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LEGISLATION TO IMPROVE AND SUSTAIN THE MEDICARE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

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CONTENTS

	Page
Advisory of June 8, 2016, announcing the hearing	2

WITNESSES

PANEL ONE	
The Honorable Charles W. Boustany, Member of Congress, Washington, D.C.	22
The Honorable Robert J. Dold, Member of Congress, Washington, D.C.	16
The Honorable Kristi L. Noem, Member of Congress, Washington, D.C.	20
The Honorable David G. Reichert, Member of Congress, Washington, D.C.	18
PANEL TWO	
The Honorable Joseph Crowley, Member of Congress, Washington, D.C.	30
The Honorable John B. Larson, Member of Congress, Washington, D.C.	28
The Honorable Patrick Meehan, Member of Congress, Washington, D.C.	25
The Honorable James B. Renacci, Member of Congress, Washington, D.C.	21
PANEL THREE	
The Honorable Alexander X. Mooney, Member of Congress, Washington, D.C.	26
The Honorable Christopher H. Smith, Member of Congress, Washington, D.C.	33
The Honorable Lee M. Zeldin, Member of Congress, Washington, D.C.	31

SUBMISSIONS FOR THE RECORD

The Honorable Diane Black, statement	48
The American College of Clinical Pharmacy, and The College of Psychiatric and Neurologic Pharmacists, statement	50
Lymphedema Advocacy Group, statement	53
Medicare Rights, statement	59
Property Casualty Insurers Association of America, statement	61

LEGISLATION TO IMPROVE AND SUSTAIN THE MEDICARE PROGRAM

WEDNESDAY, JUNE 8, 2016

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:20 p.m. in Room 1100 Longworth House Office Building, the Honorable Pat Tiberi [chairman of the subcommittee] presiding.

[The advisory announcing the hearing follows:]

WAYS AND MEANS
CHAIRMAN KEVIN BRADY

Chairman Tiberi Announces Member Day Hearing on Legislation to Improve and Sustain the Medicare Program

House Ways and Means Health Subcommittee Chairman Pat Tiberi (R-OH) today announced the Subcommittee will hold a hearing on Member proposals to improve and sustain the Medicare program. **The hearing will take place Wednesday, June 8, in Room 1100 of the Longworth House Office Building, beginning at 2:00 PM.**

Oral testimony at this hearing will be limited to Members of Congress who have either introduced or co-sponsored legislation related to improving and sustaining the Medicare program. Members wishing to testify at this hearing should contact the Subcommittee at (202) 225-3943 or Taylor.Trott@mail.house.gov by no later than noon on Friday, June 3. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

Details for Submission of Written Comments:
Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, http://waysandmeans.house.gov, select "Hearings." Select the hearing for which you would like to make a submission, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Wednesday, June 22**. For questions, or if you encounter technical problems, please call (202) 225-3625.

Formatting Requirements:
The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be printed,

but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at http://www.waysandmeans.house.gov/.

Chairman TIBERI. The subcommittee will come to order. Welcome to the Ways and Means Health Subcommittee Member Day hearing entitled, "Legislation to Improve and Sustain the Medicare Program." Today, similar to our last Member Day hearing on tax-related proposals to improve health care, this Subcommittee is providing a public platform for any and all Members of Congress interested to discuss bills that they have introduced that modify the way health care is assessed and delivered to more than 55 million seniors who rely on the Medicare program.

Members have put a lot of work into developing and drafting these pieces of legislation, and this Member Day hearing is their opportunity to share with their colleagues and the American people why these bills are important, and why this Committee should take them up.

In addition to my colleagues from Ways and Means, I am excited to hear from Members who serve on other committees who have worked equally hard on legislation to transform and improve our Medicare program.

We remain committed to working through regular order. That includes hearings like the one today from those on and off the committee.

So how is it going to work? Members will have five minutes to discuss their Medicare legislative priorities. I would remind those Members that they are also able to submit written testimony in support of their legislation.

We thank you all, witnesses and members of this Subcommittee, for taking the time out of your busy schedules to be with us today. And I hope, Dr. McDermott, we can build on the kind words you said about us yesterday. I knew it might take a little while for you to say kind words about us, and we accomplished that. So let's build on that, sir.

I yield to the ranking member.

Mr. MCDERMOTT. Thank you, Mr. Chairman. We might as well start out on a good note. And I think that I want to thank you for holding this Member Day hearing to improve and sustain Medicare. I welcome this opportunity to learn more about the ideas that my colleagues may have, and they will discuss today.

When it comes to Medicare, the policies which were put in place in 1965, those policies we have made a wide range of interests—physicians, insurers, hospitals, and many others. And the most important people affected, however, by Medicare are the beneficiaries, the 55 million seniors and Americans with disabilities who depend on Medicare for their health care.

At its core, Medicare is a fulfillment of a commitment to the health security of the American people. Individuals who have contributed to the system deserve the peace of mind of knowing that Medicare's benefits will be there when they need them. That means that Congress must work to ensure that Medicare truly strengthens the quality and accessibility of beneficiaries' health care.

