distinct privilege of having my son, Andrew, who is actually closed out a committee before. Andrew is up here for his birthday. It is his 12th birthday. And I always appreciate the committee for indulging me and allowing me to bring my kids with me.

As lawmakers, we are always away from our families. I have five kids, and the way that the committee supports us with having our kids with us, I really appreciate it. It means the world to all of us that are on the committee.

Thank you, chairman.

Mr. BURGESS. Yes, sir. The Education and Workforce Committee would ensure that he was being paid by child care—

We have votes on the floor. I think it is a series of four or five votes, and I cannot give you the exact timeframe, but the committee is going to stand in recess subject to the call of the chair immediately after the last vote on the floor.

We stand in recess. We will hear from our last three witnesses immediately upon our return.

[Recess until 12:06 p.m.]

Mr. BURGESS. The subcommittee will come back to order. As we recessed for the votes, we were about to take testimony from Mr. Morrison.

Mr. Morrison, you are recognized for 5 minutes for summary of your opening statements, please.

STATEMENT OF ALAN E. MORRISON

Mr. MORRISON. Good afternoon, Chairman Burgess, Ranking Member Green, and members. I am here on behalf of the national association for the support of long-term care, and the association of providers of services to the patients of the post acute care sector, including clinical laboratories serving nursing home and homebound beneficiaries.

The bundled payment proposal in front of this committee would modernize very old and complex payment rules for laboratory services provided to nursing home and homebound beneficiaries. It will combine the three fees now paid, one for laboratory tests, one for the collection of specimens, and one for travel to the patient's location to collect the specimens into a single bundled, per episode payment.

Personally, I have worked in healthcare for over 40 years. We rarely see an initiative that can create program savings, ensure beneficiary access, encourage service to rural beneficiaries, permit provider efficiency gains, as well as address program integrity issue. This proposal does all five of these.

According to an analysis conducted by the Moran Group, it saves approximately \$130 million over 10 years. It ensures beneficiary access during a period of other significant changes and how Medicare pays for laboratory services. It provides an add-on payment to ensure access for rural beneficiaries. It eliminates the ability of unscrupulous providers to overbill the Medicare program for the trav-

el fee, and it allows the specialized providers of these important services to better manage their logistics costs without impacting the quality of care.

We believe the proposed payment model is both good healthcare and good fiscal policy.

Let me explain how these services are provided and why they are so important. A very small segment of laboratory providers serves these frail elderly beneficiaries. These companies provide very basic laboratory studies used by ordering physicians to diagnose and monitor a wide range of conditions such as diabetes, heart disease, pneumonia, influenza, and asthma. They are very low-cost, basic tests with an average Medicare fee under \$30, some as low as \$10. In fact, in 2017, the most frequently ordered test was \$10.66.

It is important for these beneficiaries to have access to these services. It enables them to receive care in the lowest cost setting appropriate for their needs; it avoids the need to transport patients for services and the costs, risks, and inconvenience to such transports, and by having these services available around the clock, we avoid unnecessary ER visits and hospital re-admissions, and the substantial associated costs.

To provide these services, specially trained laboratory staff travel to the patient's bedside to draw blood samples and collect other specimens. They then transport them to the laboratory to process them, and the laboratory reports the results to the patient's physicians, and this entire process typically takes only 3 to 6 hours.

Because these patients often suffer from multiple disease and disorders, there is a very high percentage of critical results. These are immediately reported to the patient's physician so the needed treatment can begin at once.

As I mentioned, this specialized segment of laboratory providers serves these beneficiaries. The national laboratory companies and almost all hospital laboratories re-emphasize serving nursing home and homebound patients several decades ago.

In fact, in 2015, the two largest national laboratory companies provided less than 4 percent of these services to these frail, elderly beneficiaries.

The Medicare payment model for these services has been unchanged for over 30 years. In fact, we think it is the oldest surviving Medicare payment methodology. It is very complex, which is three separate payment components, one of which requires costly manual recordkeeping to log odometer mileage for each trip to each patient's location in order to ensure accurate and compliant billing.

This current payment model is also prone to program integrity abuses by unscrupulous providers who gain the billing for the travel allowance payment component.

We believe that the proposal in front of the committee is simply a better way to do this. It would bundle the three payment components into a single, per episode payment covering all included tests provided on a single calendar day to these beneficiaries regardless of the number of tests or number of trips.

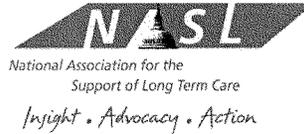
The bundled payment would apply to the 100 highest volume tests, which represent 98 percent of the tests ordered and which have remained virtually unchanged over the past 6 years. Payment would be limited to one episode per calendar day.

Further, the proposed payment model includes a rural add-on to ensure access by rural beneficiaries. The budget savings would come from the Secretary setting payment amounts, such as the total payments on this bundled payment model. In 2017, equal 97.5 percent of the amount that would have been otherwise payable for the same top 100 tests, the specimen collection fee, and the travel allowance under current law.

We believe that with this proposal, we can get budget savings as well as good health policy and ensure beneficiary access to this population.

We hope that you share our enthusiasm of this initiative and the benefits it can bring to the program and its beneficiaries, and we thank you for your time and support.

[The prepared statement of Mr. Morrison follows:]



**STATEMENT TO
THE HOUSE ENERGY & COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH**

ALAN E. MORRISON

**Vice President and Diagnostic Testing Committee Chair
National Association for the Support of Long Term Care**

July 20, 2017

My name is Alan E. Morrison. I serve as Senior Vice President for Strategy, Business Development and Government Relations at TridentUSA Health Services. I am here today on behalf of the National Association for the Support of Long Term Care (NASL) where I serve as a member of the Board of Directors, as well as a Vice President and the Chair of its Diagnostic Testing Committee.

NASL is a trade association representing providers of services to the patients of the long-term and post-acute care sector including providers of rehabilitation therapy, clinical laboratory services, and portable x-ray services along with health information technology developers and vendors that serve skilled nursing and assisted living providers.

This bundled payment proposal would modernize the very old and complex Medicare payment rules for clinical laboratory services provided to nursing home and other homebound beneficiaries. It would combine the three fees now paid – one for the laboratory tests performed, a second for the collection of specimens, and a third for the travel to the patient's location to collect the specimens – into a single per episode payment.

I have been involved with many segments of the health care industry for over 40 years. Rarely do you see an initiative that can create Medicare program savings, ensure beneficiary access, encourage services to rural beneficiaries, permit provider efficiency gains, and address program integrity issues. This bundled payment proposal does all of these:

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- According to an analysis conducted by The Moran Group, it saves the Medicare program approximately \$130 million over 10 years;
- It ensures beneficiary access during a period of other significant changes in how providers of clinical laboratory services are paid by the Medicare program;
- It provides a rural add-on payment to ensure access for rural beneficiaries;
- It eliminates the ability of unscrupulous providers to overbill the Medicare program for inappropriate travel allowance amounts; and,
- It allows these specialized providers to better manage their logistics costs without impacting the quality of services provided to beneficiaries.

This proposed payment model is both good health policy and good fiscal policy.

Before elaborating on the proposed payment model, I'd like to briefly take a minute to explain the current situation – how these services are provided and the very complex and antiquated way Medicare currently pays for these services.

Clinical Laboratory Services Provided to Medicare Beneficiaries in Nursing Homes and Homebound Settings

A small, but specialized segment of clinical laboratory providers serve nursing home and other homebound beneficiaries.¹ These companies provide very basic laboratory studies used to diagnose and monitor a wide range of conditions for nursing home and homebound Medicare beneficiaries such as diabetes, cancer, heart disease, pneumonia, urinary tract infections, influenza and flu-like diseases, asthma, COPD, and arthritis. These are low cost tests – with an average Medicare fee of less than \$30 and with some as low as under \$10. In fact, the 2017 Medicare fee for the most frequently performed test, a complete blood count, is \$10.66.

It is important for these beneficiaries to have access to these services whether they are in a nursing home or at home because:

- It enables these beneficiaries to receive their care in the lowest cost setting appropriate for their needs;
- It avoids the need to transport patients for services – whether to a hospital or another location – and the attendant costs, patient risks and patient and family inconvenience of such transports; and

¹ Kandiilow Gass, Amy M., Pope, Gregory C., Kautter, John, Healy, Deborah. (2012). The National Market for Medicare Clinical Laboratory Testing: Implications for Payment Reform. *Medicare & Medicaid Research Review* (Vol. 2 (2), pp. E16- E18). Retrieved from <http://dx.doi.org/10.5600/mmrr.002.02.a04>

- By having these services available to nursing home residents 24 hours a day, 365 days a year, clinical laboratory samples can be obtained and results reported to patients' physicians and nursing homes on a "stat" basis (when a patient's physical or mental condition requires immediate diagnosis), thus avoiding unnecessary emergency room visits and hospital readmissions and the substantial associated costs.

A patient's physician, or in many situations, nurse practitioner, order these very basic laboratory studies for several reasons, including to diagnose a disease, to monitor a patient's chronic condition, or to determine the effectiveness of their current medications. In order to provide these services, specially trained staff travel to patients' bedsides several days each week (usually in the very early morning or late evening hours), draw blood samples and collect other specimens, and then transport these specimens to the laboratory, which processes them and reports the results to the patient's physician and the facility. Results are typically reported by early afternoon in order to enable the patient's physician to make any needed changes to the patients' medications, to initiate treatment or to modify therapy. Because these patients typically suffer from multiple diseases and aging-related disorders, there is a high percentage of critical results – which are immediately reported to the patient's physician and nursing home – allowing needed treatment to begin at once.

As previously noted, a specialized segment of clinical laboratory providers serves these beneficiaries. Of note, the national clinical laboratory companies and almost all hospital laboratories de-emphasized serving nursing home and homebound patients many years ago (in fact in 2015, the two largest national laboratory companies provided less than 4% of these services).

The Current Payment Model for These Services is Outdated, Overly Complex, and Prone to Program Integrity Problems

The Medicare payment model for clinical laboratory services provided to nursing home and homebound patients is out of date as it has been essentially unchanged for over 30 years. It is very complex involving multiple payment components, one of which requires significant manual record keeping, which carries a significant administrative burden. Under current law, there are three payment components:

- The Medicare fee for the actual laboratory tests performed (the same fee is paid to all clinical laboratory providers);
- A separate fee for specimen collection; and

- A separate travel allowance (per mile or flat fee for under ten miles of travel) consisting of the IRS business mileage reimbursement rate (reflecting providers' fuel and vehicle expenses) plus a labor portion (covering providers' staff salaries and benefit costs).

The current payment model is prone to program integrity abuse by unscrupulous providers who "game" the billing for the travel allowance payment component. There are also significant administrative inefficiencies for the providers of these specialized services as a high level of compliance with Medicare law, regulations and manuals requires providers' specialized staff to log the mileage for each trip to a patient location which is then manually transcribed by billing staff to ensure accurate and compliant billing.

We believe that there is a better way to do this.

A Bundled Payment Model Can Create Savings, Address Program Integrity Concerns and Permit Efficiency Gains

The proposed new payment model would bundle the current three payment components into a single per episode payment covering all included tests provided on a single calendar day to a nursing home or homebound beneficiary. The proposed bundled payment would apply to the 100 highest volume tests, which represent 98% of tests ordered and which have remained virtually unchanged over the past six years. The proposed single bundled payment would include:

- Payment to perform the individual tests, if included in the top 100 list
- All specimen collection fees
- The travel allowance

This per episode bundled payment would be made in lieu of the three separate payments Medicare currently makes under the existing payment model – and would be limited to one episode per calendar day. The proposed new payment model also would include a rural add-on payment based on the beneficiaries' location in order to ensure access to these beneficiaries.

Any clinical laboratory tests outside of the 100 highest volume tests, which represent less than 2% of tests ordered, would be paid the Medicare fee for performing the test. There would be no additional payment for travel or specimen collection.

The budget savings would come from the Secretary setting payment amounts in a manner such that the total volume of payments under the bundled payment model in 2017 equals 97.5% of the amount that would be otherwise payable for the same top one hundred tests, the specimen collection fee, and the travel allowance in 2017 under current law. We recognize that budget

savings sometimes can drive bad policy. With this bundled payment proposal, we can get budget savings as well as good policy and beneficiary access.

Summary

We believe that the proposed new bundled payment model for clinical laboratory tests provided to nursing home and homebound beneficiaries is an improved way to pay for the important clinical laboratory services for Medicare beneficiaries who reside in a nursing facility or who are homebound. The proposed payment model would:

- Create \$130 million in projected budget savings over ten years;²
- Ensure continued beneficiary access to these services;
- Provide an incentive to serve rural beneficiaries;
- Address program integrity concerns; and
- Permit providers to better manage their logistics costs without impacting quality.

The NASL Diagnostic Testing Committee, its member companies that provide these services, and other key stakeholders strongly support the proposed bundled payment model for clinical laboratory services provided to nursing home and homebound patients. We hope you share our enthusiasm for this initiative.

² Based on a private analysis prepared for NASL by The Moran Company.

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

Dr. Kappor, you are recognized for 5 minutes, please, to summarize your opening statement.

STATEMENT OF DEEPAK A. KAPOOR

Dr. KAPOOR. Chairman Burgess and Ranking Member Green, thank you for inviting me to speak in support of H.R. 2557, the Prostate Cancer Misdiagnosis Elimination Act sponsored by Representatives Bucshon and Rush.

My name is Deepak Kappor, and I am a practicing neurologist specializing in the care of neurologic malignancies, including prostate cancer. I am also chairman and chief executive officer of Integrated Medical Professionals, the largest independent neurology group practice in the country, as well as clinical associate professor of urology at the Icahn School of Medicine at Mount Sinai Hospital.

Issues related to prostate cancer are of particular concern to physicians in my group. One out of every 80 men nationwide diagnosed and treated with prostate cancer is managed by one of my doctors. About one in seven men diagnosed with prostate cancer will be diagnosed with prostate cancer during their lifetime. This diagnosis is usually established by a test called needle biopsy of the prostate. We rely on the result of this biopsy to counsel our patients on what treatment options are available to them. The modern promise of precision medicine and targeted therapy requires complete and total diagnostic accuracy in this test. However, despite best laboratory practices, the clinical literature has recently revealed a troubling persistence of prostate biopsy complications, where a relatively high number of specimens have been switched or contaminated with tissue from another patient. These are known collectively as specimen provenance errors.

The reason for these errors is that the workflow for prostate biopsy is extremely complex. The chart before you shows 10 different places within the diagnostic testing cycle where a patient sample can be transposed or contaminated by another patient's tissue. These errors can result in the patient getting the wrong diagnosis and, tragically, inappropriate or unnecessary treatment.

The literature shows these errors are frighteningly common. A 2015 study documented that over 2 1A¹/₂ percent of biopsy patients are subject to specimen complications. Perhaps even more troubling, the study concluded that at least 1.28 percent of patients newly diagnosed with prostate cancer actually did not have cancer at all.

As noted in the recent New York Times article, these medical errors have traumatic consequences on patients. Patients inaccurately told they have prostate cancer are subject to expensive invasive treatments such as surgery and radiation therapy. Patients, on the other hand, who were inaccurately told they do not have cancer, may miss the narrow treatment window, because the cancer is not diagnosed in a timely fashion with potentially fatal consequences.

There is a simple way to eliminate these errors entirely. DNA fingerprinting with a DNA specimen provenance assignment test, which definitively rules out switching contamination errors that

could lead to prostate cancer misdiagnosis. This process involves obtaining a sample of DNA by a simple noninvasive swab of the patient's cheek and comparing that reference test to the DNA found within specimens found to have prostate cancer.

In this fashion, all 10 points of potential errors in the diagnostic testing cycle are completely bypassed, and the provenance of the specimen is 100 percent verified.

To improve diagnostic accuracy and eliminate medical mistakes, our practice changed our treatment protocol to require a DPSA test to diagnose the provenance, which is the abbreviation for the provenance test, for all positive biopsies to ensure the right patient receives the right treatment, or where it is appropriate, does not receive treatment at all.

Importantly, this service is performed by an outside laboratory and not billed by my practice. There is no financial incentive for our physicians to order this test.

Not only does this test improve patient care, but elimination of diagnostic errors would lead to savings to the Medicare program.

According to an April 26 study by Millimen potential savings to the program from eliminating medical errors will be at least \$539 million over 10 years. DPSA testing is widely used today. More than 60,000 prostate cancers per year receive the test and is offered by many labs.

In 2013, Medicare acknowledged that DPSA testing is very useful as a tool for avoiding error and misidentification of a patient with cancer. Despite this acknowledgement, Medicare asserts that it does not have the authority to pay for DPSA testing, because it does not explicitly diagnose or treat disease. This debatable interpretation of the Medicare statute is wasteful of Medicare resources and harmful to patients.

Congress can solve this problem by enacting H.R. 2577, the Prostate Cancer Misdiagnosis Elimination Act, which would require Medicare coverage for DPSA test for positive biopsies. The bill has the full support of the entire prostate cancer provider community, including the American Neurological Association, large urology group practice association, the men's health network, the Prostate Health Education Network, the Vietnam Veterans of America, and ZERO, The End of Prostate Cancer, to name but a few. I urge Congress to seize the opportunity to eliminate thousands of preventable medical errors, improve the healthcare of American men, and reduce the costs of the Medicare program by enacting this bill.

I thank you, again, for your time and attention.

[The prepared statement of Dr. Kapoor follows:]

Testimony of Deepak A Kapoor, MD

Re: H.R. 2557, Prostate Cancer Misdiagnosis Elimination Act of 2017

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Chairman Burgess and Ranking Member Green, thank you for inviting me to testify on the Prostate Cancer Misdiagnosis Elimination Act.

My name is Deepak Kapoor, and I am a practicing urologist specializing in the care of genitourinary malignancies, including prostate cancer. I also am Chairman and CEO of Integrated Medical Professionals (the largest independent urological practice in the country) as well as Clinical Associate Professor of Urology at the Icahn School of Medicine at Mount Sinai Hospital in New York. One out of every 80 men nationwide with prostate cancer are diagnosed and treated by our physicians in my practice.¹

About one man in seven will be diagnosed with prostate cancer during his lifetime. Prostate cancer is usually diagnosed via needle biopsy of the prostate. As physicians who treat cancer, we rely on the results of the biopsy to counsel our patients on what treatment options are available to them – as such, the accuracy of the biopsy is of paramount importance. Recently, the clinical literature has revealed a troubling persistence of specimen complications where a relatively high number of biopsies had been switched or contaminated with tissue from another patient. This can result in invasive and expensive treatment of patients who do not have cancer and no treatment of some who have potentially life-threatening disease.

The promise of precision medicine and targeted therapy requires complete diagnostic accuracy and the elimination of diagnostic errors due to specimen switches and contamination. To improve diagnostic accuracy and eliminate medical mistakes, our practice changed our treatment protocol to require a DNA test for *all* positive biopsies to ensure that the right patient receives the right treatment - or no treatment at all. Importantly, this service is performed by an outside laboratory and not billed by my practice – there is no financial incentive for doctors to order this test.

Despite the best laboratory practices including (1) specimen bar coding, (2) rigorous chain of custody, and (3) detailed specimen handling protocols, recent studies document a persistently high rate of specimen provenance complications among prostate biopsy specimens. Specimen complications occur when a specimen from one patient is transposed with, or contaminated by, that of another patient.

Biopsy workflow is complex. This chart shows ten different places within the diagnostic testing cycle where a patient sample can be transposed with or contaminated by another patient's sample. These errors can result in the wrong patient getting the wrong diagnosis and tragically, the wrong or unnecessary treatment.

¹ American Cancer Society, *Cancer Facts and Figures 2017*. Atlanta: American Cancer Society; 2017.

The literature shows these errors are frighteningly common. A 2015 study documented that over 2.5%² of prostate biopsy patients are subject to specimen complications. Among patients newly diagnosed with prostate cancer, the study concluded that at least 1.28% are actually cancer free.

As noted in a June 26, 2017 New York Times [article](#), these medical errors can have traumatic consequences on patients, with many being told they have prostate cancer when they do not and others inaccurately being told they are cancer free.³ Patients inaccurately told they have prostate cancer are subject to expensive, invasive treatments such as surgery and radiation therapy. Patients inaccurately told they do not have cancer, defer or delay treatment because the cancer is not diagnosed at the earliest opportunity, with potentially fatal consequences.

There is a very simple way to eliminate these errors entirely: DNA fingerprinting with a DNA Specimen Provenance Assignment (DSPA) test, which definitively rules out switching and contamination errors that could otherwise lead to prostate cancer misdiagnosis. This process is as follows:

- A patient's reference DNA profile is established by a pre-biopsy cheek swab
- Biopsy tissue samples are placed in bar-coded specimen containers.
- DNA from the tissue a pathologist reads as malignant is compared to the reference DNA from the cheek swab.
- DSPA concordance ensures assignment of the positive diagnosis to the proper patient

Not only do these tests assuredly improve patient care, but they will certainly lead to savings to Medicare. According to an April 2016 Milliman study,⁴ potential savings to the Medicare program from eliminating these medical errors would be at least \$539 million over the next 10 years from eliminating:

- Unnecessary treatment for the 1.28% of patients newly diagnosed with prostate cancer that do not actually have cancer, and
- Over-treatment of the 0.19% of newly diagnosed patients that are misdirected to active therapy when their low grade cancer should be monitored through active surveillance.

This estimate was based on a rigorous analysis of MedPAR fee-for-service data based on the weighted average cost of treating prostate cancer. It is a conservative

² Wojno, Kirk, et al. "The Clinical and Economic Implications of Specimen Provenance Complications in Diagnostic Prostate Biopsies." *The Journal of Urology*, Vol. 193, Issue 4 (2014): 1170-1177.

³ Kolata, Gina. "The Lab Says It's Cancer. But Sometimes the Lab Is Wrong." *New York Times* June 26, 2017.

⁴ Milliman, Inc. "Prostate Cancer Treatment Utilization and Cost Analysis." April 12, 2016.

estimate because it excludes Part D drugs costs, assumes zero patient volume and price growth, and limits the treatment window to three years, though prostate cancer treatments often result in chronic, lifetime conditions.

DSPA is widely used today: Physicians rely on DSPA to accurately diagnose more than 60,000 prostate cancer patients per year and offered by many labs: Cleveland Clinic, Mayo Clinic, Labcorp, Strand Diagnostics. Yet Medicare asserts it does not have the authority to pay for DSPA testing because it does not explicitly diagnosis or treat disease. This interpretation of the Medicare statute is harmful to patients, wasteful of Medicare resources, and is in direct conflict with Medicare's own acknowledgement that "...DSPA testing is very useful as a tool for avoiding error and misidentification of a patient with cancer..."⁵

Congress can solve this problem by enacting the Prostate Cancer Misdiagnosis Elimination Act, which would require Medicare coverage of the DSPA test for positive biopsies where treatment is recommended by the treating physician. The bill has the full support of the entire prostate cancer patient and provider community, including ZERO – The End of Prostate cancer, American Urological Association, the Men's Health Network, Prostate Health Education Network, the Vietnam Veterans of America, and the Alliance for Aging Research. I urge Congress to seize the opportunity eliminate literally eliminate thousands of preventable medical errors, improve health care and reduce costs by enacting this bill.

⁵ Strand Analytical Labs, Decision of Medicare Appeals Council, M-13-160 at 8 (Feb. 19, 2013). Available at https://www.q2a.com/Portals/0/MAC%20Referrals/PDF%2004012013/1-921456878%20Appeals%20Council%20DNA%20matching_Redacted.pdf

Mr. BURGESS. Thank you, Dr. Kapoor.

Mr. Earle, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF CLETIS EARLE

Mr. EARLE. Thank you, Chairman Burgess, Ranking Member Green, and members of the subcommittee. My name is Cletis Earle, and I am the Chief Information Officer at Kaleida Health and the Chairman-Elect of the College of Healthcare Information Management Executives, or CHIME, Board of Trustees.

It is an honor to be here today and to testify on behalf of CHIME concerning the Meaningful Use Program and to offer our support for H.R. 3120, a bill to reduce the need for Meaningful Use Program hardship exemptions.

In addition to serving as the chair-elect of the CHIME board of trustees, I am the CIO of Kaleida Health. Kaleida Health is the largest healthcare provider and the largest private employer in western New York State with more than 1 million patient visits recorded annually across our hospitals and health systems, 82 clinics and healthcare centers. Kaleida Health's economic impact on western New York exceeds \$2.7 billion annually.

For those of you not familiar, CHIME is an executive organization serving nearly 2,400 chief information officers, or CIOs, and other senior health information technology leaders at hospitals, health systems, and clinics across the Nation.

CHIME members represent some of the earliest and most prolific doctors of electronic health records, or EHRs, and other health IT resources for clinicians and patients.

Since the enactment of the HITECH Act in 2009, which established a Medicare and Medicaid electronic health record incentive program, also known as the Meaningful Use Program, the healthcare industry has made significant shifts in the way technology is used to treat and engage with patients.

Patients and providers have already benefited from the Nation's investments into EHRs in ways that would not have been possible without the investment made through the HITECH act.

As an example, in another health system where I previously served as CIO, we were able to track hospital re-admissions that were related to asthma and correlate asthma-related hospital re-admissions to specific neighborhoods and specific properties. With that data, we worked with local officials to coordinate discussions with landlords to improve the conditions of specific properties within those neighborhoods.

These kinds of population health activities would not have been possible if we did not have EHRs and access to data digitally.

Now, more than 8 years after passage of HITECH, we have the chance to make policy decisions apart from arbitrary deadlines and measures of EHR incentive program. The Meaningful Use Program has been plagued by the check the box, one-size-fits-all approach, that as one of my CIO colleagues put it last week, put a Ferrari in every driveway but expect us to drive on dirt roads.

The EHR mandate for use of Meaningful Use programs has made a great deal of functionality and promise and could have been even greater resourced in patient care; however, as we strive to meet

CMS program deadlines, we aren't able to pursue workflow enhancements with our EHRs or other health IT tools that would actually improve outcomes.

Moreover, our EHR vendors are so focused on meeting this specification and certifications that they don't have the bandwidth to work with us on functionalities that our clinicians actually request.

Another colleague CIO in a rural area explained that to get ready for stage three, which is slated to be in 2018, they have to re-evaluate the use of a successful postoperative telehealth program as there aren't enough resources to service both programs.

The Meaningful Use program was a resounding success in terms of adoption as EHRs use a nearly ubiquitous approach across hospitals and provider offices; however, we are all familiar with the discontent these systems have caused providers. The measure and objectives have not reflected improved outcomes for patients' and clinicians' needs. As many as 256,000 Medicare physicians in 1 year have been subject to financial penalties for the failed attempts at meaningful use requirements while as many as 30,000 others have had to apply for hardship exemptions.

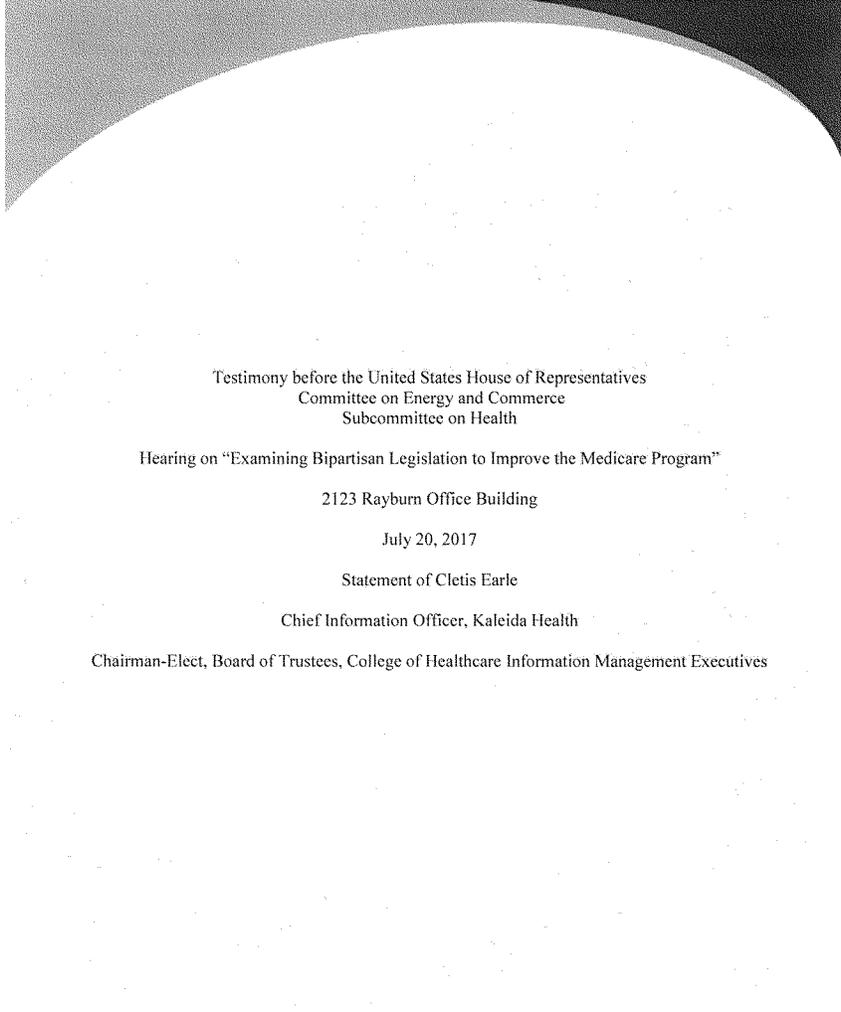
Unable to participate in a program, we have an opportunity to do better and pursue common sense policies, including H.R. 3120, which will infuse necessary flexibility to make Meaningful Use programs meaningful again.

As hospitals and providers continue to struggle to meet timelines and requirements of Meaningful Use program, there will become an increased reliance on hardship exemptions. We commend our approach taken in H.R. 3120, rather than propose the elimination of Meaningful Use programs or insist the requirements remain stagnant in perpetuity, it leaves it to the discretion of the Secretary to modify the requirements over time as deemed necessary in conjunction with the industry.

Meeting thousands of pages of requirements places unreasonable demands on limited resources and finances. The ability to shift away from continual turn would be a welcome development for provider community to bring much needed stability.

There is no question the committee's interest in the topic is timely, and efforts to usher in an era of digital care is a must. On behalf of CHIME and my colleagues and the healthcare CIOs, I sincerely thank the committee for allowing me to speak on the opportunities to improve Meaningful Use program and reiterate our support for H.R. 3120. I look forward to answering your questions.

[The prepared statement of Mr. Earle follows:]



Testimony before the United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on "Examining Bipartisan Legislation to Improve the Medicare Program"

2123 Rayburn Office Building

July 20, 2017

Statement of Cletis Earle

Chief Information Officer, Kaleida Health

Chairman-Elect, Board of Trustees, College of Healthcare Information Management Executives

Thank you, Chairman Burgess, Ranking Member Green and members of the subcommittee. It is an honor to be here today to testify on behalf of the College of Healthcare Information Management Executives, or CHIME, concerning the Meaningful Use Program and to offer our support for H.R. 3120, a bill to reduce the volume of future electronic health record-related significant hardship requests.

CHIME is an executive organization serving nearly 2,400 Chief Information Officers (CIOs) and other senior health information technology leaders at hospitals, health systems and clinics across the nation. CHIME members are responsible for the selection and implementation of the clinical and business technology systems that are facilitating healthcare transformation.

In addition to serving as chairman-elect of the CHIME board of trustees, I am the Chief Information Officer of Kaleida Health. Kaleida Health is the largest health care provider and largest private employer (10,000 employees) in Western New York State. More than one million patient visits are recorded annually at the Buffalo General Medical Center, DeGraff Memorial Hospital, Gates Vascular Institute, Millard Fillmore Suburban Hospital, Women & Children's Hospital of Buffalo, plus the health system's 82 clinics and health care centers.

Kaleida Health operates HighPointe on Michigan and the DeGraff Memorial Hospital skilled nursing facility, plus the nation's oldest – and original - Visiting Nursing Association. Kaleida Health also operates a major laboratory division and two surgery centers. The organization is also affiliated with Great Lakes Health, the entity integrating Kaleida Health, Erie County Medical Center (ECMC) Corporation and the University at Buffalo. Kaleida Health's economic impact on Western New York exceeds \$2.7 billion annually.

CHIME members represent some of the earliest and most prolific adopters of electronic health records (EHRs) and other health IT resources for clinicians and patients. Since enactment of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), which established the Medicare and Medicaid Electronic Health Record Incentive Programs also known as the Meaningful Use program, the healthcare industry has made a significant shift in the way technology is used to treat and engage with patients. The prolific adoption of EHRs and other health IT resources by clinicians and patients has and will continue to pay dividends in the nation's efforts to improve patient outcomes and reduce costs. We also believe that providers' use of these systems will continue to evolve as technology matures and as providers become more skilled with its use.

Patients and providers have already benefited from the nation's investment into EHRs, as organizations have begun to leverage the data collected in the EHRs to conduct activities to improve population health. This would not have been possible without the investments made through the HITECH Act funds. As an example, in another health system where I previously served as a CIO, we were able to track hospital readmissions that were related to asthma and correlate asthma-related hospital readmissions to specific neighborhoods and specific properties. With that data, we worked with local officials to coordinate discussions with landlords to improve conditions of specific properties within those neighborhoods. These kinds of population health activities would not be possible if we did not have EHRs and access to data digitally.

We have just begun to see the potential of EHRs and other digital health tools to transform care delivery. Given the rapid acceleration of the program since inception, we have not had the necessary time to optimize and realize anywhere near the full potential of these tools. We have not been able to focus on enhancing workflows or usability, or explore additional functionalities beyond what is required for the Meaningful Use program. Healthcare delivery has undoubtedly improved with the introduction of health IT tools, but it is far from ideal.

As we stand now, more than eight years after passage of HITECH, there exists an opportunity to make policy decisions apart from the arbitrary deadlines and measures of the EHR Incentive Program. We are at an inflection point where our gains can be used to pivot towards the long-term goal of building and supporting a national digital health ecosystem that is interoperable and which best supports patient outcomes.

Meaningful Use in Numbers

As of May 2017, of the 637,700¹ eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) were actively registered in the Medicare and Medicaid EHR Incentive Programs, more than 525,700² healthcare providers had received payment for participating in the Meaningful Use program. More than \$24.6 billion³ in Medicare EHR Incentive Program payments have been made between May 2011 and May 2017. In addition, more than \$11.9 billion⁴ in Medicaid EHR Incentive Program payments have been made between January 2011 (when the first set of states launched their programs) and May 2017.

Understandably, the requirements providers are held to should also evolve; however, they must do so in a manner that leaves adequate time for providers to absorb the pace of change and facilitates better patient care. According to the Centers for Medicare & Medicaid Services (CMS), an estimated 256,000⁵ or 43 percent of Medicare providers, were subject to negative payment adjustments under the Meaningful Use program in the 2015, while 56,000 hardship exemptions were granted for Medicare physicians. In 2016, 209,000⁶ Medicare physicians received a payment adjustment with 31,580 hardship exemptions granted. In 2017, 171,000⁷ physicians received a payment adjustment.

In 2015, about 200 hospitals out of the 4,444 hospitals that attested to the Meaningful Use program were subject to a negative market basket adjustment for failing to meet Meaningful Use requirements and hardship exemption data was not publicly released. In 2016, 206 hospitals were subject to a payment adjustment and 62 hospitals were granted a hardship exemption. In 2017,

¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>

² <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>

³ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>

⁴ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>

⁵ https://www.healthit.gov/facets/sites/faca/files/Joint_EHR_Incentive_Program_FINAL_2015-02-10_0.pdf

⁶ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016EP_PaymentAdjustmentFactSheet.pdf

⁷ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/PaymentAdj_EPTipsheet.pdf

CMS stated that about two percent⁸ of hospitals received a payment adjustment in 2017 and hardship exemption data has yet to be released for 2017.

Thus, while EHR adoption has surpassed expectations and the vast majority of providers leverage a certified EHR to deliver care, many providers are still unable to comply with the requirements set forth by CMS in the Meaningful Use program and have either been subject to financial penalties or have needed hardship exemptions.

The Escalated, Staged Approach to Meaningful Use

The escalated, staged approach adopted by CMS since the program's inception has failed to acknowledge the timelines necessary to execute the requirements they adopt through rulemaking, which go far beyond what was included in the HITECH statute. CHIME has repeatedly urged CMS to recognize the time needed for development by the EHR vendors, deployment to all eligible EPs and EOs and actual implementation by providers and health systems.

We continue to impart the importance of allowing both vendors and providers adequate time to both develop and deploy solutions. We reiterate our suggested timelines as affording adequate time to develop and test for a major upgrade, which could take months if not more than a year for an update as significant as a new edition of certified technology. This does not include the time it takes for a provider to deploy the solution. Providers, depending on their size, need anywhere from 8-18 months to install software prior to the start of a reporting period to make the necessary workflow and training changes and to do so in a manner that best supports patient safety.

This is especially timely as we approach 2018, which marks the first year that hospitals are expected to comply with the Stage 3 measures and objectives; it is an option for physicians in the Quality Payment Program (QPP). To comply with Stage 3, hospitals will need 2015 Certified Electronic Health Record Technology (CEHRT.) Unfortunately, 2015 CEHRT is not widely available to our members today. According to a small survey we conducted in April 2017, 81 percent of members surveyed have not yet received their 2015 CEHRT. More than 70 percent say they do expect to receive their updated software by July 1, 2017. Further, more than 70 percent say they will not be ready for the January 1, 2018 compliance date. CHIME members are very apprehensive about the looming requirement that mandates use of 2015 Edition CEHRT starting January 1, 2018. This issue, combined with the requirement that providers begin meeting Meaningful Use Stage 3, places many hospitals at significant risk of a penalty.

Finally, the current cadence of change is adding to development and deployment times, as well as the total operational costs of every healthcare organization. The program has been plagued by timeline changes, clarifications or amendments to measure specifications and threshold adjustments. Although the provider and vendor communities often welcome these decisions, they typically occur at the very last minute. For example, in 2015 CMS changed the reporting period for Meaningful Use program participants to 90 days on October 6, 2015, three days after the start of the final 90-day reporting period possible during that performance year.

⁸ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/PaymentAdj_HospitalsTipsheet.pdf

Reducing Reliance on Hardship Exemptions

To fully harness the power of health IT across the continuum, additional flexibility must be woven into both the construct and administration of the Meaningful Use program. Without key refinements to the program, efforts to improve nationwide interoperability and information exchange will not progress as quickly as patients deserve. Thus, we offer our enthusiastic support for H.R. 3120. We share concerns about the trajectory of the program and appreciate your efforts to provide greater stability for our members as they navigate transitions to new payment models and the drive toward high-value care.

As hospitals and providers continue to struggle with the meeting the timelines and requirements of the Meaningful Use program, there will become an increased reliance on hardship exemptions. For the 2017 program year, EPs transitioning to Advancing Care Information (ACI) performance category under the Merit-based Incentive Payment System (MIPS) in the Medicare Access and CHIP Reauthorization Act (MACRA) programs who have never participated in the Meaningful Use program can file for a hardship exemption. In 2015, CMS clarified that hospitals or physicians that are transitioning to different EHR platforms may file for a hardship exemption under the “Extreme and/or Uncontrollable Circumstances.” This clarification acknowledges that the process of “switching vendors” is immensely costly and may take years. While hardship exemptions are welcome to avoid payment adjustments, they also mean participants were not able to participate successfully in the program.

However, our members would prefer to participate in the program, whether that be through more reasonable reporting requirements or timelines, rather than file for a hardship exemption. Maintaining momentum toward a digital transformation is vital. CIOs will do anything possible to see that their institutions continue to embrace technology and embody the goals of the HITECH Act.

The Future of Meaningful Use

We commend the approach taken in H.R. 3120. Rather than propose the elimination of the Meaningful Use program or insist that requirements remain stagnant in perpetuity, it leaves it to the discretion of the Secretary to modify the requirements over time as deemed necessary in conjunction with the industry. Meeting the requirements established in regulations that often consist of 1,000 or more pages places unreasonable demands on limited resources and finances. The ability to shift away from that continual churn would be a welcome development for the provider community.

The healthcare landscape has changed dramatically since the passage of HITECH, as have CIO priorities. The 21st Century Cures Act placed a necessary spotlight on the need for nationwide interoperability, for improvements to the cybersecurity of EHRs and the importance of improving the usability, for patients and clinicians alike, of EHRs. The Meaningful Use program and the nation’s patients should benefit from the policies enacted in 21st Century Cures Act and not be forced to comply with arbitrary deadlines to advance in the program, especially as the industry evolves and matures.

The HITECH Act facilitated near ubiquitous adoption of EHRs among clinicians and hospitals. More time at the current stage will not stymie the progress that has been made to date. In fact, providers are eager to optimize the use of this valuable technology to best meet their needs and the needs of their patients. At Kaleida, we are in a Comprehensive Primary Care Plus (CPC+) region, in addition to participating in accountable care organizations (ACOs) and other clinically integrated networks. As we strive to both enhance care coordination and increase system efficiencies, health information technology, led by the EHR, will be critical. Thus, the Meaningful Use program is not the sole driver of health IT adoption and use.

Further, health system resources are needed to meet the evolving information technology needs of their clinicians and patients. For example, one of the unintended consequences of digitizing the nation's healthcare delivery system has been the explosion of cybersecurity threats.

CHIME's CIO members now identify cybersecurity as their top priority, replacing Meaningful Use and accurate patient identification. CIOs and their provider colleagues are balancing the complex Meaningful Use requirements, including the forthcoming mandate to implement Application Programming Interfaces (APIs), that are neither standardized or secure⁹. The recent Health Care Industry Cybersecurity Task Force report published by the U.S. Department of Health & Human Services (HHS) and submitted to Congress concludes, "Regulatory mandates that will force all EHR vendors to have a shared, publicly-available application interface could expose EHRs to additional attack vectors." Some of our members are also concerned that immature APIs could create new risks for the theft of patient medical records and other protected data. Yet providers are expediting adoption of APIs, not because they have been widely tested and utilized within the industry, but because they are mandated under both Meaningful Use and the Advancing Care Information performance category under MIPS. However, if the Meaningful Use program did not escalate as it does today, there may be time to test on a small scale the use of APIs, which could offer some valuable lessons learned prior to immediately moving forward with a full-scale national deployment. Providers are eager to deploy solutions that will allow for active engagement with patients and caregivers. However, they want to make sure this is done in a manner that will not jeopardize patient data and leave their networks vulnerable to external threats.

The Path Ahead

As the nation shifts away from fee-for-service care delivery and increased focus on outcomes, it will be imperative that the Meaningful Use program match the industry's trajectory and goals. Moving away from the "check-the-box" and "one-size-fits-all" approach will be imperative to ensure that providers and health systems are best able to meet the needs of their local communities, to focus on the conditions and unique needs of their patients, rather than measures that have been dictated by the federal government.

Health information exchange is in its infancy, and interoperability has not and will not be a direct result of the Meaningful Use program. It is imperative that the federal government, along with

⁹ <https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf>

the private sector, as directed in the 21st Century Cures Act, prioritize policies like the adoption of robust healthcare data standards and the ability to link patients to their records across all care settings. There is no question that the federal government must have a role in facilitating interoperability, but, it should not be implied, nor assumed, that it is going to occur with the measures proposed for the Meaningful Use program.

The Meaningful Use program expedited the digital transformation in healthcare, but we have a long journey ahead. Ensuring that policies, including what is proposed by H.R. 3120, are able to deliver commonsense flexibilities to the nation's healthcare systems and providers will be invaluable in once again making the Meaningful Use program "meaningful."

The Committee's interest in this topic is timely, and efforts to usher in an era of digital care are a must. On behalf of CHIME and my colleague healthcare CIOs, I sincerely thank the Committee for allowing me to speak on opportunities to improve the Meaningful Use program and to reiterate our support for H.R. 3120. I look forward to answering your questions.

Mr. BURGESS. And the chair thanks the gentleman.

Thank you to all of our witnesses for providing the information this morning. We are now going to move into the question-and-answer portion of the hearing.

And I am going to yield my time to Mr. Griffith of Virginia to begin the questioning, 5 minutes.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. I do appreciate that.

Dr. Kissela, you mentioned that estimates suggest approximately 522,000 Medicare beneficiaries would be eligible for a telestroke consultation, including those in rural areas who currently do not meet the definition of rural for Medicare payment of telestroke services.

Can you elaborate on how patients in many rural communities are still facing a barrier to consultation and treatment despite the current law?

Dr. KISSELA. Sure. So the definition of rural under Medicare is very arbitrary, and there certainly, in our region, for example, in our 27 hospitals, we have outlying hospitals that really have no access to stroke neurology expertise on a moment's notice for an acute stroke emergent situation and would not meet the definition.

And so being able to apply this equally will solve that problem for our outlying hospitals as well as helping the speed of treatment at our urban and suburban areas where we really need to move fast as well where most of the strokes are.

Mr. GRIFFITH. I believe I saw that the target times to try to get the treatment within 60 minutes. Is that correct?

Dr. KISSELA. That is correct. From the minute they reach medical attention, the door to needle, as we say, to the first time when the drug, TPA, is given, the national goal is 60 minutes.

Mr. GRIFFITH. Now, I think we all know the long-term consequences for patients who don't properly receive an evaluation and treatment for stroke, it can be devastating to the quality of life, if not fatal.

That being said, one of the fights we often have up here is about money, and this bill will probably score in the way CBO does things is costing money. But my gut is that these patients will receive so many services that are going to be covered by Medicare if they don't get TPA in a timely fashion that it is going to cost us a lot more.

So could you just confirm that feeling and tell me what services the patients often have to seek if they suffer from an ischemic stroke and do not receive the TPA within the window?

Dr. KISSELA. Absolutely. So to your point about quality of life. It is a devastating disease. People have rated the living with stroke to some often worse than death, although it is a fatal disease as well. So it is a terrible burden on families as well. Families, of course, have to take time to care for people who are disabled by stroke.

But the services specifically that a stroke survivor will need would include all forms of therapy services to work on trying to recover their deficit. The way to bring recovery after a stroke is for the good brain to try to take over the function that was lost, but

that is a very difficult process. It is often unsuccessful. And for the largest of strokes, institutional care is necessary.

So they may live for years in a skilled nursing facility, there racks up a tremendous expense. And so even if the estimate from the American Heart and Stroke Association that I mentioned is too high, I am completely convinced that the ability to give TPA and a lifesaving stroke therapies to other patients, more patients, in a timely fashion will no question save money for the healthcare system at large.

Mr. GRIFFITH. Well, I am not a medical person. I am a country lawyer, but I had a case one time where I had to go to an institution where a relatively young man had had a significant stroke, and we had to prepare documents for him with him blinking. His ability to reason was fine, but he couldn't move, and he couldn't talk. And so he just laid there and watched. It was heartbreaking for the family, but I prepared the legal documents and made sure that they had access to everything they needed to have access to legally to take care of him.

But there is a case where I don't know how many—probably millions of dollars, because there was absolutely nothing else physically wrong with him, but he was expected to live for quite some time.

And while it may not be commonplace, it is not rare. Would you agree with that assessment?

Dr. KISSELA. I absolutely agree. It is heartbreaking every day when we have opportunities to treat patients effectively, and we are not capturing that opportunity.

Mr. GRIFFITH. And this is not something that is new off the shelf. This TPA has been around for how long? 15, 20 years?

Dr. KISSELA. It was approved by the FDA in 1996.

Mr. GRIFFITH. 1997, so 20 years. It is high time that we get it to more people quicker. Wouldn't you agree?

Dr. KISSELA. Absolutely. Thank you, sir, for your support.

Mr. GRIFFITH. I appreciate it very much.

Mr. Chairman, I yield back, and I appreciate your patience.

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

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

Ms. ESHOO. Thank you, Mr. Chairman. I appreciate your recognizing me.

And I want to thank all of the witnesses. This is really quite a panel and it spans so many areas of care and improving care in our healthcare system.

I have to leave. I came back because I wanted to thank you, and I just wanted to make a comment about one area, and then I have to leave, because I have got to get my flight to get back to California.

So, again, my thanks for the testimony and to all of the members that have worked together to produce the bills that are being reviewed today.

I want to make some comments on—and I am going to sound look a skunk at the garden party—but I want to make some points about the Independent Payment Advisory Board, the IPAB. I don't

know how many members have read the CRS report on this. The most recent one was in March of this year, March 17th, I believe. If you haven't read it, I would suggest that you do.

I understand the resistance to this. Interest always looks at things and say, you know what, our ox may be gored.

I understand that, and some of the things that were said in opening comments that Congress is the one that should be in charge, I agree with that. But I don't think that we should rush to eliminate this. And let me tell you why.

There isn't anything that is being done about right now. There is cost shifting going on with bills relative to our healthcare system, but there isn't anything to address the costs and how we are going to sustain the costs in the system. For those that say Congress shouldn't give up, let me offer a very good example.

Congress recognized years ago that collectively it didn't have the political will, because it was really tough to do, to close military bases. And the BRAC commission was established. And you know what, I think it worked well.

Now, there are many sensitivities when it comes to the decisions relative to Medicare. I think that there still should be a commission that is put together that advises the Congress. Congress is not going to do this on its own. And just look at all of the interests, the beautiful, important interests, that are represented here today. Each one has a great case. Nobody talked about how we are going to pay for a darn thing. And that is not your responsibility to do, but it is ours.

So I think that there is a case to be made for a mechanism that would really review these things with the kind of representation that is deserved and should be a part of a commission with the seats representing all the various stakeholders, because those voices are really important, but recognizing that the Congress, yes, should be the one that accepts or rejects the advice.

So I am still driving but with an emergency brake on. I think there is a rush to judgment here about the value of having an outside group when the triggers come up that would review all of this and, overall that together, between an advisory commission that would make recommendations to Congress, that we make sure that what we are spending and investing in is actually sustainable. And I don't think that we are taking that into consideration.

Again, all of these healthcare bills that are out there now being debated, the ones that passed, the ones that didn't, the ones that are still in the hopper, there is cost shifting in it, but there is no mechanism in any of them about how we are going to sustain growth and be able to afford the growth that is in the program.

So I am really very hesitant about the bill. I think it needs to be reworked and amended. I may be the only one in the entire committee that views it this way, but there has been, I think, a very good example, BRAC. And BRAC has worked. BRAC has worked. And I am not even suggesting that this be set up like BRAC, but members are making it sound like all hell is going to break loose; the sky's going to cave in, and we just have to blow this thing apart and not have any mechanisms whatsoever.

I think that is a march to folly. We have a responsibility here to not only know what improvements need to be made, by overall

where the costs are going. And we do that because Medicare is invaluable. You can't place a price tag on it. But whatever the price tags are, we are going to have to come up with the money for it.

So thank you, Mr. Chairman, and I am sorry that there aren't more members here to hear what I said, but maybe they wouldn't be agreeing with me anyway, but I stayed to thank the witnesses and to put my statement into the record, because I think it is something that we really need to think through.

Thank you, and I yield back. And have a great weekend, everyone.

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

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions, please.

Mr. GUTHRIE. Thank you very much.