A strong Medicare doesn't mean we turn the program over to the insurance industry, and it doesn't mean we shift more costs on to the beneficiaries. A stronger Medicare is a program that provides comprehensive coverage to beneficiaries at affordable cost. To make that a reality we have to move the conversation in Congress away from harmful ideas like privatizing the program and cutting seniors' benefits toward a more productive discussion of how to make Medicare work better for beneficiaries.

To that end, I intend to discuss legislation I have recently introduced which will provide beneficiaries with access to comprehensive dental, vision, and hearing services. This is a popular, long-overdue reform that will improve the health security of millions of Americans. And I look forward to talking further about the importance of this during the hearing.

I also hope to hear from my colleagues about other ideas that will continue to build upon and expand Medicare. I intend to carefully scrutinize ideas that may not be in the best interests of the program or the beneficiaries. Today's hearing is a part of what must be an ongoing process of careful debate that will show the American people what Congress is doing or not doing to improve health security.

When Medicare was put in place, the life expectancy in this country was about 10 years lower than it is today. So we had such success in Medicare that we have got a whole lot of new problems that we didn't have before. It must be followed by substantive legislative hearings and markups and amendments, so that we could weed out bad ideas and make sure the ones that are good can have the passage of this Congress.

Thank you again, Mr. Chairman, for bringing this day together, and I look forward to hearing the witnesses.

Chairman TIBERI. Thank you, Dr. McDermott. Without objection, other Members' opening statements will be made part of the record.

Now we will hear from Members of the Subcommittee on their priorities to improve Medicare. I am the lead Republican on the Medicare Home Infusion Site of CARE Act, which we are working with the Senate and CMS to ensure it will work for all stakeholders. It is truly an important piece of legislation that will expand beneficiary access to infusion treatments in their homes, if that is where they choose to receive their care, something that private providers already cover.

I look forward to continuing to work on this legislation that will increase beneficiary access to appropriate and cost-effective care, and advancing it when it is ready.

Chairman TIBERI. With that, I turn to my left, literally, to Dr. McDermott once more for the purposes of discussing his legislation.

Dr. McDermott, you are recognized for five minutes.

Mr. MCDERMOTT. We welcome you on the left. I would like to ask unanimous consent to enter into the record a letter from the Medicare Rights organization dated 8 June 2016.

Chairman TIBERI. Without objection. Without objection.

[The information follows: The Honorable Jim McDermott]

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June 8, 2016

The Honorable Pat Tiberi
Chairman, Health Subcommittee
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

The Honorable Jim McDermott
Ranking Member, Health Subcommittee
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Re: "Member Day Hearing on Legislation to Improve and Sustain the Medicare Program"

Dear Chairman Tiberi and Ranking Member McDermott:

On behalf of the Medicare Rights Center (Medicare Rights), I am writing to submit a statement for the hearing record identifying 50 opportunities to strengthen Medicare for today's beneficiaries and for future generations. 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. Our organization serves more than two million Medicare beneficiaries, family caregivers, and professionals annually.

For more than 50 years, Medicare has provided guaranteed health benefits to millions of older adults and people with disabilities. Today, 55 million Americans and their families rely on Medicare for basic health and economic security—making Medicare an undeniable success story. Still, we greatly appreciate efforts by the Health Subcommittee to explore how to further improve the Medicare program.

In 2015, Medicare Rights commemorated the 50th anniversary of this landmark program by identifying 50 wishes for Medicare's future. We believe it is critically important for lawmakers to advance global changes to modernize benefits in both Original Medicare and private Medicare health plans and to press forward on seemingly small fixes to improve how beneficiaries navigate their coverage day-to-day. Among our 50 wishes, Medicare Rights' top recommendations include:

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www.medicarerights.org www.medicareinteractive.org

- Add comprehensive dental, vision, and hearing benefits to Original Medicare;
- Modernize Part B enrollment through enhanced notice, enrollment periods, and relief processes;
- Make Medicare more affordable by expanding access to Medicare Savings Programs;
- Streamline and update Medicare Advantage and Part D appeals processes;
- Increase funding for counseling via State Health Insurance Assistance Programs (SHIPs); and
- Rein in rising prescription drug costs through tools like Medicare rebates and price negotiations.

We encourage the Health Subcommittee to pursue these and other advancements to improve the Medicare program. Medicare Rights' 50 wishes for Medicare's future are available at: http://www.medicarerights.org/50wishes. For more information, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202-637-0961. Thank you.

Sincerely,

Joe Baker
President
Medicare Rights Center

Mr. MCDERMOTT. Mr. Chairman, I have sat here on this Committee for 25 years and watched lots of things happen. And I am really glad that we are having a hearing today when we could put some ideas up on the table that we haven't had before.

I am introducing today a bill called the Medicare Dental, Vision, and Hearing Act, a bill I introduced, I guess, yesterday, actually.