Dr. Kissela, Morgan Griffith asked a lot of what I was going to ask. But I want to ask this. He says he is a country lawyer. I am not a doctor nor a country lawyer, I am just country. But I have a lot of rural areas in my district, and so it is something that is important.

I was actually at a rotary club outside of Lexington, and a person came and presented from the neurology center on strokes, and said, these are the symptoms, get him to the hospital as soon as possible, the stuff they were talking about, and I was thinking how we deal with this with telemedicine.

Because first something, why don't we just give everybody the medicine and then one wouldn't be in an ambulance. And the reason is, they explain this, that two types of strokes—well, there is more. But as a country person would say, one is a blood clot and one is bleeding on the brain. And based on what they said, if you give medicine for a blood clot and there is bleeding on the brain, then you have more damage.

So how do you actually assess somebody via telemedicine? How does that work? We can get that quick diagnosis say, this is what you need to do as opposed to the other?

Dr. KISSELA. Absolutely.

So, first of all, I am just a plumber. So when we log into telemedicine, we are visualizing the patient; we are talking to them, and so that history and physical is an important part of any medical encounter. It is so much better to be able to do that yourself rather than rely on somebody's else account of what happened and to hear about what the exam looked like, I can see it with my eyes.

And we have a very standardized way of evaluating the patient clinically in a very rapid fashion that is helpful. But then all the telemedicine systems, these are why the systems are kind of costly and expensive to implement. They have to be secure. They have to be 100 percent reliable, because this is a life-and-death decision where every second counts.

But it is not just the capability to see the patient but also to see the radiologic film. So we do a head CT scan, and that tells us if there is a bleeding stroke or a not bleeding stroke.

Mr. GUTHRIE. Well, thank you for that.

And, Dr. Kapoor, on the biopsies for prostate, often, in your best estimate, do you think the errors in the needle occur, errors in the needle biopsy occur? How often does that happen?

Dr. KAPOOR. Well, it is important to understand that the error is not precisely the biopsies. It is in the analysis of the biopsy and the diagnostic testing cycle. So the biopsy—

Mr. GUTHRIE. Oh, yes. I said that wrong.

Dr. KAPOOR. But the data shows that it occurs in about 2 1A½ percent of cases overall. And unfortunately, nearly 1.3 percent of the time the patient doesn't have cancer. Importantly, the literature—

Mr. GUTHRIE. This is always false negative or is it a false positive?

Dr. KAPOOR. It could be either way.

Mr. GUTHRIE. Right. So some people don't get the treatment they need?

Dr. KAPOOR. It depends on the type of error. Because sometimes tissue can be contaminated from another patient, other times the tissue can be completely switched so that patient A is being diagnosed, given the diagnosis of patient B and vice versa. So the person that is being read as negative actually has cancer, and there is somebody else that is being read as positive that doesn't.

And this does occur at other malignancies as well. There was a notable case on Long Island where a woman unfortunately had a bilateral mastectomy because of a switching error. It is just because with prostate biopsies, we do 12 to 20 core samples per patient as opposed to one or two that the errors are magnified, because there is just so much more tissue that is being handled in a prostate biopsy.

Mr. GUTHRIE. Thank you very much.

And Dr. Moore, can you detail to the committee why simply extending the processes around the therapy caps for another year or two is not the best practice for beneficiaries, providers, and as matters of Medicare fiscal health?

Mr. MOORE. Yes. Thanks, Congressman. I think the best rationale is it is time to make that permanent change. We have extended this out at a cost. We have extended this out at uncertainty to the field and to the therapy providers, and we now have changes that were made as part of MACRA that the chairman recommended—or talked about in his opening statement to move to targeted medical review. It seems to be working.

And so our analysis shows that as we move toward that change that was made in MACRA, that we are striking that critical balance of ensuring access to care but also maintaining the integrity of the program. And so we think that extending the exception process only delays and costs more over time, and that we have the data and the policy solutions available for a permanent fix at this time.

Mr. GUTHRIE. OK. Thank you.

And, Dr. Richards, I am running out of time. This committee has worked with Senate Finance, and House Ways and Means on a bipartisan basis since the beginning of last year on the issue of home infusion. While not everyone got everything they wanted, do you

believe the policy with further technical changes as reported out of committee last week should advance to the House floor?

Mr. RICHARDS. Thank you for that question. Yes, I do. I think it will give us an opportunity to see this transitional payment plan come through with all support of technical changes.

Mr. GUTHRIE. OK. Thank you. And I will yield back.

Mr. BURGESS. The gentleman yields back.

Mr. GUTHRIE. I have 13 seconds. I have two requests for unanimous consent to enter it into the record.

Mr. BURGESS. Start the clock back.

Mr. GUTHRIE. National Association for Supportive of Long-Term Care, and then American Speech-Language-Hearing Association.

Mr. BURGESS. Without objection, it will be made part of the record.

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

Mr. BURGESS. The chair recognizes the gentleman from Pennsylvania, Mr. Murphy, 5 minutes.

Mr. MURPHY. Thank you, Mr. Chairman. This is fascinating to me. I like to use the analogy that if you buy a car off the lot, maybe about \$25-, \$30,000, if you buy the same car from the parts department, it may be at least \$150,000. That is the difference between fee for service and a disorganized system versus one that is very coordinated.

Along these lines, Dr. Richards, when you write about disease state management of highly complex chronic illnesses, you talk about the care coordination, the drug interaction, monitoring, et cetera, et cetera. I might add to that as well, on the issues of diabetes, which has massive amounts of complications, including behavioral issues, depression, anxiety, panic. And we know that a person with a chronic illness doubles the risk for psychological problems such as depression, and untreated depression doubles the cost, because oftentimes, it means the person is not getting better.

And Dr. De Jonge, you talked about this too in terms of working at home. That is the primary care person looking at everything. And, Ms. Sanders, when it comes to Medicare and looking at patients' rights, people are denying just based upon a number versus what does this patient need to make them better, especially in the communication area, you end up with a lot of complications. A non-communicative person, perhaps because of a stroke, who has all their faculties involved increase these problems.

So I want to know from each of your points of view real quickly, do these bills adequately address, do we need to do more when it comes to care management, disease management, and two, do you think it costs more or less to do that? Let's start with talking about diabetes. Give you about 25 seconds, each of you. Go.

Ms. APRIGLIANO. I think that for anybody who has a chronic disease, the importance is to have a successful management plan and these individualized. So looking at all of the complex issues, it is crucial. When I hear about home-based care, that is an essential way for, especially individuals with complex diseases like diabetes, to have access to multiple ways to treat.

Mr. MURPHY. So does Medicare currently provide a funding mechanism for the medical practice people for other people to co-

ordinate that care or does this happen because people are trying to do themselves? If we need more, let me know.

Ms. APRIGLIANO. So for diabetes, we are self-managed. We spend very little time with medical professionals. Diabetes is 24/7. And so we are responsible for making sure that we stay healthy. And the onus is on us to have the equipment, to have the services so that we can stay healthy to this prevent the constant complications we have.

Mr. MURPHY. Dr. Richards.

I would love to ask this of all of you, but I only have 2 minutes left, so go ahead.

Mr. RICHARDS. Most definitely there is a cost savings. And the fact that if the patients aren't going to be able to do this in the home, and these are long-term threatening illnesses, they have to seek a different site of care, which typically is going to be a higher cost. I mean, that is the bottom line. I mean, home is proven to be cost effective, safe, and it is really where patients want to be.

Mr. MURPHY. Ms. Sanders, does Medicare adequately pay for making sure that these things are coordinated, such as, for example, if a person does need a communication device, do we really pay to make sure that there is mechanisms to determine if that patient needs it, and it is improving or not improving care? Do we have a mechanism now, or do we need to fix that?

Ms. SANDERS. We, Medicare rights center, we certainly know from the direct experience on our help line that people struggle to coordinate and manage their care on their own. Many of our callers are low income. They have multiple chronic conditions, and they need help managing the variety of services, devices, and otherwise, prescription drugs that they need.

So we have been very supportive of value-based payment models and the ways in which Medicare Advantage plans are coordinating care. And I think that Congress should commitment to those efforts in all parts of Medicare.

Mr. MURPHY. Dr. De Jonge, for about 45 seconds. Because you put that measure, quoting about 5 percent of people consume about 50 percent of the costs. Do we do enough to really pay for people to manage those complex cases?

Dr. DE JONGE. Yes. Right now, there is a lot of fragmented billing for these different patients. And if you think about having a team that quarterback the care of that whole patient their whole life until they die and pay them for results and not for each little thing you do to them makes a lot more sense.

And Independence at Home, I mention the VA program have shown that if you have a team that is mobile, that does all the care in the home environment, most of the care in the home environment, you can actually have more satisfied patients and families, and you can reduce Medicare costs substantially if you do coordinate it that way.

Mr. MURPHY. No. I have seen some studies that even say as much as the 40 percent savings on some of these. Because every time someone shows up in an emergency room, that is preventable and preventable hospitalizations, and it goes on and on.

As we look at other areas to reform the health system, I think this is critical if we look at even providing a block grant to a state.

I think that when we talk about such things as high-risk pools—I don't like that term at all. I would much rather say for those who are in the 5 to 10 percent that consume the cost, the overutilizers, we ought to be thinking of a payment system that really pays for coordinated care to help them.

So I appreciate you all highlighting that. I know others had it too. But this is very, very important. Thank you very much, Mr. Chairman.

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

The chair recognizes the gentleman from Florida, 5 minutes for questions, please.

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

And I agree with Mrs. Blackburn. I think she called you all a football team. But, anyway, you all are all stars. There is no question. We have an all-star cast here this afternoon, this morning when we started.

Thank you, Mr. Chairman, for putting it together.

I have a question for Ms. Sanders. I appreciate your testimony this morning and the work you do with the Medicare beneficiaries. Thanks so very much. And I look forward to working with you in the future too on behalf of my constituents.

Medicare fraud is not a victimless crime. You reference in your testimony the impact that the Medicare fraud has on beneficiaries. Could you give us some additional detail or details on that and perhaps a case example. If you could elaborate. I know you addressed it to a certain extent this morning, but you only had the 5 minutes. So if you want to elaborate on that, I would appreciate it.

Ms. SANDERS. Sure. Yes. Thank you for the question.

So many callers to the Medicare center are calling because they either can't afford a bill, or they are concerned that they have been overcharged for some type of service. So at the Medicare aid center, our counselors then do some investigation into what is going on with that case.

And in one example, in speaking with both the beneficiary and the healthcare provider, we saw that the provider had, in fact, charged the beneficiary over the Medicare approved amount, the allowed cost sharing. That is a case where we would refer that beneficiary to the senior Medicare patrol or to the Office of the Inspector General to see if this is a simple billing error, perhaps it was an honest mistake, or it may be a case of fraud.

So, again, typically, these issues come up with respect to billing concerns. Those are the fourth most common call to the Medicare right help line, but it is not immediate to us whether or not there is fraud. We have to investigate that, our partners do.

Mr. BILIRAKIS. I see. Does it make sense to have penalties that have not been updated in over 20 years?

Ms. SANDERS. No, not from our perspective. We think that Congress should certainly update these penalties in order to ensure that we have appropriate prevention and we are deterring fraud.

Mr. BILIRAKIS. Very good.

I appreciate your support for my bill and Representative Castor's bill.

You mentioned in your testimony some findings by the OIG and GAO regarding fraud and how individuals perpetrating fraud view the penalties as a cost of doing business. At the same time, you also mentioned concerns about enforcement actions to put beneficiary access to care at risk by potentially shutting down hospitals or other providers. Are you suggesting that there needs to be a balanced approach in the application of these enhanced penalties?

Ms. SANDERS. Yes, absolutely. I think that balanced approach is very important. We need to have strong penalties to deter and prevent fraud. But I think we have to recognize that the Medicare system is very complex, and there will be incorrect billing, and there will be honest mistakes. So we really need to lean on the Office of the Inspector General and their partners to use their discretion appropriately so that they are, in fact, penalizing true fraud and not those providers who are doing their best but making mistakes along the way.

Mr. BILIRAKIS. And does the panel basically agree with that statement pretty much? Thank you.

Mr. Moore, can you detail the various program integrity measures your coalition has agreed to over the years?

Mr. MOORE. Yes. Over the years, due to the number of times the therapy cap has been addressed, there have been a number of measures that have gone into place to ensure the integrity of the program, and those include the exception process that is—expect to expire, but what has worked really well has been the targeted medical review that was put in at MACRA. It has really allowed the agency to strike that balance to ensure access without applying broad-based utilization controls that might delay or eliminate access. So that has probably been the most successful.

We also are seeing that transition to quality-based programs, whether one of the extensions reporting on functional limits has been added to the benefits to understand what is going on in therapy and then, obviously, participating in the quality programs that have come out of this committee and Congress.

Mr. BILIRAKIS. Very good. I appreciate that.

Very good. I appreciate that.

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

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

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

Mr. CARTER. Thank you, Mr. Chairman.

And thank all of you for being here. All of you represent areas that are extremely important in the healthcare system, and I can't tell you how much I appreciate that.

As a practicing pharmacist for over 30 years, I have interacted with just about every one of you, and I want you to know that it is a team approach. And all of you played an important role in that, so thank you for what you do.

I want to start with you, Ms. Grealey, if I could. As the president of the Healthcare Leadership Council, you have made it clear that you feel like we should be moving more toward a patient-centered Medicare system without the Independent Advisory Payment Board.

I know that IPAB was set up to save money and that the main way that they were going to be doing that was through cutting physicians' fees. What do you think that would have done to Medicare? What do you think that will do to Medicare if we don't pass the legislation doing away with it?

Ms. GREALEY. I think the number one effect will be to reduce access to care for Medicare beneficiaries. There are certain protections in this legislation that say you can't cut the benefit package for Medicare beneficiaries, you can't change their copays and deductibles, you can't change their eligibility.

But what it fails to recognize is cutting payments to providers will limit access to those providers for Medicare beneficiaries. So there is a very direct effect.

Mr. CARTER. Absolutely. Thank you very much for that.

I want to move now to Ms. Aprigliano. Was that pretty good? I hope it was.

Ms. APRIGLIANO. As close as anybody ever gets.

Mr. CARTER. Is that right? Good. Thank you. Thank you.

I will be quite honest with you. I was not prepared to ask you questions when I first came in here, but I was here when you gave your opening remarks, and I found it to be very relevant particularly with community pharmacists, because I know the role that community pharmacists play with consultation for all areas, but particularly for diabetics.

And that is where it is so important. And I was very interested in what you had to say about the required mail order and how that had actually resulted in something that we didn't—that we tried to push onto someone, but what happens is that they end up going back to their community pharmacists. And why is that? Why do you think that is?

Ms. APRIGLIANO. So, while the National Mail-Order Program is fantastic in the sense that for individuals who are homebound or have difficulties getting to their pharmacy or their pharmacy is very far away, this is a great program. However, a lot of patients do need that extra support from a pharmacist. They are part of their healthcare team.

And so the other issue is, is that the majority of individuals, if they are given a meter that is not accurate, they will go to the pharmacist and say, can you tell me why this doesn't seem right, because my blood sugars before were this and now all of a sudden they are this?

So we are finding individuals going back to their pharmacy and talking with their pharmacist, because these meters that we have now shown through the study through the Diabetes Technology Society are not accurate. And so this does impact.

So it is important. National mail order is great for individuals who can use it, but we do need to have the ability to have the meters that are accurate and the ones that they are comfortable working with.

Mr. CARTER. Great. Thank you for that, and I appreciate that.

Mr. De Jonge, I was a consulting pharmacist in long-term care setting for many years. And one of the primary reasons that people were admitted to the nursing homes, if not the primary reason,

was medication administration and having someone who could make sure that those patients were taking their medications.

I just wanted to get your input on how important of a role that is in the home setting.

Dr. DE JONGE. Yes, there is kind of a perfect storm in the really frail elders where they are more vulnerable and they take a lot more medications. So you need constant vigilance and the kind of home-based primary care approach, where you have NPs and docs and nurses, and we have pharmacists actually at our weekly team meetings who are reviewing the med list with us.

So, on a weekly, if not daily, basis, you need to be carefully monitoring the meds, their side effects, and their toxicities, and that prevents ER visits and unnecessary hospitalization.

Mr. CARTER. So, in the end, it saves money?

Dr. DE JONGE. I think the data both—

Mr. CARTER. And keeps them from going into the nursing home many times?

Dr. DE JONGE. Not many people I talk to want to end up in a nursing home.

Mr. CARTER. Sure.

Dr. DE JONGE. So, if they can avoid the trip to the ER and the hospital, that is often the next step to the nursing home. It helps prevent that.

Mr. CARTER. Well, running the risk of being accused of being self-serving, I mention all this because it is important, because it is a team approach. And, certainly, all of you, as I said earlier, play an important role in that. Certainly, pharmacists play an important role in that.

And I want to have a plug-in for my colleague, Representative Guthrie, who has a bill, H.R. 592, for Pharmacy and Medically Underserved Areas Enhancement Act. I hope that we will look at that, Mr. Chairman, because that is a very important bill.

Yes, it will cost some money initially, but right here, you see where it will save us a tremendous amount of money. Not only will it save money, but it will also increase the level of care that patients are getting, and that is the most important thing it does.

And I yield back.

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

The chair recognizes the gentleman from California. Just prior to recognizing the gentleman from California, for those who were concerned that I was ignoring Dr. Ruiz, he is actually not a member of the subcommittee. He is a member of the full committee. He is waived onto the subcommittee. Generally, the persons who waive onto the subcommittee go after all of the committee members have asked their questions. However, the chairman is generously going to allow Dr. Ruiz to go first. And you are recognized for 5 minutes.

Mr. RUIZ. He says that because there are a lot of my friends out here, see.

Thank you, Mr. Chairman, for holding this hearing. H.R. 849, the Protecting Seniors' Access to Medicare Act, which repeals the Independent Payment Advisory Board, or IPAB, is a terrific example of both sides working together to make commonsense changes to help patients and to help seniors.

In this day and age, it is wonderful to see some bipartisan effort to come up with some pragmatic approaches and make some changes that will result in good outcomes.

I appreciate Dr. Roe's leadership on this issue. It has been an honor to work with him on this important legislation, which will help protect seniors' access to Medicare.

And there are basically two main reasons why we must repeal IPAB: First and foremost, cuts to Medicare should not be made by unelected appointees who are not accountable to the American people. Seniors will not have a voice on determining whether they agree with those cuts or don't agree with those cuts, nor should one person in the case, if they don't agree or there is not a board, the Secretary of Health and Human Services, regardless of party, whether they are Democratic or Republican, under the direction of any President, regardless of party, be the sole decision maker on this matter.

That is not how we make decisions in something so important. Because Medicare is just simply too important for our seniors, who already struggle to make ends meet, to be subjected to cuts in this way.

Furthermore, IPAB efforts to lower Medicare costs, although well intended, by cutting Medicare payments is misguided. We need to work on lowering overall costs, like the cost of medicine and the cost of healthcare, in order to strengthen Medicare through cost savings.

The IPAB approach to cut payments may jeopardize seniors' access to care. The American Medical Association shares this concern. In a statement released today they state that, "Arbitrary IPAB physician payment cuts may create Medicare access issues for beneficiaries." Specifically, physician reimbursements under Medicare could become so low that physicians have to stop accepting Medicare patients.

I ask unanimous consent to submit this statement for the record.

Mr. BURGESS. Without objection, so ordered.

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

Mr. RUIZ. We need to rein in our out-of-control healthcare cost, no doubt about it. This is the primary reason why premiums, health insurances are going up. Medicare is having to pay too much, like the cost of medicine, in order to strengthen the solvency of Medicare not make arbitrary cuts that will hurt our seniors. Again, this bill today is a good bipartisan effort to put seniors above partisanship and solutions above ideology.

Ms. GREALEY, as we know, IPAB was not triggered this year. Can you clarify why we can't or why we shouldn't wait and repeal IPAB later?

Ms. GREALEY. Well, Congressman—and, again, thank you so much for cosponsoring H.R. 849, very important legislation—we can't afford to wait. We have an opportunity right now, through the joint resolution that you have sponsored, to go ahead and just get rid of IPAB completely.

We could wait until later in the year and do the repeal bill, but either way, it needs to occur as soon as possible. Because if IPAB does trigger and that whole process goes into effect, there is a very short timeframe. One, the cuts have to be achieved within a 1-year

time period. And the opportunity for Congress to head off those cuts is not much of an opportunity at all.

Mr. RUIZ. So let's talk about that. Let's say they make a decision. Cuts are being made. What are the chances of overriding it? Tell me about that process, and can Congress override recommendations that they don't like or the policies that they don't like?

Ms. GREALEY. If Congress does not like the recommendations made by IPAB, they would then have to propose cuts equal in size to what IPAB was trying to reduce. And they would have a very short time period in which to do that.

Mr. RUIZ. In other words, they are set up to fail that endeavor because it is a short time and—I was going to give a dig at my friend here, their side, but I won't in the sake of bipartisanship. Sometimes it takes a long time to fulfill promises that people make to try to—

Mr. BURGESS. Would the gentleman yield?

Mr. RUIZ. Yes, sir.

Mr. BURGESS. The chair reminds the gentleman that the Independent Payment Advisory Board was not supported by a single Republican in the 109th Congress.

Mr. RUIZ. Oh, that is not the promise I was thinking about, but never mind. We have a good relationship.

Many people think that because no one has been appointed to IPAB that there can be no cuts at all. Is that true?

Ms. GREALEY. Absolutely not true. If there is no member of the board appointed, we don't have a board, that authority, legal requirement then goes to the Secretary of HHS. So, today, that would be Secretary Tom Price. It could also be a Democrat in the future. But, either way, the Secretary of HHS then has that legal responsibility to make those cuts.

Mr. RUIZ. Thank you.

I know Dr. Burgess and I have had multiple conversations about IPAB throughout the years. He is very supportive of this. And I urge the chairman and the Democratic leadership to expedite this process so that we can have a markup hearing as soon as possible. Let's pass some legislation that is a true bipartisan effort that will help seniors throughout the Nation.

Thank you. I yield back my time.

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

I will recognize myself now for questions. And, Ms. Grealey, on the Independent Payment Advisory Board, since Dr. Ruiz brought it up—I didn't bring my copy of the Affordable Care Act; normally I have it with me and I am able to hold it up. I used to have the section on the Independent Payment Advisory Board section memorized because it upset me so much. And when you look at the list of people who are board members on the Independent Payment Advisory Board, it outlines—you have government officials. You have eggheads from think tanks. At the very last, a practitioner of medicine or osteopathy. One. But you must not earn outside income, so that means someone who is not in active practice. You have no practicing physician on the Independent Payment Advisory Board. And, yet, as you point out, Ms. Grealey, it would have an outsized effect on patients and providers.

So, Mr. Morrison, let me just ask you. You spent some time talking about bundle payments. I will admit, not a big fan. But some of the things that you talked about as you went through trying to bring some sense into your world actually did make sense. So how did we end up with something that is as convoluted as what you describe?

Mr. MORRISON. Beats me.

Mr. BURGESS. The chair thanks the gentleman for his honest answer.

Mr. MORRISON. It is about the most convoluted payment system in Medicare, and I think it is the oldest existing system in Medicare that has not been looked at for at least three decades. I wasn't in the industry then, so I bear no responsibility for it. But—

Mr. BURGESS. Me either.

Mr. MORRISON [continuing]. We just think it is time to move forward. And in deference to the member from Pennsylvania, Medicare forces us to bill for parts. We are happy to bill for an entire car.

Mr. BURGESS. I got you.

Well, thank you, and thank you for your testimony today. Again, I feel a little bit like Representative Carter. I hadn't prepared to ask you a question, but when you detailed how you have to circumnavigate the globe to get from point A to point B, it really was troubling.

Mr. Earle, thank you for being here. Thank you for the work you do on the efficiency and the efficacy of electronic health records. You know the legislation, 3120, that I have cosponsored with Representative Dingell from Michigan that removes the mandate to make meaningful use standards increasingly more stringent.

I am going to ask you a softball question. Do you support the policy?

Mr. EARLE. Absolutely.

Mr. BURGESS. Right answer. Good deal. So why is it important to allow providers to catch up?

Mr. EARLE. The ball has been moving significantly when it comes to electronic medical records and meaningful use. So this will give us the time to, if we are able to pause, it gives us the time to actually work at giving and delivering the right technology and solutions for our providers, in essence, for our patients and provide the right amount of care.

So pausing it out would allow us that opportunity to, again, drive our technology initiatives to have a better result.

Mr. BURGESS. And then is there a downside if we don't allow that pause?

Mr. EARLE. No. I don't think there is a downside. From our perspective, you talk about bundle payments and what we are doing with the 21st Century Cures Act.

What we are seeing is the legislation out there, it is really allowing us to continue to push our efforts forward when it comes to interoperability and sharing information so that we can actually continue improving the system and having better results without the stick, as far as you have to make these changes every year or in a more routine basis. So I don't see, and I don't think our organization sees, a downside. There is just upside here.

Mr. BURGESS. OK. And it is sort of a recurrent theme throughout the entire panel. Things are written into stone, Mr. Morrison. Things are written into Federal law, and, yet, the world moves much faster. The real world requires a great deal more adaptability.

And I appreciate all of you being here this morning. We have heard some compelling testimony from a number of different aspects as to the delivery of healthcare, about how best of intentions have made your lives more difficult. And as a consequence, the patients on the receiving end have suffered.

Dr. Kissela, I just want to probably finish up with you. Mr. Griffith asked the important questions. 1996 was the FDA approval of TPA. Is that what you told us?

Dr. KISSELA. Yes, sir.

Mr. BURGESS. And then Mr. Guthrie had asked the appropriate question: Gee, how do you tell who gets what? Or you don't want to hurt anyone by giving them the TPA if they have had a hemorrhagic stroke.

I just have to tell you my own experience, 1988, and my dad had a very serious stroke. And I remember sitting there in the ICU that night wondering if that brand new drug that they were giving people with heart attacks could possibly make a difference. And, of course, you talk about an off-label indication; no one would have gone there.

I don't know if I asked about it, but I certainly thought about it. There had to be a way. Now, with what you described, and not just the clot-busting medications, but actually going in with a catheter and pulling the offending clot out and discarding it in the bedpan, I mean, a wonderful, wonderful outcome for that scenario.

Because I know the other side of that, which was almost 20 years of survival with never being able to speak a word. Ms. Bardach talks about the speech-generating devices. I became very familiar with the very rudimentary tools that were available, as my dad, who was an accomplished general surgeon, spent the rest of his life unable to communicate.

And so these are not just theoretic concerns. When Mr. Griffith brought up the Congressional Budget Office—and, yes, we have had a lot of discussion about the Congressional Budget Office in this committee the last 6 months, and all of it valid. They do good work over there.

But doggone it, when you look at what you do, and they say, well, we are going to calculate, but all we can calculate is the cost, because it is the cost of the time under the C-arm, it is the time in the fluoroscopy, it is the cost of the medication, the cost of the catheters—you really don't capture what happens way downstream.

With someone like my dad, who lives almost 20 years after the stroke, the first 10 years, you have captured all the costs. But if you were able to prevent what happened next, the next 10 years, who knows? Maybe even continuing productive life, continuing to be a general surgeon in our little town.

When we look at CBO stuff—and we will have this opportunity on this committee. I feel certain that I am going to be successful in bringing this—we look at the cost. But we have got to be able to widen out that window, not just to the 10-year budget cycle to

which we are wedded currently, but we have got to have a wider look to get to the stuff that Dr. Murphy was talking about, even Dr. Ruiz was talking about. We have to have the ability to do that.

So it has been a thought-provoking morning. I want to thank all of you for spending so much time with us.

Do I have another member? I would yield to Mr. Guthrie for a followup question since I went over.

Mr. GUTHRIE. I am fine. I am good.

Mr. BURGESS. So, seeing that there are no further members wishing to ask questions, I once again want to thank all of our witnesses for being here today.

We have received outside feedback from another number of organizations on these bills, imagine that. So I would like to submit statements from the following for the record: the National Multiple Sclerosis Society; the American Medical Association; CHIME; Health IT Now; Intermountain Health; United Surgical Partners; Steve Gleason; the ALS Association; Focus on Therapeutic Outcomes, Incorporated; the NARA; the NASL; the Private Practice Section of the APTA; PTPN; the Coalition to Preserve Rehabilitation; the Brain Injury Association of America; AMRPA; Covington; and a letter from 12 advocacy groups on prostate cancer.

So, without objection, so ordered. Those will be made part of the record.

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

Mr. BURGESS. Pursuant to committee rules, I remind members that they have 10 business days to submit additional questions for the record.

And I will just tell you: I have several that I went way over my time, but I still have multiple questions that I am going to be submitting.

I ask the witnesses submit their response within 10 business days upon receipt of the questions.

And, without objection, the chair again thanks our witness panel for a very, very informative morning and afternoon. The subcommittee stands adjourned.

[Whereupon, at 1:13 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



Statement of the
National Association for the Support of Long Term Care
House Energy & Commerce Committee, Health Subcommittee Hearing
“Examining Bipartisan Legislation to Improve the Medicare Program”
July 20, 2017

The National Association for the Support of Long Term Care (NASL) represents providers and suppliers of ancillary services serving patients in long term and post-acute care (LTPAC) settings. NASL members include rehabilitation therapy companies that employ more than 300,000 physical therapists, occupational therapists, and speech-language pathologists who furnish rehabilitation therapy to hundreds of thousands of Medicare beneficiaries in nursing facilities and other care settings along the long-term care continuum. NASL members include providers of clinical laboratory services, portable x-ray/EKG and ultrasound, complex medical equipment and other specialized supplies for the LTPAC sector. Other NASL member develop and distribute health information technology (IT) including full clinical electronic medical records (EMRs), billing and point-of-care IT systems and other software solutions that serve the majority of LTPAC providers. NASL is proud to be a founding member of the LTPAC Health IT Collaborative, which formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders. NASL is also a long standing active member of the Therapy Cap Coalition and fully supports the efforts of the Therapy Cap Coalition over the years to work to end this policy for the patients we serve.

NASL is pleased to submit a statement for the record of the Committee’s hearing on **“Examining Bipartisan Legislation to Improve the Medicare Program.”** The Committee’s focus on Medicare Part B services is of particular interest to NASL as our members deliver these services for America’s seniors and individuals with disabilities.

NASL thanks Chairman Burgess, Vice Chairman Guthrie and Ranking Member Green for inviting NASL Vice President and Diagnostic Testing Committee Chair Alan Morrison to testify today. We wish to associate ourselves with Mr. Morrison’s written statement regarding the clinical laboratory bundling proposal and will focus the remainder of our statement on the Part B therapy benefit.

NASL appreciates the bipartisan support for repeal of the arbitrary Part B therapy caps, which have the potential to negatively affect the lives of many of our most vulnerable citizens. Medicare beneficiaries do not have an effective way to voice their concerns on the arbitrary caps on their care. Our therapists treat patients in the more than 1.5 million patients in nursing facilities and other settings and bring their patient’s voice in advocating for their care. NASL thanks Representatives Erik Paulsen (R-MN), Ron Kind (D-WI), Marsha Blackburn (R-TN), and

Doris Matsui (D-CA) for championing repeal of the therapy caps by introducing H.R. 807, *Medicare Access to Rehabilitative Services Act*. The Senate companion legislation has been introduced by Senators Ben Cardin (D-MD), Dean Heller (R-NV), Susan Collins (R-ME), and Bob Casey (D-PA). We are encouraged by the leadership that members of this Committee and others in Congress have demonstrated in working on policies that protect beneficiary access to the Part B outpatient therapy benefit, while refraining from undue administrative and regulatory burden on providers.

NASL members treat patients who are most vulnerable to these therapy cap policies as evidenced in CMS claims information and in a data analysis project NASL completed in 2011. Patients relying on the 24-hour and 7-day a week care in the nursing facility are sicker, and most likely to be female. Nursing facility patients are more likely to have chronic conditions including Alzheimer's, chronic kidney disease, COPD and diabetes. Most importantly, our patients are more likely to need therapy above the caps & threshold ¹. The data analysis indicates that of the SNF patients receiving Part B outpatient therapy, 31% of patients exceeded the PT/SLP cap while 71% exceeded the OT cap. Additional percentages exceeded the thresholds. The therapy cap policies discriminate against the sickest and those needing therapy the most and it imposes undue burden on both patients and providers. Considering the known research and based on our history of service to the most vulnerable Medicare beneficiaries, ***NASL supports repeal of the arbitrary Part B Therapy Cap. We support replacing the cap with policies that protect beneficiary access to their Part B Outpatient Therapy benefit, allow the continuity of care and that do not impose an undue administrative and regulatory burden on providers. Given the challenges that may exist with repeal of the therapy cap, and absent Congress enacting repeal, we must have an extension of the exceptions process to preserve patient access to their therapy benefit. We recognize the exceptions process is not a long-term solution, it is an essential policy floor protecting beneficiaries by assuring access to required therapy services.***

Background on the Medicare Part B Outpatient Therapy Benefit

Medicare Part B pays for outpatient therapy including the distinct disciplines of physical therapy, occupational therapy and speech language pathology. Physical therapy (PT) restores and maintains physical function and treat or prevent impairments that result from disease, surgery or injury. Occupational therapy (OT) improves and compensates for a patient's ability to conduct activities of daily living, such as dressing, bathing, eating and toileting and the cognitive processes to complete these activities. Speech language pathology (SLP) services help patients with difficulties communicating and or swallowing because of disease, injury or surgery as well as the cognitive requirements of memory, decision-making, language and functional communication.

¹ NASL engaged The Moran Company to undertake a data collection and analysis of Part B therapy claims data in 2011.

Outpatient therapy services are covered under Medicare Part B and to receive services, a beneficiary must be referred by a physician or nonphysician practitioner. Medicare regulations and coverage rules require that the beneficiary's medical record include a written plan of treatment with information on diagnosis and therapy goals.

Part B outpatient therapy is provided in many different settings including nursing facilities, hospital outpatient departments, physicians' offices, outpatient rehabilitation facilities, and comprehensive outpatient rehabilitation facilities, as well as by therapists in private practice and home health agencies. Approximately 70% of rehab therapy services are provided in private offices and nursing facilities.² **All settings use the same CPT codes and are subject to the same payment policies — despite patients being treated in these various settings having a wide range of acuity levels and medical needs.**

Because the patients our members treat are often among the sickest with several chronic diseases and comorbidities and most in need of rehabilitative care, they often reach the cap more quickly than those who are living at home and who may receive outpatient therapy in a physician's office. Unlike those who may live independently and speak on their own behalf, many patients we serve have progressive complex conditions that render them unable to provide for themselves and are best treated in this setting. Among those most in need of rehabilitation services are those who required rehabilitation to assure comfort and safety during the end stages of life. Others may be in need of care to assure a safe and functionally independent transition to home. In either case and for any number of those in need of medically necessary rehabilitation to attain a safe and independent discharge from the need for additional Medicare Part B rehabilitation services, we ask that you remove the arbitrary financial cap that can compromise successful completion of the planned care or may increase potential for premature return to the hospital.

The Value of Rehabilitative Therapy: Maintenance and or Improvement

The three distinct disciplines of PT, OT and SLP in a program of rehabilitative therapy work to maintain or improve patient's functional abilities for self-care and mobility and work to help patients with their activities of daily living such as dressing, bathing, toileting, transferring (walking and moving), food preparation and self-feeding, problem solving, functional communication and personal safety. These therapies play an important role in assessing and improving cognitive abilities. The Supreme Court recognized the importance of therapy in maintaining function in the recent decision, *Jimmo v. Sebelius* and preventing deterioration of function for patients.

CMS began several years ago an effort to assess and collect data on function for patients receiving Part B outpatient therapy. Providers are required to report functional data in the form

² MedPAC Payment Basics: Outpatient Therapy Services Payment System. Retrieved from http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_opt_final.pdf?sfvrsn=0

of "G-codes" on the claim form as a requirement for reimbursement. CMS requires therapists to choose a test that best matches one of the goals of the patient's therapy and fit the results of that test into CMS's scale of 1-7. CMS has collected the "G-codes" since 2013 and has never released the data. At best, this data is not scientific. It certainly contrasts with the standardized quality data developed as mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) to be collected by SNFs, IRFs, LTCHs and HHs. Absent scientific data capture and or reports from CMS, our members have undertaken an effort to self-assess the outcome and functional changes in the patients we serve.

History of Therapy Cap Payment Policies

Medicare Therapy Caps took effect in 1999 under the Balanced Budget Act of 1997 (BBA). There are two caps, one cap that limits the dollar amount of PT and SLP services combined to \$1,980³ for 2017. Another cap limits OT services to \$1,980 per person during 2017. In 2006, Congress established an exceptions process that allows an exception to the cap when a patient's condition/medical circumstances warrant additional medically necessary therapy above the caps. The exceptions process requires reauthorization by Congress and Congress has extended it many times since 2006. The current exceptions process expires on December 31, 2017.

Congress imposed an additional therapy cap policy in *The Middle Class Tax Relief and Job Creation Act of 2012*, enacted in February 2012. The Act required CMS to conduct manual medical review (MMR) of requests for exceptions for therapy claims over an annual threshold of \$3,700 for OT and \$3,700 for PT and SLP services combined on or after October 1, 2012. A GAO report on the 2012 MMR process was also required⁴. The GAO report studied the first three months of the program and detailed many problems with the preapproval process.

CMS Institutes Program of Preapproval for Services

CMS implemented the MMR program in September 2012 and it was clear very early that the MACs could not handle the process. Providers submitted requests for preapproval for therapy services above the \$3,700 threshold. Providers were permitted to request up to 20 days of treatment up to 15 days before providing the services above \$3,700. Preapproval requests could only be submitted by U.S. Mail or by facsimile. To expedite the preapproval process, CMS instructed the MACs to review preapproval requests within 10 business days of receipt of all requested documentation to determine whether the services were medically necessary. NASL received multiple reports from providers across the nation that when providers submitted

³ Statute provides for an inflationary increase in the therapy cap amount each year as announced in the annual CMS Physician Fee Schedule.

⁴ GAO: Medicare Outpatient Therapy, Implementation of the 2012 Manual Medical Review Process. July 2013. Report to Congress. Retrieved from <http://www.gao.gov/assets/660/655806.pdf>

their documentation package to the MACs, often additional documentation requests would come from the MACs before the 10th day effectively stopping the clock on the medical review while the provider mailed or faxed in more documentation. Because much communication was by US mail, there were delays in communication. Also, MACs were not prepared with sufficient number of fax machines to receive the large paper medical records they were requesting from providers. This is especially important to patients in nursing facilities because they cannot wait weeks for approval of the rehab therapy that they need immediately. In fact, a delay in treatment such as those we have described have the potential to reverse progress already achieved.

The GAO report detailed that during the first three months of this preapproval review, MACs were overwhelmed by the volume of what they needed to review, they did not receive guidance from CMS timely to institute it, MACs were unclear how to count the 10-day time frame, the MACs were not prepared for the volume of paper files they had to manage which created a lag time for their response, MACs did not fully automate systems to receive and track preapproval requests in the time allotted. CMS staff estimated that the MACs reviewed more than 167,000 preapproval requests in a three-month period, affecting more than 115,000 Medicare beneficiaries. The GAO report stated, "Both CMS officials and MAC staff acknowledged that the MACs were not able to process all the preapprovals submitted in a timely manner."⁵

CMS Moves the MMR to Other Contractors

CMS moved the MMR process to the RACs, contractors that ordinarily do not approve services before they are provided and current RAC contracts were utilized. Then, through the *Medicare Access & CHIP Reauthorization Act (MACRA)*, Congress enacted two important changes to therapy cap policies. *MACRA* changed the manual medical review of all claims above the \$3,700 threshold to a system of *targeted* medical review of claims above the \$3,700 threshold. Also, it mandated that entities other than RACs could perform the reviews. Subsequently, CMS contracted with a Supplemental Medical Review Contractor to undertake the reviews. These targeted medical reviews continue to today. In deciding which services to target for review, CMS may consider services furnished by providers with high claims denial rates, patterns of billing that are aberrant compared with their peers, or other factors.

Lessons Learned: The Impact of the Preapproval Process on Patients and Providers

The impact of the preapproval process/ prior authorization of services that began in 2012 is that it delays necessary care which places patients at risk, decreases patient satisfaction and increases provider cost through inefficiencies. It's a well-meaning system, but using the U.S. Mail and fax machines – experience shows the system as it stands today cannot respond quickly enough for care decisions—especially for the highest acuity patients-- that need to be

⁵ GAO: Medicare Outpatient Therapy, Implementation of the 2012 Manual Medical Review Process. July 2013. Report to Congress. [GAO-13-613 Outpatient Therapy Manual Reviews](#) page 19.

made for patients in nursing facilities. If these patients have to wait several days for therapy to be approved, their functional levels can and will decrease. Consider the cognitively intact and independent patient who has a severe accident. On a fixed income, this person had to be told that the provider was waiting for approval from Medicare to continue treatment. Suddenly, he must decide to remain in the SNF and hope Medicare approves treatment, consider paying for treatment out of dwindling savings or request to be discharged and hope that he can be "safe enough" on his own at home. None of these options are optimal nor should any Medicare beneficiary have to experience this. There is ample evidence that older adults are at risk for further decline in mobility and other activities of daily living, often leading to the need for hospitalization, when therapy services are delayed (and/or interrupted).

During the preapproval process time, it was very confusing for providers and beneficiaries with different MACs using different procedures across the country. Medicare beneficiaries receiving rehab therapy services in nursing facilities such as those who were temporarily disabled but cognitively aware were not aware of the MMR process and continued to be confused regarding the differences in the types of plans they have as well as what the coverage is and what the processes were.

Here are some examples of what happens with the beneficiary when they are facing the stoppage of care under a preapproval process. Under MMR, nursing facility patients were progressing to complete a course of therapy treatment only to be told that Medicare hadn't approved continued treatment and providers were waiting for permission to proceed. The patient doesn't understand that approval is needed once the doctor prescribes the treatment. The beneficiary needs to focus on treatment and healing had to ask themselves the question: should I continue with agreement to private pay or continue paying room & board and agree to pay for treatment if Medicare doesn't provide approval?

Also, patients who were progressing in their therapy treatment plan and wanted to complete treatment to exit the system and return home found themselves having to increase the overall time in treatment and/or personal costs while waiting to return to the community and improved level of independence, no longer draining the system.

It is important to consider the special case of patients receiving rehab therapy in facilities such as skilled nursing facilities, nursing facilities and rehab hospitals. These patients need skilled therapy services at the moment of recognized decline or change in condition. They cannot afford the time to wait for prior authorization and then schedule an evaluation with therapy. This may work for other settings like outpatient private practice physical therapy where the treatment they need is not critical or urgent.

NASL Recommendations:

NASL Statement
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NASL recommends that policies enacted by Congress should build upon the lessons learned from the previous and current medical review programs and consider what is best for patient access and not creating undue provider burden in providing the rehab therapy benefit.

In creating policy, Congress needs to be cognizant that the therapy cap policies it enacts are a one size fits all for the wide range of acuity of patients receiving therapy services in various Part B outpatient settings. Policies that may work for patients in one setting may not work for the patients in other settings, yet patients are subject to the same policies.

NASL recommends that Congress repeal the caps and in their place, enact a targeted program of review of services for medical necessity. NASL members support providing only medically necessary therapy. NASL recommends these Guiding Principles including elements for programs of medical review:

1. Must provide for and protect patient access to care and allow for continuity of care
 - a. Must allow for special consideration for providers and practices who work with critically complex conditions.
 - b. Maintain beneficiary protections and limitations to preserve beneficiary and provider appeal rights
2. Accountability for providers who consistently over-utilize while minimizing the administrative burden of Medicare audits and reviews
 - a. Continuation of current targeted medical review for those providers who were found to have consistently high utilization and aberrant billing patterns
3. Enhance transparency
 - a. Require that Medicare review contractors provide information to providers who receive denials and mandate GAO assess contractor performance
 - b. Direct the Secretary to make electronic submission of information available within 6 months after enactment
 - c. CMS to report on findings of targeted medical review process
4. Alignment of therapy cap alternative policy with current quality and value-based initiatives
 - a. Exemptions for participation in the merit-based incentive payment system and alternative payment models
5. Align data collection with other efforts already underway such as the IMPACT Act regarding reporting of outcomes.

NASL opposes prior authorization or preapproval of services because this type of review interferes with the physician/NPP-patient relationship and clinical decision-making, risks access to care, and can result in delayed or incomplete treatment plans, increasing risk for re-admission to the system and higher overall costs. If Congress were to institute a program of prior authorization or preapproval review, NASL recommends:

1. CMS should be mandated to create a refined and proven system of pre-approval that can provide timely *i.e.* 24-hour responses or no more than 3 days to authorize requests to avoid any delay in care and only when CMS can certify that it has such a process/structure ready, should it be deployed. In setting up such a system, CMS should be required to institute electronic means for providers to submit required documentation along with a system that allows providers to verify that documents were received and the status of the review.
2. Review should be based on clinical best practice and known standards of care, not an arbitrary dollar amount.
3. CMS must be provided adequate funds, technology and resources to be able to manage and promptly address the requests.
4. Beneficiaries as well as providers need to be educated to this Medicare Policy Change, potential costs and timelines.

Conclusion

NASL thanks the Committee for holding the hearing to highlight these important issues. NASL is dedicated to working with the committee and others in Congress to repeal the therapy caps and put in place the right policies that keep the patient at the center and protect beneficiary access to the Part B Outpatient Therapy benefit. We believe new policies should also provide for continuity of care and should not impose an undue administrative and regulatory burden on providers. Absent Congress enacting repeal, we must have an extension of the exceptions process to preserve Medicare beneficiary access to their outpatient therapy benefit.

###

For Further Information, contact:
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NASL Statement
Energy and Commerce Health Subcommittee
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AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

American Speech-Language-Hearing Association

**Statement for the Record for the
Health Subcommittee of the Energy and Commerce Committee**

Examining Bipartisan Legislation to Improve the Medicare Program

I, Gail Richard, President of the American Speech-Language-Hearing Association (ASHA), appreciate the opportunity to provide this statement on two bipartisan issues: 1) the discussion draft pertaining to extending the current exceptions process for outpatient rehabilitation services and 2) H.R. 2465, the Steve Gleason Enduring Voices Act of 2017. We look forward to working with the Committee on both of these issues, which will ensure that Medicare beneficiaries have access to outpatient rehabilitation services as well as access to speech-generating devices.

ASHA is the national professional, scientific, and credentialing association for 191,500 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. Our members work in health care settings to evaluate and treat the language, hearing, swallowing, cognition, and communications skills for individuals across the lifespan.

Outpatient Rehabilitation Services

ASHA has been working with the American Physical Therapy Association (APTA) and the American Occupational Therapy Association (AOTA) on the development of a replacement policy. The principles of the policy are listed below, and we respectfully request the Committee's careful consideration of this proposal.

One possible policy for a permanent fix could include a three-step process of oversight for therapy claims. The first step would be to utilize the current \$3,700 threshold as a trigger for post-payment medical review of claims submitted by providers who meet certain criteria. Additional oversight mechanisms could be utilized for those providers on post-payment medical review who are identified as meeting additional factors, in other words, those providers who are not "succeeding" on post-payment review. This oversight, coupled with a pathway for therapy providers to be part of alternative payment models and other performance-based models, will better align therapy services with the transition of Medicare to a value-based system.

For any new proposals presented to the Committee, ASHA respectfully requests the inclusion of the following principles:

- 1) **Ensuring Patient Access:** Any permanent therapy cap policy should ensure patient access to outpatient therapy services. The fundamental flaw with the current policy is the barrier to care that does not take into account the individual needs of the patient. Additionally, any new policy should ensure that care is not disrupted for long periods of time. In the past, when the Centers for Medicare & Medicaid Services (CMS) has been asked to do a broad review for a large number of claims, they have been unable to efficiently execute the review in a timely manner. As a result, care has been delayed for patients, and high administrative burden has been placed on providers. Not only is

delayed care detrimental for the patient, but it could lead to higher costs to the Medicare program as the beneficiary's progress may regress if care is disrupted.

- 2) **Developing a Targeted Approach to Oversight of Outpatient Therapy Spending:** ASHA supports a mechanism to ensure appropriate delivery and utilization of outpatient therapy services. This includes targeted reviews of those claims that exceed certain thresholds and are provided by therapy providers that have been identified based on specific factors. Additional scrutiny could be given to providers who continue to have claims rejected under the review process. However, any additional scrutiny, whether through post-payment review or prior-authorization, should include protections for patients and ensure that care is not delayed (see principle #1). This process would be similar to the current \$3,700 threshold and post-payment medical review process. Blanket mechanisms, such as the current therapy cap or broad application of prior-authorization across the patient spectrum, are not effective because they restrict patient access, do not take into account medical severity, interrupt the continuity of care, and cannot realistically be implemented by CMS.
- 3) **Aligning with Value-Based and Performance-Based Models:** We believe that therapy services provided in a qualifying Alternative Payment Model (APM) should be exempt from any permanent outpatient therapy policy. Providers who participate in APMs would already be subject to quality and outcome requirements, as well as a shared risk for the cost of care, which would ensure efficient provision of services. In addition, while therapy providers are not currently part of the Merit-Based Incentive Payment System (MIPS), we anticipate that these providers will be added to the program in 2019. MIPS provides performance-based penalties and payment adjustments to providers. Under MIPS, the therapy cap and ongoing short-term fixes could impede the ability of providers to maximize outcomes, decrease costs, and improve performance. A permanent fix is essential in order for therapy providers to effectively participate in MIPS.

Therapy Cap Overview

For the past 20 years, since the inception of the therapy cap under Balanced Budget Act of 1997, Congress has acted 16 times to avoid implementation of the cap in order to avoid the devastating impact on the rehabilitation needs of Medicare beneficiaries. Continuing discussions on the possibility of extending the current therapy cap exceptions process would be a missed opportunity to permanently resolve this perennial issue that drains time and resources on a policy provision that is opposed by the overwhelming majority of the members of Congress. Each extension of the exceptions process diverts resources away from the need to permanently replace the cap and implement strategies that would improve the integrity of the Medicare program while ensuring that its beneficiaries retain access to the care they require.

We recognize that there are many competing issues that require the attention of the Committee, but none have plagued Congress and Medicare beneficiaries for as long as the therapy cap. The legislation has received a majority of cosponsors within both the House and Senate over the past several Congresses and currently has the bipartisan support of 177 members of the House, including 46 original cosponsors.

Impact on Beneficiaries

Patients with medically complex conditions and comorbidities are far more likely to exceed the cap than beneficiaries with a single distinct illness, injury, or condition (with certain exceptions). Of those requiring care beyond the 2017 level of the therapy cap, which is \$1,980, are some of the most vulnerable and medically complex beneficiaries covered by Medicare. Most negatively and unfairly impacted are those beneficiaries who require both speech-language pathology and physical therapy services within the same year. The combined cap on speech-language pathology and physical therapy (PT) services forces the beneficiary with the unenviable dilemma of choosing between communicating (talking), independent feeding, and swallowing OR essential physical activities (walking) associated with daily living. While the exceptions process allows for medically necessary care beyond the cap, the impermanency of the policy places a high level of stress on consumers who know they rely on rehabilitative services to maintain their daily function and extend their lives.

Cost Containment

Provisions imposed through various versions of the exceptions process, including targeted manual medical review, have proven successful at providing cost containment while maintaining some level of access to Medicare beneficiaries. However, the burden on providers and Medicare contractors alike is over-whelming and unnecessary. Furthermore, Medicare beneficiaries are dealing with the insecurity of whether or not their essential rehabilitative care will continue to be covered. The arbitrary application of reviews do not fully take into account available data to help both providers and CMS identify the areas of most significant concern regarding potential and perceived over-utilization. Even with such inefficiencies under the current review process, between the years of 2011 and 2015, per beneficiary spending has been reduced by nearly 8% across rehabilitation disciplines (Moran Corporation). **In fact, total spending on speech-language pathology services was reduced by 7% from 2011 to 2015, even though the percentage of Medicare beneficiaries seeking speech-language pathology services expanded by 14%.** This data provides direct evidence that targeted medical review can successfully contain cost and ensure that services are provided based on medical necessity. **Elimination of the cap and replacing it with a modernized utilization threshold would ensure continued integrity of the Medicare program and appropriate access to care for beneficiaries.**

Modernization of the Rehabilitation Benefit

The current therapy cap exceptions process was established and implemented under the traditional fee-for-service program related to the Sustainable Growth Rate. ASHA urges the Committee to revise any new aspects of utilization control for therapy services so that they are in alignment with the principles established by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (P.L. 114-40) and implemented under the Quality Payment Program (QPP). Under the QPP, the Medicare program is moving away from fee-for-service and provides for the expansion of APMs, which would emphasize outcomes and shared risk financing to help ensure program integrity and quality. In addition, the MIPS includes required categories of reporting that also ensure program integrity by focusing on quality reporting, advancing care information, and improving clinical practice activities and resource use data in order to modify provider payments and incentivize improvement, efficiency, and quality.

ASHA Statement on Legislation to Improve the Medicare Program
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 Page 4

Upon repeal of the therapy cap, all outpatient services should be subject to the provisions of MACRA; thereby, enhancing the importance of quality, efficiency, and outcomes. Utilization of therapy services under APMs would be scrutinized based upon value to the patient in achieving desired functional outcomes and avoiding unnecessary procedures or re-hospitalizations. An example would be the provision of speech-language pathology dysphagia evaluation and treatment to ensure patients did not aspirate or remain on feeding tubes longer than medically necessary. Under MIPS, therapy payments would be modified based on quality and resource use, which directly incentivizes providers for efficiency and best practices.

In addition, provider scores would be publicly available, which would continue to work with the clinical improvement activities and advancing care information categories to further incentivize improvement. **Under the QPP, every dollar of therapy spending would be subject to review and payment modification based upon, quality, efficiency, and outcomes.** In regard to therapy services, any additional utilization controls contemplated by Congress should consider the impact of the QPP provisions and more narrowly target outliers. Such an approach would better address CMS's limited resources and focus on providers who are already demonstrating a certain level of difficulty in complying with the QPP activities.

H.R. 2465, the Steve Gleason Enduring Voices Act of 2017

The Steve Gleason Act of 2015 removed speech-generating devices (SGD) from capped-rental requirements for durable medical equipment under Medicare for three years. Capped-rental requires the patient to rent an SGD over a 13-month period before owning a device. Prior to the legislation, in accordance with Medicare rules, if an SGD user resided in a nursing home, hospice, or hospital, Medicare payment for the SGD stopped. Many of these facilities did not and could not supply beneficiaries with a uniquely configured SGD substitute. Ongoing and permanent access to Medicare coverage of SGDs will ensure individuals who medically qualify for an SGD to continue to use their personalized devices. The Steve Gleason Act of 2015 is expected to expire on October 1, 2018. It is imperative to make this law permanent so that individuals in need of these customized devices will continue to have access to them.

Speech-Generating Devices (SGDs)

SGDs are highly customized electronic augmentative and alternative communication (AAC) devices, which are used to supplement or replace speech, enabling individuals with functional communication impairments to verbally communicate their needs. Patients that require SGDs are those with medically complex conditions, including those with unstable progressive and degenerative diseases. The largest population requiring SGDs are patients with neurodegenerative diseases (e.g., ALS, or amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis), conditions where cognitive function and the need for communication remains intact, but the physiological ability to speak diminishes. SGDs are the only effective communication means for these patients, offering greater control of their health and their lives. SGDs are durable and customizable medically-purposed technologies that allow the speech-language pathologist, caregiver, and patient to modify the vocabulary, language, and accessibility options to meet the unique and changing needs of the patient and family.

Data are not available to determine the average length of use for the SGDs because it is a device that is almost exclusively purchased for individual use. There would not be a cost-advantage for rental over purchase of the device because SGDs are used long-term. The treatment and medical care advances that have resulted in an increased life expectancy for the general American population are also prolonging the lives of patients with neurodegenerative disease. The National Institute of Neurological Disorders and Stroke reports the average age of onset of Parkinson's is 60-years-old, but states that with medications most people can live productive lives for many years after diagnosis. Thus, the expectation of increased longevity for these populations also supports the long-term use of the SGD and the importance of purchase rather than rental.

As rental units, SGDs cannot be readily substituted because they require a high level of customization. Under the current Medicare rules, substitution of the rented unit would need to be arranged upon admission to a hospital, skilled nursing facility (SNF), or hospice because monthly Medicare payments to the durable medical equipment supplier are terminated during institutionalization. Institutions and facilities do not have ready access to SGDs and are not funded to supply the device. When purchased, the patient has the ability to bring in their personalized device and continue the method of effective communication that they have mastered prior to the inpatient stay. The patient's need for an alternative communication device is most critical in an institutionalized setting because of the need for effective communication with health care staff.

If a rented SGD were to be returned to the vendor upon admission, the vendor would need to delete all customized and personalized information, including customized vocabulary. Vendors would not be able to retain copies of the vocabulary (e.g., download the personalized information), store it, and then reload it when the next rental period went into effect. Because of the rental reimbursement rules and equipment liability issues, it would not be possible for the manufacturers to support the SGD without reimbursement. These rules, which are meant to protect the Medicare program from misuse, inadvertently place the most fragile Medicare patients in a vulnerable situation, leaving them without the ability to effectively communicate their needs.

It is predictable that the impact of bundled rental payment would negatively impact many small businesses, limit options, and create access issues in this very specialized industry. The SGDs are only available from four to five major manufacturers, with a few smaller companies that primarily provide accessories. Because the overall utilization is relatively low when compared to other medical devices, there are very few SGD suppliers. Delivery is not a regularly scheduled event to the patient's home, such as with oxygen or diabetic supplies, and repairs or replacements often require shipping and time. The rental program, along with the ever-increasing requirements and cost, places SGD suppliers at risk of losing financial viability. In addition, accessories (e.g., mounts, switches) are sometimes supplied by a different manufacturer who may not provide these accessories for rentals.

The loss of options for obtaining and servicing SGDs, along with the precarious issues related to the inpatient stay, has the potential to leave patients with neurodegenerative diseases without an essential means of communication, particularly at their most medically vulnerable times.

ASHA Statement on Legislation to Improve the Medicare Program
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Once the Steve Gleason Act of 2015 expires, patients who enter an inpatient facility will be stripped of their personalized rented SGD because of the capped-rental policy. This action will limit the ability of the speech-language pathologist to provide communication options for critical situations, including health care decisions and end-of-life scenarios. For these patients, there are communication needs that are extremely personal and privacy issues arise in the process of returning the device. When the device is personally owned, it allows the speech-language pathologist to include the most intimate and private details the patient needs to communicate with medical professionals and family. Finally, the negative impact of not being able to effectively communicate with all caregivers cannot be underestimated. **ASHA urges the Committee to remove Medicare's capped-rental requirement on durable medical equipment, specifically SGDs.**

Conclusion

Thank you for the opportunity to provide this statement for the record. ASHA looks forward to continuing to work with the Committee and Congress to find permanent solutions to both the therapy caps and access to SGDs. For more information, contact Ingrida Lusic, ASHA's director of federal and political advocacy, at 202-624-5951 or ilusic@asha.org.



JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

July 19, 2017

The Honorable Michael Burgess, MD
U.S. House of Representatives
2336 Rayburn House Office Building
Washington, DC 20515

Dear Dr. Burgess:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our support for H.R. 3120, legislation that would remove the requirement that Meaningful Use (MU) measures become more stringent over time. We believe that this relief is an important step to ensure that physicians and other providers are able to meet MU and Merit-Based Incentive Payment System (MIPS) requirements and continue to participate in both programs.

Physicians have faced significant problems with the MU program, including poor performing technology, rigid standards, and shifting regulatory requirements. While the Centers for Medicare & Medicaid Services (CMS) has published regulations to address some of these concerns, the agency's ability to provide relief is limited by the statutory requirement to continually make the program more challenging. CMS has had to repeatedly implement hardship exemptions to avoid creating an unworkable MU program while still following this statutory provision. Indeed, MU participation data have validated our concerns, as many eligible professionals have been penalized under the early stages of the program or have sought hardship exemptions to avoid financial penalties.

Adding more stringent measures makes little sense given that many physicians are now struggling with existing MU requirements and that the program continues to operate on a pass-fail basis. Furthermore, since the MIPS program references the MU statute, we believe this requirement could also impact physicians in the Quality Payment Program and discourage participation before this program has a chance to get off the ground.

Accordingly, we support the relief offered by this legislation and believe such a change can reinforce the significant investments in electronic health records and ensure future physician use of these important tools. We appreciate your leadership on this important issue and look forward to working with you to advance this legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, written over a light blue horizontal line.

James L. Madara, MD



July 5, 2017

The Honorable Michael Burgess
2336 Rayburn House Office Building
Washington, DC 20515-4326

The Honorable Mike Thompson
231 Cannon House Office Building
Washington, DC 20515-0505

The Honorable Debbie Dingell
116 Cannon House Office Building
Washington, DC 20515-2212

The Honorable Pat Tiberi
1203 Longworth House Office Building
Washington, DC 20515-3512

Dear Representatives Burgess, Dingell, Thompson, and Tiberi:

The College of Healthcare Information Management Executives (CHIME) is pleased to support the bi-partisan bill, H.R. 3120, introduced on June 30. The legislation would enable greater flexibility for the participants of the Medicare and Medicaid EHR Program, also known as Meaningful Use.

CHIME is an executive organization serving more than 2,300 chief information officers (CIOs) and other senior health information technology leaders at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation. Our members represent some of the earliest and most prolific adopters of electronic health records (EHRs) and other health IT resources for clinicians and patients.

Since enactment of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), our members have made significant investments into electronic health records (EHRs) and other health IT because they recognize how transformative this can be to the delivery of patient care. This said, they believe being required to meet an ever-increasing set of complex requirements will hinder rather than hurt their ability to use technology in a manner they deem most appropriate to care for their patients. This bill addresses this issue by removing the clause that indicates the program must create an escalated set of requirements to be met by providers over time.

We appreciate your continued interest and leadership on this subject and stand ready to continue to work with you and your colleagues on improving this program. Should you have questions about our position or require additional information, please contact Leslie Krigstein, Vice President of Congressional Affairs, at krigstein@chimecentral.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell P. Branzell".

Russell P. Branzell, CHCIO, LCHIME
President and CEO
CHIME

College of Healthcare Information Management Executives (CHIME)
710 Avis Drive, Suite 200 | Ann Arbor, MI 48108 | 734.665.0000 | www.chimecentral.org



July 11, 2017

The Honorable Michael Burgess
 Chairman, Subcommittee on Health
 House Committee on Energy & Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515

The Honorable Debbie Dingell
 116 Cannon House Office Building
 Washington, DC 20515

The Honorable Patrick Tiberi
 Chairman, Subcommittee on Health
 House Committee on Ways & Means
 1102 Longworth House Office Building
 Washington, DC 20515

The Honorable Mike Thompson
 231 Cannon House Office Building
 Washington, DC 20515

Dear Chairmen Burgess and Tiberi, Representatives Dingell and Thompson:

Health IT Now, a broad-based coalition of patient groups, provider organizations, employers, and payers that supports incentives to deploy health information technology to improve quality, outcomes, and patient safety, and to lower costs, is writing in support of H.R. 3120. We appreciate your work to ensure electronic health records (EHRs) can be utilized to their fullest potential for providers and patients.

The Meaningful Use program has been successful in spurring adoption of EHRs - as of 2015, nearly nine in ten office-based physicians had adopted an electronic health record (EHR) compared to less than fifty percent in 2009.¹ Unfortunately, many providers and patients are frustrated by a lack of interoperability that not only threatens patient safety, it also increases health care costs. The reality is that taxpayers invested \$35 billion into EHRs that largely do not exchange information well.²

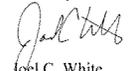
With this legislation, the Center for Medicare and Medicaid Services (CMS) will have the opportunity to transform the focus of Meaningful Use program from "check-the-box" activities to truly meaningful outcomes, including reaching widespread interoperability. In the *Medicare Access and CHIP Reauthorization Act* (MACRA), Congress declared it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018. If passed, CMS should fully use the flexibility provided by this legislation to hasten its work to reach this deadline and admirable goal.

¹ Office of the National Coordinator for Health Information Technology. 'Office-based Physician Electronic Health Record Adoption,' Health IT Quick-Stat #50. dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php. December 2016.

² United States of America, Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2016, May). *EHR Incentive Program*. Retrieved July 10, 2017, from https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2016_SummaryReport.pdf

We appreciate your work on this issue and look forward to continuing to work together to pass H.R. 3120.

Sincerely,


Joel C. White
Executive Director



36 South State Street, Suite 1700
Salt Lake City, UT 84111-1486
801.442.2000

July 5, 2017

The Honorable Michael Burgess, MD
Chairman, House Energy and Commerce Health Subcommittee
2125 Rayburn House Office Building
Washington, DC 20515

RE: Intermountain Healthcare Support for H.R. 3120

Dear Chairman Burgess:

On behalf of Intermountain Healthcare, we write to express our strong and enthusiastic support for H.R. 3120. Intermountain greatly appreciates your continued leadership in working to ensure that the goals Congress envisioned in enacting the Meaningful Use program are realized.

We are pleased to see that this important legislation would infuse the Meaningful Use program with the flexibility needed to enable providers to successfully participate in the program. Facilitating success in the Meaningful Use program is, we believe, an important and foundational element in the nation's path forward to interoperability.

H.R. 3120 would allow the Meaningful Use program to re-focus on advancing the standards and building the infrastructure needed for national interoperability. This legislation would also honor the spirit of a learning health care system by allowing the Meaningful Use to reflect actual experience in and an evaluation of the program.

We look forward to working together to advance this much-needed policy change. We would be pleased to provide a supportive witness should a legislative hearing be scheduled.

We also want to commend Danielle Steele of your office and James "J.P." Paluskiewicz of the Committee on Energy and Commerce. Their outstanding work to improve the Meaningful Use program will ensure that patients, providers, and payers alike increasingly realize the benefits of health information technology.

Please do not hesitate to contact me; Bill Barnes, Intermountain's Director of Government Relations ([801.442.3240](tel:801.442.3240)/bill.barnes@imail.org); or Karen Sealander, Intermountain Washington Counsel at McDermott Will & Emery ([202.756.8024](tel:202.756.8024)/ksealander@mwe.com), with questions or for further information.

Sincerely,

A handwritten signature in black ink, appearing to read "Marc Probst".

Marc Probst
Vice President and Chief Information Officer
Intermountain Healthcare

cc: Danielle Steele, Senior Health Policy Advisor, Office of Congressman Burgess
James "J.P." Paluskiewicz, Professional Staff, House Energy and Commerce Committee

DM_US 82873955-2.018242.0014



July 14, 2017

Congressman Michael C. Burgess
2336 Rayburn House Office Building
Washington DC20515-4326

Dear Congressman Burgess:

USPI supports H.R. 3120 as the increasing requirements of Meaningful Use continue to create barriers for our patients and physicians for high quality and low cost care. Meaningful Use currently is more focused on physician practices and acute care hospitals. There are many providers included in the longitudinal process of caring for patients that are significantly impacted by Meaningful Use but the current state does not adequately address the full scope of care. USPI operates surgical hospitals that must each year find increasingly costly workarounds to meet new requirements that apply to acute care hospitals and are not applicable in our environment. We are increasing our cost of care, impacting the quality and efficiency of care in order to check boxes that are not appropriate in our setting. MACRA is bringing a new set of needs for physicians practicing at our facilities that are not in alignment and are competing for resources with inpatient Meaningful Use. While we see the benefits of Meaningful Use there needs to be time to re-evaluate the requirements from a full scope of care perspective and the future of Meaningful Use should align for a complete longitudinal patient record.

Sincere Regards,

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The silence and isolation that comes from losing the ability to communicate does not discriminate between types of injuries, diseases, accidents or conditions. Speech Generating Devices (SGDs) are a critical pathway out of the silence and isolation for those who have experienced strokes, traumatic brain injury, cerebral palsy, Parkinson's, ALS, spinal cord injuries, chemical accidents, many other types of injuries, and other complex neurological conditions.

I have ALS (Lou Gehrig's Disease). When I was diagnosed in 2011, I was expected to fade away quietly and die, much like Lou Gehrig did after his famous speech 75 years ago. I am unable to move my body, except for my eyes. Through the use of eye tracking technology, I communicate through a device much like a tablet computer. This tablet is called a Speech Generating Device - SGD. The SGD allows me to maintain contact with the world around me – to express my thoughts, feelings and needs. It allows me to participate in everyday life with my family, friends, and community, to retain some independence. To continue living productively and purposefully.

A few others who have used SGD's to communicate include Professor Stephen Hawking, and critic Roger Ebert. Imagine a world where they were silenced. Just as important are the tens of thousands who use this technology daily to continue living their lives with purpose. Teachers continuing to teach, architects continuing to design, veterans reentering society, and parents continuing to parent.

Congress is on the verge of considering legislation, known as the Steve Gleason Enduring Voices Act of 2017, that continues to allow Americans covered by Medicare to have uninterrupted coverage of their ability to communicate. Without this legislation, Medicare could once again take away a person's SGD if they have to leave their home to be admitted into a

health care facility. Without the current Steve Gleason Act, Medicare took away a person's SGD if they chose to elect home hospice care. Without the Steve Gleason Act, Medicare may not have covered the accessories that are necessary to make an SGD work properly. Without this removing the sunset to the Steve Gleason Act and passing the Steve Gleason Enduring Voices Act, we will be turning the dial back to the days of Lou Gehrig, when people with debilitating diseases were simply expected to fade away quietly and die. That is not ok.

The Steve Gleason Enduring Voices Act removes barriers to continuous, effective SGD Medicare coverage. It provides complete confidence and security. If a person qualifies for an SGD, they will be allowed to communicate for the rest of their lives. Medicare will not take away their SGD nor ability to communicate, and be productive. They will not be silenced nor isolated when they are the most vulnerable.

The Senate and House passed the previous Steve Gleason Act unanimously. It was signed into law and proven successful with no fiscal impact.

People who use SGDs are assured they have access to communication without fear of being silenced and isolated. People may have come to need SGDs by way of many types of injuries, diseases, accidents, or conditions, but like everyone, they all share a fundamental human need to communicate and live purposefully.

We need your support to help pass the Steve Gleason Enduring Voices Act. Every day that passes without this legislation means people who want to be productive, fear they will be forced to fade to a silent death.



TESTIMONY FOR THE ENERGY AND COMMERCE COMMITTEE
 SUBCOMMITTEE: HEALTH
 EXAMINING BIPARTISAN LEGISLATION TO IMPROVE THE MEDICARE PROGRAM
 JULY 20, 2017
 THE ALS ASSOCIATION

The ALS Association strongly supports passage of the *Steve Gleason Enduring Voices Act of 2017 (H.R. 2465)* and appreciates the opportunity to submit testimony to the Energy and Commerce Committee on this bill. The legislation, named for Steve Gleason, a NFL star with the New Orleans Saints and activist living with ALS, is critical to individuals who require speech generating devices. The bill will make permanent the protections achieved in the *Steve Gleason Act of 2015* including ensuring that patients can retain their personal speech generating devices in all healthcare setting and that “effective use” of the devices includes critical eye-gaze coverage.

Amotrophic Lateral Sclerosis (ALS) is a neurological disease that causes severe muscle weakness resulting in disability and death. There is no known cause or cure for ALS. This disease is complex and variable with an average life expectancy of two to five years from the time of diagnosis. Those who have served in the military are twice as likely to be diagnosed with ALS. For people living with ALS – as well as people with other medically complex conditions - speech generating devices (SGDs) are the primary means they have to communicate with their loved ones and express their health care and personal needs

SGDs are systems used to supplement or replace speech or writing for individuals whose cognitive function and need for communication remains intact, but the physiological ability to speak diminishes. Speech generating devices are the only effective communication means for these people living with these conditions, offering greater control of their health and their lives. SGDs are durable and customizable medically-purposed technologies that allow the person living with ALS, along with their caregiver or speech-language pathologist, to utilize vocabulary, language and accessibility options to meet the unique changing needs of their situation. The patient’s need for an alternative communication system is most critical in an institutionalized setting because of the need for effective communication with healthcare staff.

When access to SGDs in all care settings (including nursing homes) was threatened, the ALS Community worked with Team Gleason, the American Speech-Language and Hearing Association and advocates in the field to protect access to these vital devices, which resulted in the passage of the *Steve Gleason Act of 2015* which will expire on October 1, 2018.



Our Vision
 Create a world without ALS.
 Our Mission
 To discover treatments and a cure for ALS, and to serve, advocate for,
 and empower people affected by ALS to live their lives to the fullest.

In response, a bipartisan bill, *the Steve Gleason Enduring Voices Act of 2017* (H.R. 2465), has been introduced by Representatives Cathy McMorris Rodgers (WA-5) and John B. Larson (CT-1) and has already gained support from 66 other Representatives. A companion bill has been introduced in the Senate (S. 1132) by Senators Bill Cassidy (LA) and Sen. Amy Klobuchar (MN).

This legislation's passage would make the changes that were implemented by the *Steve Gleason Act of 2015* permanent including maintaining the payment category for these personalized devices, letting people keep their SGDs in all care settings (including nursing homes) and providing coverage for the accessories needed to allow for the devices to work effectively.

The ALS Association thanks the Energy and Commerce Committee for including this bill in today's hearing and strongly urges Congress to support and pass the *Steve Gleason Enduring Voices Act of 2017* this year to ensure that there is no break in access. The passage of this legislation will ensure that Medicare's most vulnerable patients have access to SGDs and related accessories in all healthcare settings. People living with ALS and other unstable and degenerative diseases deserve the peace-of-mind that their ability to communicate will not be taken away from them when they enter a healthcare facility.

The ALS Association looks forward to working with Congress in a bipartisan fashion on this and other issues critical to those living with ALS and their families. The ALS Association is the only national non-profit fighting ALS on every front by fostering public and private research, providing care support for people with ALS through a nationwide network of chapters, coordinating multidisciplinary healthcare through certified care centers and promoting public policies to improve the lives of people with ALS and their families.

For further information on this and other legislation of importance to people living with ALS and their families, please contact Kathleen Sheehan, Vice President for Public Policy, The ALS Association at ksheehan@alsa-national.org/(202) 464-4684 or visit our website at www.alsa.org.



Our Vision
Create a world without ALS.
Our Mission
To discover treatments and a cure for ALS, and to serve, advocate for,
and empower people affected by ALS to live their lives to the fullest.



Testimony for the Written Record

Hearing of July 20, 2017

Subcommittee on Health

Committee on Energy and Commerce

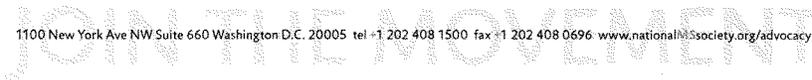
United States House of Representatives

"Examining Bipartisan Legislation to Improve the Medicare Program"

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

Thank you for this opportunity to submit testimony for the written record on behalf of the National Multiple Sclerosis Society (NMSS, the Society) on the issue of Medicare outpatient therapy caps discussed during the Committee's hearing, "Examining Bipartisan Legislation to Improve the Medicare Program." Our testimony focuses on the experiences of Medicare beneficiaries living with multiple sclerosis (MS) and their need for access to rehabilitation therapies including skilled physical, occupational and speech/language services. Additionally, we offer the Society's observations as advocates of Medicare beneficiaries living with MS regarding Medicare policies that can limit beneficiaries' access to them, particularly as they relate to medically necessary rehabilitation therapies.

The Society mobilizes people and resources so that everyone affected by multiple sclerosis can live their best lives as we stop MS in its tracks, restore what has been lost and end MS forever. To fulfill this mission, the Society funds cutting-edge research, drives change through advocacy, facilitates professional education, collaborates with MS organizations around the world, and provides services designed to help people with MS and their families move their lives forward. Last year alone, through our comprehensive nationwide network, the Society devoted \$122.2 million to help more than one million individuals connect to the people, information and resources they need. To move closer to a world free of MS, the Society also invested \$54 million to support more than 380 new and ongoing research projects around the world.



Multiple sclerosis is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted, and a person with MS typically experiences the same approximate life expectancy as those without the disease. These facts and more make the challenge of planning for one's future medical, mobility, housing, transportation and quality of life needs highly complex. The lifetime financial cost of MS, including both direct and indirect cost of the disease, has been estimated at \$1.2 million. Fortunately, advances in research and treatment are leading to better understanding of the disease and are moving us toward a world free of MS.

The Role of Rehabilitation in Quality MS Care

From the time of diagnosis onward, rehabilitation specialists provide education and strategies designed to promote good health and overall conditioning, reduce fatigue, and help those living with the disease to feel and function at their best. If symptoms begin to interfere with everyday activities, rehabilitation can address problems with mobility, dressing and personal care, driving, functioning at home and work, and participation in leisure activities. Rehabilitation experts can also provide evaluation and treatment of speech and swallowing difficulties, and problems with thinking and memory. Notably, some rehabilitation therapists choose to specialize in treating people with MS, and enjoy the process of developing expertise in the challenging and unique needs of this population of patients. The Society strongly encourages clinicians in training to consider specializing in MS through fellowship programs, targeted research, educational resources and more.

The goal of rehabilitation therapy in the treatment of MS is to improve and maintain function. For people living with MS, achieving that goal often means maintaining the ability to stay employed, to walk without assistance, drive a car, run a household or live independently in the home of one's choice. As such, the role of rehabilitation for a person with MS is different than it is for a person recovering from an injury or surgery, whose treatment progress is generally characterized by improved mobility, the obvious restoration of function, and reduced pain. By comparison, successful rehabilitation therapy for a person with MS is characterized by slowing the functional deterioration associated with disease progression, or simply stated, not getting worse. As a result, payers and others unfamiliar with MS often fail to appreciate the value of professional rehabilitation therapy in quality MS care, resulting in un-informed decisions to limit benefits or unrealistic criteria as a condition for authorizing additional treatment.

Medicare Benefits for Outpatient Rehabilitation Therapies

Medicare is the primary source of health coverage for roughly one half of all people in the U.S. currently living with MS. (Malachy, 2017) Preliminary results of a recent study of working age individuals with MS (between the ages of 18 and 65) revealed over 30% relied on Medicare for their access to care. The population of people under age 65 qualify for Medicare because they have been determined to be disabled by the Social Security Administration, and have been receiving Social Security Disability Insurance payments for at least 24 months. As such, they are no longer able to work at their previous capacity, and are more likely to have severe disease and complex care needs, often compounded by other health conditions.

Rehabilitation therapists specializing in MS report that most of the Medicare beneficiaries they treat for the effects of MS do not have trouble in obtaining coverage for the full amount of physical, occupational and/or speech pathology services they need. But certain individuals present clinicians with extraordinary needs and face major obstacles to medically necessary treatments due to one or more current Medicare coverage policies.

The current annual limit on outpatient therapy services is insufficient for certain Medicare beneficiaries with MS. For example, Travis G. is a 43-year-old father of two from Minnesota who lives with advanced MS. His case illustrates the harsh impact the \$3,700 cap on physical and/or speech pathology services can bring to a person with MS. As Travis' upper body has weakened over the years, his ability to chew, swallow, speak and breath properly has declined, putting him at high risk of choking and aspiration pneumonia from food particles entering his lungs. The risk of these rare but life-threatening effects of MS can be minimized through a therapy program to strengthen ventilatory muscles and enhance respiration. In recent years however, Travis has been hospitalized numerous times for aspiration pneumonia after his therapy was stopped as he reached the annual limit on benefits. When asked about documenting his case and the need for additional therapy benefits to continue his therapy, his physical therapist reported she has been un-successful despite repeated attempts and concerted efforts. Although Travis tends to reach the capped level during the summer or fall of every year, his therapist now routinely provides a limited amount of treatment to him on a pro bono basis. Nonetheless, Travis still experiences emergencies requiring ER visits every summer or fall.

The combined annual limit of \$3,700 for physical therapy (PT) and speech-language pathology (SLP) *in combination* exacerbates the problem of arbitrary dollar limits even more. Not only is the amount insufficient for certain individuals with unusually high-cost needs, the fact that it is imposed as a cap on physical or speech/language pathology alone or in combination leads beneficiaries to choose one need over the other, and often without a full understanding of the implications. Speech-language pathologists report cases involving Medicare beneficiaries with MS who realize and act on their need for speech pathology services only to learn they have

used up their annual allotment of covered therapy on physical therapy. Their only option is to pay out of pocket for speech pathology, delay treatments until the new year, or go without these needed treatments altogether.

As mentioned, most Medicare beneficiaries with MS are adequately served through the current amount of rehabilitation benefits allowed within a single year, but exceptional cases do exist. These must be considered and accommodated to assure beneficiaries have access to medically necessary therapies. The common scenarios in which the current limits adversely impact people with MS include:

- Individuals like Travis who live with severe forms of MS, or in advanced stages of the disease;
- People who experience severe exacerbations of the disease, or new and unexpected symptoms that require extraordinary amounts of therapy immediately in an attempt to slow deterioration and restore as much function as possible;
- Beneficiaries that suffer heart attacks, strokes or injuries unrelated to their MS who require other types or courses of rehabilitation therapy for that condition in addition to their MS.

The Society has been a longtime supporter of the exceptions process to enable those with greater needs to receive necessary and timely treatment. Yet the current system is meaningless if beneficiaries with extraordinary needs for care that exceed the cap limits cannot rely on reasonableness when making their case for requesting additional services. The time has come for Medicare to implement permanent and improved patient-centered processes for obtaining medically necessary outpatient therapies so that none will suffer the way Travis, his family and providers now do.

Medicare Improvement Standard

While not a subject of the committee's July 20th hearing, the other major impediment to adequate coverage of rehabilitation therapies in the Medicare program has been the so-called "improvement standard." Stemming from an erroneous interpretation of Medicare law, for years Medicare carriers denied coverage of prescribed rehabilitation therapies to people with MS and others who were determined not likely to improve with additional therapy. As previously described, people with MS do not "improve" from rehabilitation in the same manner as many other patients. The Society was pleased to be among the organizational plaintiffs in the class action suit 'Jimmo v. Burwell' which resulted in a settlement and Medicare's agreement that "consideration of the need for skilled care, not the potential for improvement, should govern Medicare coverage determinations – for skilled nursing facility, home health, and outpatient therapy." Such determinations continue to this day, and have been the subject of a

second suit against HHS for non-compliance with the settlement. We are optimistic that unwarranted denials of coverage for beneficiaries not likely to improve will cease now that the court has ordered a “corrective action” by CMS, including greater outreach and education about proper coverage determinations. It is important for Committee members and others to understand the impact of the improvement standard as a confounding variable in the administration of Medicare’s outpatient therapy benefits, and help Medicare beneficiaries by encouraging enforcement of the court’s orders. People with MS and their providers are understandably confused by denials for coverage or reimbursement when they could be attributed to the therapy caps, improvement standard, or both. The lack of clear and consistent coverage policy and appeals process creates additional confusion, additional paperwork and administrative burdens for patients, providers and Medicare carriers alike.

Conclusion

The Society urges all members of the Committee to repeal Medicare’s therapy caps by supporting HR 807/S 253, the Medicare Access to Rehabilitation Services Act of 2017 and assure that any replacement of it facilitates access to extraordinary levels of care when necessary. While the exceptions process is imperfect, the Society supports its extension if consensus on an improvement and replacement for it is not possible before the end of 2017.

If you have any questions, please contact the Society’s Director of Health Policy Kimberly Calder at kimberly.calder@nmss.org or 212-476-0450.



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Statement for the Record

July 19, 2017

The Honorable Michael Burgess
The Honorable Gene Green
Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Re: Medicare Therapy Caps

Dear Chairman Burgess and Ranking Member Green:

On behalf of Focus On Therapeutic Outcomes, Inc., (FOTO) I am pleased to submit this statement for the record pertaining to the Medicare Therapy Caps, one of the topics to be addressed by the House Energy and Commerce Health Subcommittee on July 20.

As the leading developer of quality and outcomes measurement systems for outpatient rehabilitation therapies, FOTO serves providers and facilities nationwide. For over eighteen years, FOTO has been developing, improving, perfecting and providing valid and reliable methods for the assessment of function in patients receiving outpatient physical and occupational therapy services. Using data gathered from over 3,900 clinical practice locations, FOTO has developed a robust database of over 3.1 million episodes of therapy and has advanced user-friendly, economical methods for collecting, analyzing and utilizing functional status measures.

FOTO's measures have been endorsed by the National Quality Forum (NQF) and FOTO is a certified registry recognized by the Centers for Medicare and Medicaid Services (CMS) for data collection and transmission in compliance with the Physician Quality Reporting System (PQRS). In 2006, FOTO conducted a feasibility study for CMS entitled "Pay-for-Performance for Physical Therapy and Occupational Therapy: Medicare Part B Services." (Grant #18-P-93066/9-01). The purpose of this project was to implement a pay-for-performance simulation, which would align financial incentives with the achievement of better clinical outcomes. The project was designed to demonstrate the feasibility of implementing a pay-for-performance process in outpatient physical and occupational therapy, provide information to Medicare concerning payment policy for outpatient physical and occupational therapy, and discuss implications for the development of an alternative payment method as required by Balanced Budget Amendment of 1997.

More recently, in September 2015, the American Physical Therapy Association selected FOTO to contribute its outcomes measures as one of the primary global outcomes measures to be used for the Physical Therapy Outcomes Registry. Outcomes are being used to develop new value-based payment models and enable physical therapists to prove their value to payers and enhance patient care. The registry will serve to inform payment for physical therapy services, improve practice, fulfill quality reporting requirements and promote research.

FOTO strongly endorses the bipartisan *Medicare Access to Rehabilitation Services Act* (H.R. 807) which currently has 173 cosponsors. (The Senate companion bill [S. 253] has garnered 26 cosponsors to date). This legislation would permanently repeal the \$1,980/year arbitrary therapy cap imposed on each Medicare beneficiary. Because the current exceptions mechanism expires on December 31, 2017, corrective legislation must be passed before the end of this year.

The Medicare therapy cap was included in the Balanced Budget Act of 1997 and since then has regularly been altered by Congress by the use of waivers or exceptions processes. This is because shortly after passage Congress heard from Medicare beneficiaries all over the country who were adversely affected by this provision.

This therapy cap was part of a budget gimmick that solved a government budget problem but created a health policy nightmare for seniors most of whom have more than three chronic conditions. Physical therapy is the solution to keeping these individuals functioning independently, enjoying their lives and contributing to society.

There are numerous ways to repeal this outdated policy and replace it with contemporary methods utilized in the private sector in the 21st century. These include recognized and accepted practices that were embraced in a Senate amendment (introduced by Sen. Ben Cardin in 2015) that garnered the bipartisan support of 58 senators (thus falling just two votes shy of the 60 vote threshold required during that debate). These include:

- Per episode (rather than per year) limits with continuation allowed upon demonstration of progress toward rehabilitation goals
- Automatic exceptions for patients who need more than one type of rehabilitation therapy (e.g., physical and speech therapy)
- Targeted medical review of therapy services
- CMS monitoring of medical reviewers for accountability
- Prior authorization of services in certain circumstances
- Mandatory objective reporting on the patient's **physical function** upon patient intake and patient discharge from a course of outpatient therapy services to demonstrate effectiveness of services received
- Improvement of data collection on patient function during course of outpatient therapy services. This should include updating of the functional limitation reporting currently required but not being utilized by Medicare to perform predictive analytics which contemporary methods now make possible.

FOTO commends Chairman Burgess and the Energy and Commerce Health Subcommittee for holding this July 20 hearing and for your leadership efforts to relieve this burden from the Medicare beneficiaries who are so unfairly impacted by the current law. And we urge Congress to use the important findings from FOTO's pay-for-performance feasibility study conducted for CMS to implement an effective and updated therapy policy that allows our nation's seniors to access the type and amount of care that enable them to achieve and maintain optimal function.

Thank you for your consideration of our comments. FOTO stands ready to work with Congress and CMS in any constructive way to advance the most cost-effective and sound policy with respect to this old policy that negatively impacts thousands of Medicare beneficiaries every year.

Sincerely,



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NARA
The National Association of
Rehabilitation Providers and Agencies

**STATEMENT FOR THE RECORD
of the
NATIONAL ASSOCIATION OF REHABILITATION PROVIDERS AND
AGENCIES**

**Committee on Energy and Commerce
Subcommittee on Health
Hearing on “Examining Bipartisan Legislation to Improve the Medicare Program”
July 20, 2017**

The National Association of Rehabilitation Providers and Agencies (“NARA”) commends and thanks the Subcommittee on Health for conducting this hearing on bipartisan legislation to improve the Medicare program. In particular, NARA urges Congress to enact legislation repealing the outpatient therapy caps on physical therapy, outpatient therapy, and speech-language pathology services established 20 years ago in the Balanced Budget Act of 1997. Since they were implemented, Congress has had to act sixteen times to prevent them from harming Medicare beneficiaries who require rehabilitative services, particularly those who are most in need of such care—e.g. individuals with chronic diseases or serious injuries. NARA respectfully submits that the time has come to repeal the therapy caps and replace them with a viable, efficient, and fair medical review policy which ensures that Medicare beneficiaries who require rehabilitation services are able to secure them.

NARA is a professional association which represents Medicare-certified rehabilitation agencies that furnish physical therapy, occupational therapy, and speech-language pathology services to hundreds of thousands of patients across the nation. Rehabilitation providers who are members of NARA retain the services of over 45,000 health care professionals who provide skilled therapy services in multiple settings including inpatient, outpatient, skilled nursing, assisted living, education systems, occupational health settings, and, of course, in home health agencies.

The outpatient therapy caps impose an annual limit in 2017 of \$1,980 per beneficiary for occupational therapy services and a combined cap of \$1,980 for both speech therapy and physical therapy services in all Part B practice settings including rehabilitation agencies, skilled nursing facilities, long term care facilities, and hospital outpatient departments (critical access hospitals excluded). The therapy caps are an arbitrary approach to controlling the cost of rehabilitative care. They bear absolutely no relation to the therapy needs of individual patients nor do they in any way take into account the value and quality of the services provided to Medicare beneficiaries. Furthermore, the therapy caps frequently reduce patient access to rehabilitation services by limiting their choice of providers, rationing their care to avoid

exhausting their benefits, or by forcing them to bear 100% of the cost of care once they exceed the applicable cap.

Incontrovertible data demonstrate that beneficiaries who fail to receive medically necessary rehabilitation care are more likely to require higher-cost interventions to remain functional. It is also beyond quibble that patients who have chronic or complex health challenges (e.g. a stroke, hip fracture, or multiple disabilities) are most likely to be injured by the therapy caps.

Recognizing the draconian impact which the therapy caps may have on Medicare beneficiaries, Congress has passed legislation 16 times in an effort to protect patients—first through a series of moratoria on the caps and then through numerous iterations of an exceptions process. While the exception processes have afforded a modicum of relief from the full brunt of the therapy caps, they have certainly not proven to be an efficient and effective mechanism. For example, three years ago Congress authorized the Centers for Medicare and Medicaid Services to establish a manual medical review process for patients who exceed the therapy cap through the exceptions process. This process, however, has been inconsistently applied and, for the most part, has materially hindered the delivery of needed services. Delays in authorization and inconstant criteria by intermediaries to obtain authorization have been widespread.

Statutory authority for the current exception process expires on December 31, 2017 and unless Congress takes action, the full force of the arbitrary therapy caps will impact Medicare beneficiaries in 2018. Now is the perfect time for Congress to bring an end to twenty years of moratoria and exceptions processes by repealing the outpatient therapy caps. Bipartisan legislation to do precisely that has been introduced in both the House and Senate. The Medicare Access to Rehabilitation Services Act, H.R. 807, has 177 cosponsors and its companion measure, S. 253, has 26 cosponsors. This straightforward legislation would repeal the therapy caps for outpatient physical therapy, occupational therapy, and speech language pathology services. NARA, in the strongest possible terms, urges passage of this critical legislation.

NARA supports the written testimony of Justin Moore, PT, DPT, the Chief Executive Officer of the American Physical Therapy Association which he submitted on behalf of APTA, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association. NARA also looks forward to working with this Congress to craft a permanent solution to the two decade-old challenges presented by the therapy caps.



Statement of the
National Association for the Support of Long Term Care
House Energy & Commerce Committee, Health Subcommittee Hearing
“Examining Bipartisan Legislation to Improve the Medicare Program”
July 20, 2017

The National Association for the Support of Long Term Care (NASL) represents providers and suppliers of ancillary services serving patients in long term and post-acute care (LTPAC) settings. NASL members include rehabilitation therapy companies that employ more than 300,000 physical therapists, occupational therapists, and speech-language pathologists who furnish rehabilitation therapy to hundreds of thousands of Medicare beneficiaries in nursing facilities and other care settings along the long-term care continuum. NASL members include providers of clinical laboratory services, portable x-ray/EKG and ultrasound, complex medical equipment and other specialized supplies for the LTPAC sector. Other NASL member develop and distribute health information technology (IT) including full clinical electronic medical records (EMRs), billing and point-of-care IT systems and other software solutions that serve the majority of LTPAC providers. NASL is proud to be a founding member of the LTPAC Health IT Collaborative, which formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders. NASL is also a long standing active member of the Therapy Cap Coalition and fully supports the efforts of the Therapy Cap Coalition over the years to work to end this policy for the patients we serve.

NASL is pleased to submit a statement for the record of the Committee’s hearing on **“Examining Bipartisan Legislation to Improve the Medicare Program.”** The Committee’s focus on Medicare Part B services is of particular interest to NASL as our members deliver these services for America’s seniors and individuals with disabilities.

NASL thanks Chairman Burgess, Vice Chairman Guthrie and Ranking Member Green for inviting NASL Vice President and Diagnostic Testing Committee Chair Alan Morrison to testify today. We wish to associate ourselves with Mr. Morrison’s written statement regarding the clinical laboratory bundling proposal and will focus the remainder of our statement on the Part B therapy benefit.

NASL appreciates the bipartisan support for repeal of the arbitrary Part B therapy caps, which have the potential to negatively affect the lives of many of our most vulnerable citizens. Medicare beneficiaries do not have an effective way to voice their concerns on the arbitrary caps on their care. Our therapists treat patients in the more than 1.5 million patients in nursing facilities and other settings and bring their patient’s voice in advocating for their care. NASL thanks Representatives Erik Paulsen (R-MN), Ron Kind (D-WI), Marsha Blackburn (R-TN), and

Doris Matsui (D-CA) for championing repeal of the therapy caps by introducing H.R. 807, *Medicare Access to Rehabilitative Services Act*. The Senate companion legislation has been introduced by Senators Ben Cardin (D-MD), Dean Heller (R-NV), Susan Collins (R-ME), and Bob Casey (D-PA). We are encouraged by the leadership that members of this Committee and others in Congress have demonstrated in working on policies that protect beneficiary access to the Part B outpatient therapy benefit, while refraining from undue administrative and regulatory burden on providers.

NASL members treat patients who are most vulnerable to these therapy cap policies as evidenced in CMS claims information and in a data analysis project NASL completed in 2011. Patients relying on the 24-hour and 7-day a week care in the nursing facility are sicker, and most likely to be female. Nursing facility patients are more likely to have chronic conditions including Alzheimer's, chronic kidney disease, COPD and diabetes. Most importantly, our patients are more likely to need therapy above the caps & threshold¹. The data analysis indicates that of the SNF patients receiving Part B outpatient therapy, 31% of patients exceeded the PT/SLP cap while 71% exceeded the OT cap. Additional percentages exceeded the thresholds. The therapy cap policies discriminate against the sickest and those needing therapy the most and it imposes undue burden on both patients and providers. Considering the known research and based on our history of service to the most vulnerable Medicare beneficiaries, ***NASL supports repeal of the arbitrary Part B Therapy Cap. We support replacing the cap with policies that protect beneficiary access to their Part B Outpatient Therapy benefit, allow the continuity of care and that do not impose an undue administrative and regulatory burden on providers. Given the challenges that may exist with repeal of the therapy cap, and absent Congress enacting repeal, we must have an extension of the exceptions process to preserve patient access to their therapy benefit. We recognize the exceptions process is not a long-term solution, it is an essential policy floor protecting beneficiaries by assuring access to required therapy services.***

Background on the Medicare Part B Outpatient Therapy Benefit

Medicare Part B pays for outpatient therapy including the distinct disciplines of physical therapy, occupational therapy and speech language pathology. Physical therapy (PT) restores and maintains physical function and treat or prevent impairments that result from disease, surgery or injury. Occupational therapy (OT) improves and compensates for a patient's ability to conduct activities of daily living, such as dressing, bathing, eating and toileting and the cognitive processes to complete these activities. Speech language pathology (SLP) services help patients with difficulties communicating and or swallowing because of disease, injury or surgery as well as the cognitive requirements of memory, decision-making, language and functional communication.

¹ NASL engaged The Moran Company to undertake a data collection and analysis of Part B therapy claims data in 2011.

Outpatient therapy services are covered under Medicare Part B and to receive services, a beneficiary must be referred by a physician or nonphysician practitioner. Medicare regulations and coverage rules require that the beneficiary's medical record include a written plan of treatment with information on diagnosis and therapy goals.

Part B outpatient therapy is provided in many different settings including nursing facilities, hospital outpatient departments, physicians' offices, outpatient rehabilitation facilities, and comprehensive outpatient rehabilitation facilities, as well as by therapists in private practice and home health agencies. Approximately 70% of rehab therapy services are provided in private offices and nursing facilities.² **All settings use the same CPT codes and are subject to the same payment policies — despite patients being treated in these various settings having a wide range of acuity levels and medical needs.**

Because the patients our members treat are often among the sickest with several chronic diseases and comorbidities and most in need of rehabilitative care, they often reach the cap more quickly than those who are living at home and who may receive outpatient therapy in a physician's office. Unlike those who may live independently and speak on their own behalf, many patients we serve have progressive complex conditions that render them unable to provide for themselves and are best treated in this setting. Among those most in need of rehabilitation services are those who required rehabilitation to assure comfort and safety during the end stages of life. Others may be in need of care to assure a safe and functionally independent transition to home. In either case and for any number of those in need of medically necessary rehabilitation to attain a safe and independent discharge from the need for additional Medicare Part B rehabilitation services, we ask that you remove the arbitrary financial cap that can compromise successful completion of the planned care or may increase potential for premature return to the hospital.

The Value of Rehabilitative Therapy: Maintenance and or Improvement

The three distinct disciplines of PT, OT and SLP in a program of rehabilitative therapy work to maintain or improve patient's functional abilities for self-care and mobility and work to help patients with their activities of daily living such as dressing, bathing, toileting, transferring (walking and moving), food preparation and self-feeding, problem solving, functional communication and personal safety. These therapies play an important role in assessing and improving cognitive abilities. The Supreme Court recognized the importance of therapy in maintaining function in the recent decision, *Jimmo v. Sebelius* and preventing deterioration of function for patients.

CMS began several years ago an effort to assess and collect data on function for patients receiving Part B outpatient therapy. Providers are required to report functional data in the form

² MedPAC Payment Basics: Outpatient Therapy Services Payment System. Retrieved from http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_opt_final.pdf?sfvrsn=0

of "G-codes" on the claim form as a requirement for reimbursement. CMS requires therapists to choose a test that best matches one of the goals of the patient's therapy and fit the results of that test into CMS's scale of 1-7. CMS has collected the "G-codes" since 2013 and has never released the data. At best, this data is not scientific. It certainly contrasts with the standardized quality data developed as mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) to be collected by SNFs, IRFs, LTCHs and HHs. Absent scientific data capture and or reports from CMS, our members have undertaken an effort to self-assess the outcome and functional changes in the patients we serve.

History of Therapy Cap Payment Policies

Medicare Therapy Caps took effect in 1999 under the Balanced Budget Act of 1997 (BBA). There are two caps, one cap that limits the dollar amount of PT and SLP services combined to \$1,980³ for 2017. Another cap limits OT services to \$1,980 per person during 2017. In 2006, Congress established an exceptions process that allows an exception to the cap when a patient's condition/medical circumstances warrant additional medically necessary therapy above the caps. The exceptions process requires reauthorization by Congress and Congress has extended it many times since 2006. The current exceptions process expires on December 31, 2017.

Congress imposed an additional therapy cap policy in *The Middle Class Tax Relief and Job Creation Act of 2012*, enacted in February 2012. The Act required CMS to conduct manual medical review (MMR) of requests for exceptions for therapy claims over an annual threshold of \$3,700 for OT and \$3,700 for PT and SLP services combined on or after October 1, 2012. A GAO report on the 2012 MMR process was also required⁴. The GAO report studied the first three months of the program and detailed many problems with the preapproval process.

CMS Institutes Program of Preapproval for Services

CMS implemented the MMR program in September 2012 and it was clear very early that the MACs could not handle the process. Providers submitted requests for preapproval for therapy services above the \$3,700 threshold. Providers were permitted to request up to 20 days of treatment up to 15 days before providing the services above \$3,700. Preapproval requests could only be submitted by U.S. Mail or by facsimile. To expedite the preapproval process, CMS instructed the MACs to review preapproval requests within 10 business days of receipt of all requested documentation to determine whether the services were medically necessary. NASL received multiple reports from providers across the nation that when providers submitted

³ Statute provides for an inflationary increase in the therapy cap amount each year as announced in the annual CMS Physician Fee Schedule.

⁴ GAO: Medicare Outpatient Therapy, Implementation of the 2012 Manual Medical Review Process. July 2013. Report to Congress. Retrieved from <http://www.gao.gov/assets/660/655806.pdf>

their documentation package to the MACs, often additional documentation requests would come from the MACs before the 10th day effectively stopping the clock on the medical review while the provider mailed or faxed in more documentation. Because much communication was by US mail, there were delays in communication. Also, MACs were not prepared with sufficient number of fax machines to receive the large paper medical records they were requesting from providers. This is especially important to patients in nursing facilities because they cannot wait weeks for approval of the rehab therapy that they need immediately. In fact, a delay in treatment such as those we have described have the potential to reverse progress already achieved.

The GAO report detailed that during the first three months of this preapproval review, MACs were overwhelmed by the volume of what they needed to review, they did not receive guidance from CMS timely to institute it, MACs were unclear how to count the 10-day time frame, the MACs were not prepared for the volume of paper files they had to manage which created a lag time for their response, MACs did not fully automate systems to receive and track preapproval requests in the time allotted. CMS staff estimated that the MACs reviewed more than 167,000 preapproval requests in a three-month period, affecting more than 115,000 Medicare beneficiaries. The GAO report stated, "Both CMS officials and MAC staff acknowledged that the MACs were not able to process all the preapprovals submitted in a timely manner."⁵

CMS Moves the MMR to Other Contractors

CMS moved the MMR process to the RACs, contractors that ordinarily do not approve services before they are provided and current RAC contracts were utilized. Then, through the *Medicare Access & CHIP Reauthorization Act (MACRA)*, Congress enacted two important changes to therapy cap policies. *MACRA* changed the manual medical review of all claims above the \$3,700 threshold to a system of *targeted* medical review of claims above the \$3,700 threshold. Also, it mandated that entities other than RACs could perform the reviews. Subsequently, CMS contracted with a Supplemental Medical Review Contractor to undertake the reviews. These targeted medical reviews continue to today. In deciding which services to target for review, CMS may consider services furnished by providers with high claims denial rates, patterns of billing that are aberrant compared with their peers, or other factors.

Lessons Learned: The Impact of the Preapproval Process on Patients and Providers

The impact of the preapproval process/ prior authorization of services that began in 2012 is that it delays necessary care which places patients at risk, decreases patient satisfaction and increases provider cost through inefficiencies. It's a well-meaning system, but using the U.S. Mail and fax machines – experience shows the system as it stands today cannot respond quickly enough for care decisions—especially for the highest acuity patients-- that need to be

⁵ GAO: Medicare Outpatient Therapy, Implementation of the 2012 Manual Medical Review Process. July 2013. Report to Congress. [GAO-13-613 Outpatient Therapy Manual Reviews](#) page 19.

made for patients in nursing facilities. If these patients have to wait several days for therapy to be approved, their functional levels can and will decrease. Consider the cognitively intact and independent patient who has a severe accident. On a fixed income, this person had to be told that the provider was waiting for approval from Medicare to continue treatment. Suddenly, he must decide to remain in the SNF and hope Medicare approves treatment, consider paying for treatment out of dwindling savings or request to be discharged and hope that he can be "safe enough" on his own at home. None of these options are optimal nor should any Medicare beneficiary have to experience this. There is ample evidence that older adults are at risk for further decline in mobility and other activities of daily living, often leading to the need for hospitalization, when therapy services are delayed (and/or interrupted).

During the preapproval process time, it was very confusing for providers and beneficiaries with different MACs using different procedures across the country. Medicare beneficiaries receiving rehab therapy services in nursing facilities such as those who were temporarily disabled but cognitively aware were not aware of the MMR process and continued to be confused regarding the differences in the types of plans they have as well as what the coverage is and what the processes were.

Here are some examples of what happens with the beneficiary when they are facing the stoppage of care under a preapproval process. Under MMR, nursing facility patients were progressing to complete a course of therapy treatment only to be told that Medicare hadn't approved continued treatment and providers were waiting for permission to proceed. The patient doesn't understand that approval is needed once the doctor prescribes the treatment. The beneficiary needs to focus on treatment and healing had to ask themselves the question: should I continue with agreement to private pay or continue paying room & board and agree to pay for treatment if Medicare doesn't provide approval?

Also, patients who were progressing in their therapy treatment plan and wanted to complete treatment to exit the system and return home found themselves having to increase the overall time in treatment and/or personal costs while waiting to return to the community and improved level of independence, no longer draining the system.

It is important to consider the special case of patients receiving rehab therapy in facilities such as skilled nursing facilities, nursing facilities and rehab hospitals. These patients need skilled therapy services at the moment of recognized decline or change in condition. They cannot afford the time to wait for prior authorization and then schedule an evaluation with therapy. This may work for other settings like outpatient private practice physical therapy where the treatment they need is not critical or urgent.

NASL Recommendations:

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NASL recommends that policies enacted by Congress should build upon the lessons learned from the previous and current medical review programs and consider what is best for patient access and not creating undue provider burden in providing the rehab therapy benefit.

In creating policy, Congress needs to be cognizant that the therapy cap policies it enacts are a one size fits all for the wide range of acuity of patients receiving therapy services in various Part B outpatient settings. Policies that may work for patients in one setting may not work for the patients in other settings, yet patients are subject to the same policies.

NASL recommends that Congress repeal the caps and in their place, enact a targeted program of review of services for medical necessity. NASL members support providing only medically necessary therapy. NASL recommends these Guiding Principles including elements for programs of medical review:

1. Must provide for and protect patient access to care and allow for continuity of care
 - a. Must allow for special consideration for providers and practices who work with critically complex conditions.
 - b. Maintain beneficiary protections and limitations to preserve beneficiary and provider appeal rights
2. Accountability for providers who consistently over-utilize while minimizing the administrative burden of Medicare audits and reviews
 - a. Continuation of current targeted medical review for those providers who were found to have consistently high utilization and aberrant billing patterns
3. Enhance transparency
 - a. Require that Medicare review contractors provide information to providers who receive denials and mandate GAO assess contractor performance
 - b. Direct the Secretary to make electronic submission of information available within 6 months after enactment
 - c. CMS to report on findings of targeted medical review process
4. Alignment of therapy cap alternative policy with current quality and value-based initiatives
 - a. Exemptions for participation in the merit-based incentive payment system and alternative payment models
5. Align data collection with other efforts already underway such as the IMPACT Act regarding reporting of outcomes.

NASL opposes prior authorization or preapproval of services because this type of review interferes with the physician/NPP-patient relationship and clinical decision-making, risks access to care, and can result in delayed or incomplete treatment plans, increasing risk for re-admission to the system and higher overall costs. If Congress were to institute a program of prior authorization or preapproval review, NASL recommends:

1. CMS should be mandated to create a refined and proven system of pre-approval that can provide timely *i.e.* 24-hour responses or no more than 3 days to authorize requests to avoid any delay in care and only when CMS can certify that it has such a process/structure ready, should it be deployed. In setting up such a system, CMS should be required to institute electronic means for providers to submit required documentation along with a system that allows providers to verify that documents were received and the status of the review.
2. Review should be based on clinical best practice and known standards of care, not an arbitrary dollar amount.
3. CMS must be provided adequate funds, technology and resources to be able to manage and promptly address the requests.
4. Beneficiaries as well as providers need to be educated to this Medicare Policy Change, potential costs and timelines.

Conclusion

NASL thanks the Committee for holding the hearing to highlight these important issues. NASL is dedicated to working with the committee and others in Congress to repeal the therapy caps and put in place the right policies that keep the patient at the center and protect beneficiary access to the Part B Outpatient Therapy benefit. We believe new policies should also provide for continuity of care and should not impose an undue administrative and regulatory burden on providers. Absent Congress enacting repeal, we must have an extension of the exceptions process to preserve Medicare beneficiary access to their outpatient therapy benefit.

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Energy and Commerce Health Subcommittee
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July 20, 2017
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PRIVATE PRACTICE SECTION, APTA



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July 19, 2017

Honorable Mike Burgess, Chairman
Honorable Gene Green, Ranking Member
Health Subcommittee – Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Re: Medicare Therapy Cap – Hearing July 20, 2017

Dear Chairman Burgess and Ranking Member Green:

The Private Practice Section (PPS) of the American Physical Therapy Association urges Congress to consider and pass legislation that would provide relief for the thousands of Medicare beneficiaries who are unfairly and negatively affected by the arbitrary per beneficiary therapy cap each year.

The over 4200 members of PPS own and operate small businesses that provide convenient, cost-effective rehabilitative therapy to patients across the spectrum of impairments and functional limitations secondary to neurologic and/or musculoskeletal conditions. The PPS endeavors to foster the growth, economic viability, and business success, of physical therapist-owned physical therapy services provided for the benefit of the public.

The PPS has strongly endorsed the bipartisan *Medicare Access to Rehabilitation Services Act* (H.R.807) which currently has 177 cosponsors. (The Senate companion bill [S.253] has garnered 26 cosponsors to date). This legislation would permanently repeal the \$1,980/year arbitrary therapy cap imposed on each Medicare beneficiary. Because the current exceptions mechanism expires on December 31, 2017, corrective legislation must be passed before the end of this year.

The Medicare therapy cap was included in the Balanced Budget Act of 1997 and since then has regularly been altered by Congress by the use of waivers or exceptions processes. This is because shortly after passage Congress heard from Medicare beneficiaries all over the country who were adversely affected by this provision.

They heard from seniors such as 89-year old Libby Frank living with her husband in Philadelphia who wrote:

I have both rheumatoid arthritis and osteoarthritis. I have been going for helpful physical therapy for years – and the more I go, the better I'm able to manage my life.

I have had to stop therapy in the past when the [Medicare therapy] cap kicked in. My health suffered.

We live independently in a comfortable apartment. Without the therapy and the exercises prescribed by the therapist, it is not likely we could remain independent. The handicaps would control my life. The only option would be a wheel chair in a nursing home which would cost money from public funds – and cut short our long active life.

Chairman Mike Burgess
 Ranking Member Gene Green
 July 17, 2017 -- Page 2

This therapy cap was part of a budget gimmick that solved a government budget problem but created a health policy nightmare for seniors most of whom have more than three chronic conditions. Physical therapy is the solution to keeping these individuals functioning independently, enjoying their lives and contributing to society.

There are numerous ways to repeal this outdated policy and replace it with contemporary methods utilized in the private sector in the 21st century. These include recognized and accepted practices that were embraced in a Senate amendment (introduced by Sen. Ben Cardin in 2015) that garnered the bipartisan support of 58 senators (thus falling just two votes shy of the 60 vote threshold required during that debate). These include:

- **Per episode (rather than per year) limits with continuation allowed upon demonstration of progress toward rehabilitation goals**
- **Automatic exceptions for patients who need more than one type of rehabilitation therapy (e.g., physical and speech therapy)**
- **Targeted medical review of therapy services**
- **CMS monitoring of medical reviewers for accountability**
- **Prior authorization of services in certain circumstances**
- **Objective reporting on the patient's function upon patient intake and patient discharge from a course of outpatient therapy services**
- **Improvement of data collection on patient function during course of outpatient therapy services. This should include updating of the functional limitation reporting currently required but not being utilized by Medicare to perform predictive analytics which contemporary methods now make possible**
- **Methods and provisions compatible with the transition to value-based payment programs including Medicare's Merit-based Incentive Payment System (MIPS).**

Congress and the Centers for Medicare and Medicaid Services (CMS) have limped along for 20 years trying to work around this unfair and unworkable therapy cap policy. It is now time to repeal this misguided policy and replace it with workable provisions that allow the seniors in need to receive the care they deserve and to do so in a cost-effective way for the Medicare program. That solution is within reach.

PPS commends Chairman Burgess and the Energy and Commerce Health Subcommittee for holding this July 20 hearing and for your leadership efforts to relieve this burden from the Medicare beneficiaries who are so unfairly impacted by the current law. And we urge thorough, thoughtful action to implement an effective and updated therapy policy that allows our nation's seniors to access the type and amount of care that enable them to achieve and maintain optimal function.

Sincerely,



Terence Brown, PT, DPT
 President, Private Practice Section
 American Physical Therapy Association



July 17, 2017

The Honorable Michael Burgess
 The Honorable Gene Green
 Subcommittee on Health
 House Energy and Commerce Committee
 U.S. House of Representatives
 Washington, DC 20515

Re: Medicare Therapy Caps

Dear Chairman Burgess and Ranking Member Green:

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This therapy cap was part of a budget gimmick that solved a government budget problem, but created a health policy nightmare for seniors most of whom have more than three chronic conditions. Physical therapy is the solution to keeping these individuals functioning independently, enjoying their lives and contributing to society.

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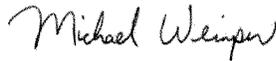
Page 2

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And we urge thorough, thoughtful action to implement an effective and updated therapy policy that allows our nation's seniors to access the type and amount of care that enable them to achieve and maintain optimal function

Sincerely,



Michael Weinper, PT, DPT, MPH
President and Chief Executive Officer



TESTIMONY FOR THE WRITTEN RECORD

FROM THE

COALITION TO PRESERVE REHABILITATION

**SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

BENEFICIARY ACCESS TO MEDICARE OUTPATIENT REHABILITATION THERAPY

HEARING ON

“EXAMINING BIPARTISAN LEGISLATION TO IMPROVE THE MEDICARE PROGRAM”

JULY 20, 2017

COALITION TO PRESERVE REHABILITATION
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Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

Thank you for the opportunity to submit testimony for the written record on behalf of the Coalition to Preserve Rehabilitation (“CPR”) on the issue of Medicare outpatient therapy caps in connection with your hearing entitled, “Examining Bipartisan Legislation to Improve the Medicare Program.” Our testimony focuses on the discussion draft legislation “To amend title XVIII of the Social Security Act to extend the therapy cap exceptions process and manual medical review under the Medicare program” currently contemplated by the House. CPR is a consumer-led, national coalition of forty-nine (49) patient, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain their maximum level of health and independent function. Members of the CPR Steering Committee include the Center for Medicare Advocacy, the National Multiple Sclerosis Society, the Brain Injury Association of America, United Spinal Association, the Christopher and Dana Reeve Foundation, and the Falling Forward Foundation.

The Importance and Value of Rehabilitation

Intensive and ongoing rehabilitation care is vital for individuals with stroke, brain injury, multiple sclerosis, spinal cord injury, amputation and other serious disabilities and chronic conditions to improve their health status, and in the spirit of the recent *Jimmo v. Sebelius* decision, maintain their functional abilities, and prevent deterioration of function. To demonstrate the importance of rehabilitation, on June 27, 2017, CPR Coalition, along with the Habilitation Benefits (HAB) Coalition and the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition jointly hosted a bipartisan Congressional Briefing entitled *The Value Of Rehabilitation And Habilitation Services And Devices In America's Healthcare System*. The briefing was endorsed and sponsored by 60 national organizations, attracted over 200 attendees, and included speakers Senator Tammy Duckworth (D-IL), Representative Glenn Thompson (R-PA), Eric LeGrand (a former Rutgers football star with a spinal cord injury) Roseann Sdoia (a Boston Marathon bombing survivor) Lisa Smith (a mother of a child with developmental disability who uses habilitation therapy), and Gregory J. O'Shanick, MD (President and Medical Director of the Center for Neurorehabilitation Services). The briefing attracted a large number of House and Senate staff interested in the effectiveness of rehabilitation services and devices.



Over 1 million Americans per year experience catastrophic medical events, including over 700,000 strokes, over 400,000 traumatic brain injuries, and over 12,000 spinal cord injuries, all of which necessitate intensive outpatient therapy. Outpatient rehabilitation therapy is a critical component of an overall rehabilitation plan of care for many Medicare beneficiaries, and helps such individuals recover from illness or injury, achieve health and functional status, and live as independently as possible in their homes and communities, rather than in institutionalized settings. For people with disabilities and chronic conditions, outpatient therapy services are vital to avoiding unnecessary and expensive acute care visits and preventing secondary conditions. It has been estimated that almost 70% of Medicare beneficiaries have more than one chronic condition that may require outpatient therapy.

Rehabilitation therapy has demonstrated value in increasing quality and decreasing costs to taxpayers. One study showed that occupational therapy “lead[s] to significant, lasting positive change in bodily pain, social functioning, mental health, composite mental functioning, life satisfaction, and depressive symptomatology (Clark, et. al., 1997, 2012). This intervention approach has also been shown to lead to health care savings that exceed the intervention’s modest costs (Hay, et. al., 2002).”¹ Another study showed that “occupational therapy is the only spending category where additional spending has a statistically significant association with lower readmission rates’ for the three health conditions studied: heart failure, pneumonia, and acute myocardial infarction.”² A third study showed that rehabilitation therapy reduced nursing home admissions.³

Several case study videos produced by the Falling Forward Foundation, a CPR Coalition Steering Committee member and signatory below, further demonstrate the value of rehabilitative therapy. “Cayden” experienced spinal cord injury as a result of a car accident. He was initially paralyzed from the chest down. Thanks to rehabilitative therapy, he is currently walking with no assistance, as well as engaging in rock climbing, golfing and paddle-boarding. “Jason” experienced a

¹ Hart EC and Parsons H, “Occupational Therapy: Cost-Effective Solutions for a Changing Health System,” *American Occupational Therapy Association*, 2015. Available at: <https://www.aota.org/-/media/Corporate/Files/Advocacy/Federal/Fact-Sheets/Cost-Effective-Solutions-for-a-Changing-Health-System.pdf>

² “Health Policy Researchers Find Occupational Therapy is Only Spending Category That Reduces Hospital Readmissions,” *American Occupational Therapy Association*, September 2016. Available at: <https://www.aota.org/Publications-News/AOTANews/2016/Occupational-Therapy-Reduces-Hospital-Readmissions.aspx>

³ “Occupational Therapy Can Reduce Nursing Home Admissions,” *American Occupational Therapy Association*, September 2016. Available at: <https://www.aota.org/Publications-News/AOTANews/2016/Reduce-Nursing-Home-Admissions.aspx>



traumatic brain injury from a bicycle accident, which initially resulted in a loss of memory and motor function. Thanks to rehabilitative therapy, today he is able to work, drive and parent. “Ed” experienced two strokes, initially leaving him paralyzed on his left side. Because of rehabilitative therapy, today he is able to walk, dance and return to work. “Lisa” experienced a spinal cord injury from a horseback riding accident, initially leaving her paralyzed from the shoulders down. Rehabilitative therapy has enabled her to walk with a quad-cane and live independently.

History of the Medicare Outpatient Therapy Caps and Exceptions Process

2017 marks the dubious anniversary of Medicare outpatient therapy cap implementation. In 1997, as a result of the Balanced Budget Act, Congress capped the benefit for Medicare outpatient rehabilitation services (excluding hospital outpatient services until recently, when the caps were applied to these settings as well). The purpose of this policy was to address alleged overutilization of the benefit, limit Medicare spending in order to balance the federal budget, and improve the solvency of the Medicare Trust Fund. Congress established one cap of \$1,500 for physical therapy and speech language pathology services combined, and another \$1,500 cap for occupational therapy services.

Congress later delayed implementation of these caps on multiple occasions by placing a moratorium on their enforcement until 2006. The Deficit Reduction Act of 2005 (DRA) implemented the caps but coupled them with a new “exceptions process” to ensure beneficiary access to vital rehabilitation services for those whose treatment needs exceeded the therapy caps. The therapy caps and exceptions process has been extended numerous times to the present day. In 2017, annual inflation adjustments have brought the therapy cap limits to \$1,980 for each cap. Outpatient therapy “thresholds” of \$3,700 per episode were also established to further limit alleged overutilization. Once a beneficiary exceeds this threshold, Medicare contractors are permitted to perform targeted claims reviews (i.e., audits) of providers who submit these claims.

The Medicare outpatient therapy caps are particularly onerous given the recent *Jimmo v. Sebelius* decision, i.e., that Medicare coverage is available for skilled services to maintain an individual’s function, not only to improve it. Pursuant to *Jimmo*, medically necessary skilled nursing and therapy services (including outpatient therapy) provided by or under the supervision of skilled personnel are covered services by Medicare if the services are needed to improve a beneficiary’s condition, maintain the individual’s condition, or prevent or slow their decline. CPR believes that access to outpatient therapy is essential, and that patients need not demonstrate improvement in order



for skilled services to be covered as reasonable and necessary. The therapy caps and exceptions process significantly complicate compliance with *Jimmo* for Medicare beneficiaries in need of greater-than-average outpatient skilled therapy. Resolution of the therapy cap issue will eliminate obstacles to full and effective implementation of the *Jimmo* decision.

For years, annual extensions of the therapy caps and exceptions process rode along with the annual legislation to fix the Medicare Sustainable Growth Rate (SGR) formula for physician payment, which was a compelling political issue that Congress invariably passed. Now that the physician fee schedule “fix” has been permanently resolved in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), a permanent repeal of the therapy caps is necessary. Whether the caps are repealed permanently or only another short-term fix is possible, the therapy cap fix needs another legislative vehicle. MACRA merely extended the therapy caps exceptions process through December 31, 2017, a necessary but not sufficient step.

If Congress passes no further legislation, the full caps (without the exceptions process) will be imposed beginning in January 2018. Therefore, the CPR Coalition strongly urges Congress to finally resolve the therapy cap issue once and for all before the end of this calendar year.

Permanent Solution is Needed, but the Exceptions Process is an Important Fall-Back Strategy

The current exceptions process provides a relatively effective solution for beneficiaries in need of therapy services that exceed the caps. An extensive list of condition codes determines which patients can receive therapy beyond the cap, as long as the services can be documented as medically necessary. This is a diagnosis-based system that accommodates most beneficiaries in need, but by definition, leaves some beneficiaries to fend for themselves once the cap applies. Still, the exceptions process is certainly better public policy than an arbitrary cap that cuts off access to therapy services when beneficiaries need them most.

The therapy cap exceptions process, however, is not fiscally sustainable over the long term. There needs to be a more comprehensive solution that resolves this perennial problem once and for all. Beneficiaries and providers alike should not be exposed to the uncertainty that accompanies the near-annual process to suspend imposition of the therapy caps as enacted twenty years ago. *The CPR therefore advocates for an outright repeal of the therapy caps, and enactment of a thoughtful replacement policy that ensures patient access.* That said, if Congress is not able to pass a permanent repeal bill by the end of this calendar year, it must extend the current exceptions process so that



Medicare beneficiaries who have outpatient therapy needs that exceed the caps continue to have access to rehabilitation therapy services.

The CPR Coalition understands that the cost of an outright repeal of the Medicare outpatient therapy caps may need to be mitigated through certain CMS procedures to monitor and grant judicious coverage of outpatient therapy. Some of these mitigation strategies have been debated in the context of Senator Ben Cardin (D-MD)'s efforts to help resolve this issue. We address some of these issues below.

Concerns with Prior Authorization and So-Called “Aberrant” Billers

CPR has had reservations with last year’s Senate language to employ the use of prior authorization of claims submitted by “aberrant” billers, i.e., therapy providers that provide a disproportionate amount of services, in its efforts to repeal the therapy caps. Our concerns with this proposal focus on the fact that prior authorization has the potential to dilute the authority of rehabilitation professionals to practice rehabilitation medicine and could lead to significant delays in access to patient care.

Additionally, we are concerned that a focus on “aberrant” billers may misidentify for prior authorization specialty therapy practices that focus on high users of therapy services (i.e., patients with spinal cord injuries, brain injuries, stroke, etc.). That American Occupational Therapy Association (AOTA), American Speech-Language-Hearing Association (ASHA), and American Physical Therapy Association (APTA) (all CPR members and signatories below), in coordination with the Therapy Cap Coalition, have been working to try to address these concerns in revised legislative language. As the committee develops a repeal bill, any provisions targeted at controlling utilization or aberrant billers must include patient protections, so as not to delay patient care, and should not unduly target specialty providers.

Combined PT/SLP Therapy Cap is Arbitrary; Not Based on Medical Necessity

As already stated, Medicare outpatient therapy caps are arbitrary, and are not based on medical necessity. Such caps deny rehabilitative care to beneficiaries who need it most. Additionally, the combined cap of physical therapy and speech-language pathology is problematic as these are distinct clinical services that occur at different times in the continuum of care and address related but separate areas of impairment. For instance, a patient with a stroke might receive extensive physical therapy to



regain mobility but then see the cap limit their ability to obtain services to improve swallowing or the ability to communicate. This example of giving the patient a choice between walking and talking is an oft-cited example of the complicating factors and poor public policy surrounding the therapy caps.

Permanently Removing Therapy Caps Yields Long-Term Cost Savings

Permanently removing the therapy caps is in fact a sound economic decision that will save money for federal taxpayers. Short-sighted denials of additional rehabilitation lead to beneficiaries making partial recoveries, or not maintaining function that would have otherwise not been the case with adequate rehabilitation. This in turn drives up healthcare costs, as these patients require more expensive long-term care in settings such as skilled nursing facilities and nursing homes.

The taxpayer is better served in the long term if Congress invests in lifting the therapy caps and granting access to those in need depending on the severity of their illness or injury. Long-term cost savings will be derived from:

- A reduced need for long-term medical care (e.g., re-admission, nursing care to support daily living, etc.);
- Avoidance of long-term disability; and
- Increased tax revenue from people who are able to return to work.

Further evidence for the economic case for full repeal was provided by a report commissioned by the American Occupational Therapy Association (a CPR member, and signatory below) from the Moran Company. This report looked at patterns in therapy utilization, and compared therapy utilization in 2011 to 2015. The data debunked the common criticism that therapy is over-utilized. The average per beneficiary, Part B therapy spending *decreased by 8%* across all therapy types between 2011 and 2015. This compares to an *increase* of 8% in per overall beneficiary Part B spending.

CPR has long argued that the Medicare outpatient therapy caps are arbitrary and harm beneficiaries most in need of rehabilitation. CPR members believe that outpatient therapy services should be administered in the best interest of individuals needing rehabilitation, rather than on arbitrary limitations on coverage. We therefore wholeheartedly support a permanent repeal of the Medicare outpatient therapy caps, and urge this subcommittee to go beyond simply extending the current therapy



cap exceptions process. However, if a permanent repeal is not possible this year, Congress must pass an extension of the exceptions process to the therapy caps to be in effect next year. We thank the subcommittee for its leadership in addressing this critically important policy for Medicare beneficiaries and appreciate the opportunity to submit this written testimony.

Sincerely,

CPR Steering Committee

Judith Stein	Center for Medicare Advocacy	JStein@medicareadvocacy.org
Alexandra Bennewith	United Spinal Association	ABennewith@unitedspinal.org
Kim Calder	National Multiple Sclerosis Society	Kim.Calder@nmss.org
Amy Colberg	Brain Injury Association of America	AColberg@biausa.org
Kim Beer	Christopher and Dana Reeve Foundation	KBeer@ChristopherReeve.org
Sam Porritt	Falling Forward Foundation	fallingforwardfoundation@gmail.com

Supporting Organizations

Academy of Spinal Cord Injury Professionals
 ACCSES
 American Academy of Physical Medicine and Rehabilitation
 American Association of People with Disabilities
 American Association on Health and Disability
 American Congress of Rehabilitation Medicine
 American Dance Therapy Association
 American Heart Association/American Stroke Association
 American Music Therapy Association
 American Occupational Therapy Association
 American Physical Therapy Association
 American Speech-Language-Hearing Association
 American Spinal Injury Association
 American Therapeutic Recreation Association
 Amputee Coalition
 The Arc of the United States
 Association of Academic Physiatrists
 Association of Rehabilitation Nurses
 Association of University Centers on Disabilities
 Brain Injury Association of America
 Christopher and Dana Reeve Foundation
 Clinician Task Force
 Disability Rights Education and Defense Fund
 Easterseals
 Epilepsy Foundation
 Falling Forward Foundation
 Lakeshore Foundation
 Lupus Foundation of America
 The Michael J. Fox Foundation for Parkinson's Research
 National Association for the Advancement of Orthotics and Prosthetics
 National Association of State Head Injury Administrators



The National Athletic Trainers' Association
National Council for Behavioral Health
National Council on Independent Living
National Disability Rights Network
National Multiple Sclerosis Society
National Rehabilitation Association
National Stroke Association
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America
Uniform Data System for Medical Rehabilitation
United Cerebral Palsy
United Spinal Association



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THE VOICE OF BRAIN INJURY

**Brain Injury Association of America
 Testimony for the hearing record
 United States House of Representatives
 Committee on Energy and Commerce
 Subcommittee on Health
 Examining Bipartisan Legislation to Improve the Medicare Program
 July 20, 2017**

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

The Brain Injury Association of America (BIAA) is the nation's oldest and largest brain injury patient advocacy organization advocating for individuals with brain injury and their families since 1980. BIAA has led the effort in Congress to make rehabilitation accessible to individuals with brain injury. BIAA is pleased to submit testimony in regards to the discussion draft of *H.R. _____, to amend title XVII of the Social Security Act to extend the therapy cap exceptions process and manual medical review under the Medicare program*. BIAA strongly supports permanent repeal of the Medicare outpatient therapy caps.

Traumatic brain injury (TBI) is a misdiagnosed, misunderstood, under-funded neurological disease affecting at least 2.5 million children and adults in the U.S. each year. According to the Centers for Disease Control and Prevention, over 5 million individuals live with a disability as a result of a TBI. Depending on type and severity, brain injuries can lead to physical, cognitive, and psychosocial or behavioral impairments ranging from balance and coordination problems to loss of hearing, vision or speech. Fatigue, memory loss, concentration difficulty, anxiety, depression, impulsivity and impaired judgment are also common after brain injury. Even so-

called “mild” injuries can have devastating consequences that require intensive treatment and long-term care. Often called the “silent epidemic,” brain injury affects people in ways that are invisible. The injury can lower performance at school and at work, interfere with personal relationships and bring financial ruin.

For many people with brain injury, rehabilitation is the single most effective treatment to restore function and arrest, reverse or mitigate disease-causative and disease-accelerative processes subsequent to injury. Rehabilitation is provided in a variety of settings, depending on the needs of the individual, including acute care hospitals, inpatient rehabilitation centers, and nonhospital alternative medical delivery settings, such as residential/transitional rehabilitation programs and day treatment programs. Cognitive rehabilitation is a systematically applied set of medical and therapeutic services designed to improve cognitive functioning. Cognitive rehabilitation can play a key role in treatment and management of behavioral, emotional and psychosocial problems including problems of suicide and substance abuse.

Intensive and ongoing rehabilitation care is vital for individuals with brain injury to improve their health status, and in the spirit of the recent *Jimmo v. Sebelius* decision, maintain their functional abilities, and prevent deterioration of function. To demonstrate the importance of rehabilitation, on June 27, 2017, BIAA through our work with the Coalition to Preserve Rehabilitation, along with the Habilitation Benefits (HAB) Coalition and the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition jointly hosted a bipartisan Congressional Briefing entitled *The Value Of Rehabilitation And Habilitation Services And*

Devices In America's Healthcare System. The briefing was endorsed and sponsored by BIAA, the only brain injury association to do so, and 60 additional national organizations, attracted over 200 attendees, and included speakers Senator Tammy Duckworth (D-IL) and Representative Glenn Thompson (R-PA). BIAA's Medical Director Emeritus, Gregory J. O'Shanick, MD (President and Medical Director of the Center for Neurorehabilitation Services) was a panelist. The briefing attracted a large number of House and Senate staff interested in the effectiveness of rehabilitation services and devices.

Outpatient rehabilitation therapy is a critical component of an overall rehabilitation plan of care for many Medicare beneficiaries. Rehabilitation helps individuals recover from illness or injury, achieve health and functional status, and live as independently as possible in their homes and communities, rather than in institutionalized settings. For individuals with brain injury, outpatient therapy services are vital to avoiding unnecessary and expensive acute care visits and preventing secondary conditions. It has been estimated that almost 70 percent of Medicare beneficiaries have more than one chronic condition that may require outpatient therapy.

This year marks the anniversary of Medicare outpatient therapy cap implementation. In 1997, as a result of the Balanced Budget Act, Congress capped the benefit for Medicare outpatient rehabilitation services (excluding hospital outpatient services until recently, when the caps were applied to these settings as well). The purpose of this policy was to address alleged over-utilization of the benefit, limit Medicare spending in order to balance the federal budget, and improve the solvency of the Medicare Trust Fund. Congress established one cap of \$1,500 for

physical therapy and speech language pathology services combined and another \$1,500 cap for occupational therapy services.

Congress delayed implementation of these caps on multiple occasions by placing a moratorium on their enforcement until 2006. The Deficit Reduction Act of 2005 (DRA) implemented the caps but coupled them with a new “exceptions process” to ensure beneficiary access to vital rehabilitation services for those whose treatment needs exceeded the therapy caps. The therapy caps and exceptions process has been extended numerous times to the present day. In 2017, annual inflation adjustments have brought the therapy cap limits to \$1,980 for each cap. Outpatient therapy “thresholds” of \$3,700 per episode were also established to further limit alleged over-utilization. Once a beneficiary exceeds this threshold, Medicare contractors are permitted to audit providers who submit these claims.

The Medicare outpatient therapy caps are particularly onerous given the recent *Jimmo v. Sebelius* decision. That decision determined that Medicare coverage should be available for skilled services to maintain an individual’s function, not only to improve it. Pursuant to *Jimmo*, medically-necessary skilled nursing and therapy services (including outpatient therapy) provided by or under the supervision of skilled personnel are covered services by Medicare if the services are needed to improve a beneficiary’s condition, maintain the individual’s condition, or prevent or slow their decline.

BIAA believes that access to outpatient therapy is essential and that patients need not demonstrate improvement in order for skilled services to be covered as reasonable and necessary. The therapy caps and exceptions process significantly complicate compliance with *Jimmo* for Medicare beneficiaries in need of greater-than-average outpatient skilled therapy. Resolution of the therapy cap issue will help implement full and effective compliance with the *Jimmo* decision.

For years, annual extensions of the therapy caps and exceptions process rode along with the annual legislation to fix the Medicare Sustainable Growth Rate (SGR) formula for physician payment, which was a compelling political issue that Congress invariably passed. Now that the physician fee schedule “fix” has been permanently resolved in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), a permanent repeal of the therapy caps is necessary. Whether the caps are repealed permanently or only another short-term fix is possible, the therapy cap fix needs another legislative vehicle. MACRA merely extended the therapy caps exceptions process through December 31, 2017, a necessary but not sufficient step.

If Congress passes no further legislation, the full caps (without the exceptions process) will be imposed beginning in January 2018. Therefore, BIAA strongly urges Congress to resolve the therapy cap issue once and for all before the end of this calendar year.

The current exceptions process provides a relatively effective solution for beneficiaries in need of therapy services that exceed the caps. An extensive list of condition codes determines which

patients can receive therapy beyond the cap, as long as the services can be documented as medically necessary. This is a diagnosis-based system that accommodates most beneficiaries in need, but by definition, leaves some beneficiaries to fend for themselves once the cap applies. Still, the exceptions process is better public policy than an arbitrary cap that cuts off access to therapy services when beneficiaries need them most.

The therapy cap exceptions process is not fiscally sustainable over the long term. There needs to be a more comprehensive solution to this perennial problem. Beneficiaries and providers alike should not be exposed to the uncertainty that accompanies the nearly annual process to suspend imposition of the therapy caps as enacted twenty years ago. That's why **BIAA urges an outright repeal of the therapy caps**. That said, if Congress is not able to pass a permanent repeal bill by the end of this calendar year, it must extend the current exceptions process so that Medicare beneficiaries, including individuals with brain injury, who have outpatient therapy needs that exceed the caps continue to have access to rehabilitation therapy services.

BIAA understands that the cost of an outright repeal of the Medicare outpatient therapy caps may need to be mitigated through certain CMS procedures to monitor and grant judicious coverage of outpatient therapy. Some of these mitigation strategies have been debated in the context of Senator Ben Cardin's efforts to help resolve this issue. We address some of these issues below.

BIAA had reservations with last year's Senate language, which sought to employ the use of prior authorization of claims submitted by "aberrant" billers in its efforts to repeal the therapy caps. Our concerns with this proposal focus on the fact that prior authorization has the potential to dilute the authority of rehabilitation professionals to practice rehabilitation medicine and could lead to significant delays in access to patient care.

Additionally, we are concerned that a focus on "aberrant" billers may target specialty therapy practices that focus on high users of therapy services including patients with brain injury. The revised Cardin 2.0 Amendment, currently under discussion in the Senate, does not include prior authorization, which reduces the likelihood of delays in patient access to care and also modifies how "aberrant" billers are defined by accounting for case mix. Both of these provisions are improvements over the original Cardin Amendment.

As already stated, Medicare outpatient therapy caps are arbitrary and are not based on medical necessity. Such caps deny rehabilitative care to vulnerable beneficiaries who need it most, including individuals with brain injury. Additionally, the combined cap of physical therapy and speech-language pathology is problematic as these are distinct clinical services that occur at different times in the continuum of care and address related but separate areas of impairment. For instance, a patient who has a stroke, which is an acquired brain injury, might receive extensive physical therapy to regain mobility but then see the cap limit their ability to obtain services to improve swallowing or the ability to communicate. The choice between walking and

talking is an oft-cited example of the complicating factors and poor public policy surrounding the therapy caps.

Permanently removing the therapy caps is a sound economic decision that will save money for federal taxpayers. Short-sighted denials of additional rehabilitation lead to beneficiaries making partial recoveries or failing to maintain function. This drives up healthcare costs as these patients require more expensive long-term care in settings, such as skilled nursing facilities and nursing homes.

Taxpayers are better served in the long term if Congress invests in lifting the therapy caps and granting access to those in need depending on the severity of their illness or injury. Long-term cost savings will be derived from:

- A reduced need for long-term medical care (e.g., re-admission, nursing care to support daily living, etc.);
- Avoidance of long-term disability; and
- Increased tax revenue from people who are able to return to work.

BIAA has long argued that the Medicare outpatient therapy caps are arbitrary and harm beneficiaries most in need of rehabilitation. BIAA believes that outpatient therapy services should be administered based on medical need, not arbitrary coverage limitations. We wholeheartedly support a permanent repeal of the Medicare outpatient therapy caps and urge this subcommittee to go beyond simply extending the current therapy cap exceptions process.

We thank the subcommittee for its leadership in addressing this critically important policy for Medicare beneficiaries and appreciate the opportunity to submit this written testimony.



July 19, 2017

Testimony of the American Medical Rehabilitation Providers Association (AMRPA)

**To the Energy and Commerce Health Subcommittee Hearing on
“Examining Bipartisan Legislation to Improve the Medicare Program”**

The American Medical Rehabilitation Providers Association (AMRPA) thanks Chairman Burgess, Ranking Member Green, and Members of the Health Subcommittee for holding a hearing to examine bipartisan legislation to improve the Medicare program. AMRPA is the national trade association representing more than 500 freestanding inpatient rehabilitation hospitals and units of general hospitals (IRFs), outpatient rehabilitation service providers, and other medical rehabilitation providers working with hundreds of thousands of patients each year to maximize their health, functional skills, independence, and participation in society.

AMRPA supports the Committee’s efforts to ensure that the Medicare program remains solvent and sustainable for the millions of beneficiaries who rely on Medicare. Access to rehabilitation and therapy services is a key part of the program’s commitment to seniors and persons with disabilities. In general, medical rehabilitation providers must be reimbursed under a sustainable payment system and Congress should prevent additional cuts through regulations that jeopardize providers’ ability to serve Medicare beneficiaries and other patients. AMRPA believes that there are commonsense ways to reform Medicare that will align payment policies with the needs of the program’s beneficiaries, and we look forward to working with the Committee on post-acute care policies that promote access to medically necessary, quality rehabilitative care.

As it relates to legislation currently before this Committee, AMRPA strongly supports a full and permanent repeal of the therapy caps. Arbitrary limits on the dollar value of outpatient therapy services delivered to Medicare beneficiaries complicate the delivery of efficient, coordinated care and decrease the ability of patients to achieve maximum health outcomes. Patients have unique demands for therapy and other rehabilitative services and, like most one-size-fits-all approaches to health care utilization, flat annual caps are disconnected from medical necessity and the realities of delivering rehabilitative care. Differential treatment based on original diagnoses is equally baseless and imposes daunting obstacles for patients seeking medically necessary care.

Congress has acted to prevent full implementation of the caps are by extending the exceptions process thirteen times since it was first enacted. At multiple points in the last decade, Congress has attempted to permanently repeal the therapy caps. Many Members of this Committee have joined bipartisan Members of the House and Senate in cosponsoring legislation to fully repeal the caps. In 2015, Congress passed the Medicare Access and CHIP



Reauthorization Act (MACRA) in order to move away from payment cliffs associated with physician payment which resulted in uncertain payment policies, hurried legislation, and ultimately more administrative cost than comprehensive reform. Permanently repealing this ill-advised policy is in the best interests of patients, providers, and the Medicare program, as well as taxpayers.

Absent full repeal, AMRPA supports extending the therapy caps exceptions process, but believes there is a need to reform the restrictive exemption process particularly in light of the broader shift towards performance-based payment systems. Congress created an exceptions process in recognition of the arbitrary nature of the caps and in an attempt to minimize its adverse impact on Medicare beneficiaries. However, the arduous exceptions process creates stress for patients and imposes a significant administrative burden on providers. Given the inherent uncertainties in the current exceptions process, providers must apprise beneficiaries of the potential that Medicare will not cover therapy, which may dissuade patients from obtaining medically necessary services. For those exceeding the therapy caps, providers must go through bureaucratic review processes and submit excessive documentation. Delays in the manual medical review process further compromises beneficiary access to care. We therefore urge the Committee to support bipartisan proposals to permanently repeal the caps, or move forward with extending the exception process indefinitely.

As Congress considers legislation to address the therapy caps policy, two fundamental principles should provide the underpinning for any new regulatory policy. First, any replacement must protect beneficiary access to critical therapy services. And second, any replacement policies must not impose undue regulatory and administrative burdens on providers. Reverting to past regulatory approaches with well-documented failures cannot be a viable solution. Broad preauthorization policies have been unsuccessful, particularly for patients attempting to access the use of medically necessary therapy services. As outlined in a July 2013 Government Accountability Office (GAO) report that assessed the implementation of medical manual review for Medicare outpatient therapy, the policy proved to be costly at multiple levels.¹ With inadequate guidance from CMS, Medicare contractors struggled to clinically and administratively operationalize the policy. As a result of their inability to fully process the preapproval requests in an efficient or timely manner, providers faced additional burdens and patients suffered the fallout.

Like other aspects of the Medicare payment policy, Congress and the Administration should use the impending expiration of the exception process as an opportunity to make more meaningful and lasting reforms that are deregulatory in nature, reduce costs on providers and

¹ GAO, IMPLEMENTATION OF THE 2012 MANUAL MEDICAL REVIEW PROCESS (Jul. 2013), <https://www.gao.gov/assets/660/655806.pdf>.



thereby the health care system, and simplify the patient experience. Of course, repealing the therapy caps in their entirety would be the most sensible approach. However, reforms that simplify the process for patients without imposing new administrative requirements on providers would be a step in the right direction. Should Congress need to pass a shorter-term delay in order to continue working on outpatient therapy policy, we urge the Committee to make use of that time to meaningfully reform the current policies.

AMRPA appreciates the Committee's leadership on these issues and recognizes Congress' efforts to strengthen the Medicare program and improve its capacity to ensure access to high-quality care for seniors and persons with disabilities. Access to medical rehabilitation is a critical part of this commitment and our membership is committed to work with Congress on this issue. We fully recognize the need for the therapy services to continue, but object to the arbitrary cap thresholds and policy approaches that are unsubstantiated and lacking in evidentiary basis. Twenty years since this policy was first implemented it is time for Congress to reconsider how this flawed payment policy affects patient care and access to medically necessary therapy. We urge Congress to align future proposals with the Merit-based Incentive Payment System (MIPS) and ensure payment for outpatient rehabilitation services appropriately reflects the skill of therapy providers and protects beneficiary access.

Again, AMRPA thanks and commends the Committee's efforts to tackle longstanding challenges within the Medicare program, including the therapy caps policy. We appreciate the opportunity to provide testimony for the hearing record.

COVINGTON

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July 18, 2017

Memorandum

From: Robert Long, Muftiah McCartin, and Thomas Brugato

Re: Overview of IPAB Termination Provisions

This memorandum provides an overview of the statutory provisions governing termination of the Independent Payment Advisory Board (“IPAB”), 42 U.S.C. § 1395kkk. As explained below, a Joint Resolution introduced between January 1 and February 1, 2017, and enacted by August 15, 2017 terminating the IPAB will effectively terminate the statute, because (1) the Chief Actuary’s determination issued in July 2017 did not trigger the statute, and (2) the Chief Actuary will be prohibited from triggering the statute in any future year.

I. Overview of IPAB

The IPAB provisions are designed to limit the growth of Medicare spending. *Id.* § (b). They require the IPAB to propose Medicare spending cuts if the Chief Actuary of the Centers for Medicare and Medicaid Services finds, in any given year, that the projected actual growth rate in Medicare spending will exceed a target growth rate. *Id.* § (c)(3)(A), (c)(6). Although the Chief Actuary is likely required to issue such a determination by April 30 each year, the Chief Actuary has failed to meet that deadline since 2013. *Id.* § (c)(6)(A).¹

If the Chief Actuary determines that the projected growth rate in Medicare spending exceeds the target growth rate set by the statute, the IPAB—or the Secretary of Health and Human Services, if the IPAB has not been constituted (which it has not, as no members have been appointed to it)—must develop a proposal to reduce spending to “at least” the savings target set by the Chief Actuary. *Id.* § (c)(1)-(3). The proposal must be submitted to Congress in January the year after the Chief Actuary’s determination. *Id.* § (c)(3). The Secretary must implement the proposal beginning on August 15 of that year, unless it is revised by Congress. *Id.* § (e)(1).

¹ The Chief Actuary must make the determination “not later than April 30, 2013 and annually thereafter.” *Id.* § (c)(6)(A). This language could be interpreted to impose an April 30 deadline only for 2013, but that interpretation would allow the Chief Actuary to delay a determination until December 31, just two weeks before the IPAB (or the Secretary, if no IPAB has been established) is required to submit spending proposals based on the Chief Actuary’s determination.

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July 18, 2017

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II. Joint Resolution to Discontinue IPAB Provisions

The statute provides that Congress may discontinue the IPAB by enacting a Joint Resolution. To be effective, the Joint Resolution must be introduced between January 1 and February 1 of 2017, and be enacted by August 15, 2017.² *Id.* § (f)(1)(A), (f)(3). The Joint Resolution must be passed by a three-fifths vote of each house of Congress. *Id.* § (f)(2)(F).³ In the Senate, the Joint Resolution process is governed by fast-track procedures. *Id.* § (f)(2).

III. Consequences of Enacting a Joint Resolution

Enactment of the Joint Resolution by August 15, 2017 would have the practical effect of terminating the IPAB process.

The statute provides that a timely Joint Resolution terminates the authority of the Chief Actuary to “make any determinations” under the statute “after May 1, 2017.” *Id.* § (f)(3)(A)(i). Accordingly, no such determinations can be issued after the date of enactment of any Joint Resolution.

The Chief Actuary issued a determination on July 13, 2017, before enactment of a Joint Resolution, but did not find that spending cuts are required for 2019.⁴ Accordingly, no proposal would need to be submitted in January 2018. *Id.* § (c)(3)(A)(ii).

As a result, enactment of the Joint Resolution by August 15, 2017 will effectively terminate the statute. That is because the Chief Actuary will no longer be able to make determinations that could trigger an obligation to submit a proposal. Moreover, the Joint Resolution also terminates the IPAB’s ability to submit a proposal “after January 16, 2018.”⁵ *Id.*

² August 15, 2017 refers to the date by which the Joint Resolution is (1) signed by the President, (2) becomes law after the President takes no action for 10 days (not including Sundays), or (3) Congress overrides the President’s veto. *See* U.S. Const. Art. 1 § 7.

³ Consideration of a Joint Resolution in the House will be under procedures prescribed by a rule reported to the House by the House Rules Committee. Such rule will likely turn off the three-fifths’ vote requirement in subsection (f)(2)(F), allowing the Joint Resolution to pass by a simple majority.

⁴ Chief Actuary Determination (July 13, 2017) (“Because the projected 5-year Medicare per capita growth rate does not exceed the Medicare per capita target growth rate, there is no applicable savings target for implementation year 2019 (determination year 2017).”), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/IPAB-2017-07-13.pdf>

⁵ If the July 2017 determination had found that spending cuts were required, a proposal would have been required to be submitted by the IPAB “on January 15” of 2018, and that would not have been prevented by the Joint Resolution, which would only have barred the IPAB from submitting proposals “after January 16, 2018.” *Id.* § (f)(3)(A)(ii), (c)(3)(A)(i). Because the IPAB would not have been constituted, the Secretary would have had an obligation to submit a proposal in place of the IPAB in January 2018. *Id.* § (c)(5). Such a proposal could, of course, have been halted by separate legislation.

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July 18, 2017

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§ (f)(3)(A)(ii). Because the statute was not triggered in 2017, and no determinations could be issued in 2018 or beyond (nor any proposals submitted after January 2018), the IPAB would effectively be terminated by enactment of the Joint Resolution by August 15, 2017.

Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

July 12, 2017

Dear Mr. Chairman and Ranking Member,

Every 20 minutes another American man dies from prostate cancer. That is more than 75 deaths per day and over 26,700 per year, enough to fill a baseball stadium. The American Cancer Society estimates in its Cancer Facts & Figures 2017 report that 161,360 men will be told they have prostate cancer in 2017. Early detection is critical. The most recent research shows the five-year survival rate for all men with prostate cancer is nearly 100%.

The current method to diagnose prostate cancer is via needle biopsy of the prostate. Over 800,000 prostate biopsies are performed on men each year. However, despite the most rigorous protocols for obtaining and handling specimens, about 2.5% are subject to specimen provenance complications (SPCs), where a specimen from one patient is transposed with or contaminated by that of another patient.

This clearly poses an immense issue for the American public. Not only do patients receiving false- negatives lose the opportunity to treat their cancer at its earliest possible stage, but patients receiving false-positives – an estimated 1.3%, according to peer-reviewed literature -- are erroneously told they have prostate cancer when they do not. This results in extreme financial and emotional stress and unnecessary, expensive and invasive procedures, including radical prostatectomy and radiation therapy.

Misdiagnosis and this unnecessary medical care can be eliminated through the use of DNA Specimen Provenance Assay, or "DSPA." This method of testing has evolved over the last several years, and it is recognized as the highest standard of care among prostate biopsy procedures. DSPA simply matches each patient's unique genetic profile to that of the diagnostic tissue read by a pathologist or genetic counselor, in order to rule out the presence of undetected provenance complications prior to treatment. This ensures the proper patient is matched to his specimen.

Despite widespread adoption of DSPA as standard of care, the Centers for Medicare & Medicaid Services (CMS) has adopted the position that this critical testing does not fall within a permitted Medicare benefit category, and is, therefore, not reimbursed by Medicare. This interpretation poses a tremendous threat to hundreds of thousands of Medicare beneficiaries. To deprive

Medicare beneficiaries of access to an important test which eliminates medical errors is contrary to the best interests of patients.

The undersigned organizations support H.R. 2557, The Prostate Cancer Misdiagnosis Elimination Act of 2017, which would make DSPA testing available to Medicare beneficiaries for prostate biopsies. We urge members of Congress to protect patients from the devastating impact of misdiagnosis that can result from SPCs by enacting this legislation that provides Medicare reimbursement for the simple and cost-saving DNA test that can eradicate tragic medical errors.

Sincerely,

Alliance for Aging Research
American Association of Clinical Urologists
American Urological Association
Large Urology Group Practice Association
Malecare Cancer Support
Men's Health Network
Prostate Conditions Education Council
Prostate Health Education Network
Us TOO International Prostate Cancer Education & Support
The Veterans Health Council
Vietnam Veterans of America and
ZERO - The End of Prostate Cancer

CC: Honorable Larry Bucshon

Encl: Appendix.

Appendix.

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