The creation of Medicare in 1965 was one of the great policy achievements in the history of this country. The benefits that Medicare provided ensured that 55 million citizens and people with disabilities would enjoy the peace of mind and the security that comes with having quality health coverage. The best way to improve and sustain Medicare is by expanding it and strengthening it because, unfortunately, there are holes in the program that weaken health security of our beneficiaries.

One of the largest holes in the Medicare system is that it does not currently cover most dental, vision, or hearing expenses. In fact, not only does it not pay for these crucial health services, they are specifically excluded from coverage by the statute that was passed in 1965. This is a misguided policy that, for decades, has had harmful consequences on beneficiaries.

Doing without dental coverage frequently leads to preventable health problems. Patients who have poor or no dental care often find themselves suffering from costly and potentially fatal conditions such as cardio-vascular disease and oral cancers. We had recently here in Washington, D.C. a young kid who didn't have dental care and got encephalitis of the brain from an infected tooth.

Now, similar untreated vision disorders substantially increase the risk of falls among senior citizens. One of the biggest problems for senior citizens is falling. And if they have bad vision and don't have glasses, or they got cataracts or whatever, they are having trouble. These falls can result in serious injuries and expensive hospitalizations.

Hearing loss, for those of us who grew up in the age of rock music, and used to stand next to the woofers and the tweeters at full volume, today have hearing aids because we did things with our ears that we didn't understand then. There are lots and lots of seniors who have hearing loss and that is an isolating event.

When you have no ability to hear, you are cut out of everything. And that is why it is—if we are having seniors live longer and longer and longer, into their eighties and nineties, we are going to see more of the hearing and the vision loss that we have not dealt with in the past. It is a widespread—the hearing loss is as widespread among Medicare beneficiaries, often leading to social isolation, depression, and cognitive impairments. We wind up treating them for depression, we treat them for all kinds of other things, basically, because they can't hear.

Yet research shows that a majority of the elderly who need hearing aids do not have them, in large part due to cost. That is why the reforms made by the Medicare Dental, Vision, and Hearing Benefit Act are so important. This bill modernizes and strengthens Medicare's benefit package to address the full spectrum of beneficiaries' health needs. It amends Part B to provide coverage of important health services, including routine and major dental care, refractive eye exams, and hearing exams, and adds coverage for im-

portant supplies including dentures, glasses, and hearing aids. It repeals the harmful statutory exclusions that prevent Medicare from paying for these costs.

And to control costs and ease the burden as we implement these major reforms, it places reasonable limitations on coverage and provides that new benefits will be phased in gradually. All too often at this Committee our policy discussions focus on how much we can cut from Medicare and how to further shift the costs onto beneficiaries. In the process we fail to recognize the possibilities before us and the enormous power we wield.

The truth is that Medicare must be strengthened, not cut, and benefits must be expanded, not scaled back. As the Ways and Means Committee, we owe a duty to the American people to discuss how we can make that happen.

And I yield back the balance of my time. I thank the chairman.

Chairman TIBERI. Thank you. Thank you, Dr. McDermott. My phone was ringing and I was thinking it was my mom and dad calling me about your legislation there.

[Laughter.]

Chairman TIBERI. Very well done. Mr. Roskam is recognized for five minutes.

Mr. ROSKAM. Thank you, Mr. Chairman and Ranking Member McDermott. Five minutes, three bills, let me do this quickly. Buckle up, I think I can do it.

So H.R. 512 is the Disarm Act, and it is designed to incentivize the development of new antibiotic drugs. The Administration recognizes that we have an incredible problem here. The CDC recognizes that we have an incredible problem here. And the incredible problem is that we have got infections that are unwilling to yield to some of the antibiotics, and we don't have enough incentive out there in the private sector to invest, essentially. And this is a plague.

Let me just give you one quick example. In March and April in the Midwest 18 people died from 57 inspections in 3 states. And this is here, it is upon us, and we need to deal with it. H.R. 512 would address this by reimbursing hospitals for the cost of acquired new certain agents.

It passed in Chairman Upton's Cures Act. We will see where that is in the Senate, Mr. Chairman, but in my view, we would be wise to reclaim jurisdiction here and move it again.

Bill number two, H.R. 3220, the Common Access Card. This is a bill that I have introduced with Mr. Blumenauer. Some of the work of the Oversight Subcommittee has shown that the fraud and erroneous payments rate at Medicare is 12.7 percent. I mean this is a shocking figure. And, you know, you begin to ask yourself, "How is this possible?" Well, it is possible in part because you got these flimsy old Medicare cards, and it is a bunch of nonsense.

And what we are proposing is this, to take the technology that the Department of Defense uses currently, try a pilot program, and create a common access card.

Ready for a statistic? February 2016, a few months ago, GAO revealed that 22 percent of health care fraud cases ultimately prosecuted by the Federal Government could have been prevented by use of a smart card—22 percent. Marinate in that for a second.

When we are running around here, grubbing around, looking for nickels and dimes, thinking about 22 percent, thinking about 12.7 percent—you take my point.

So here is what we need to do. We need to pass this bill, number one. But you need to give us good feedback.

I spoke with Secretary Burwell this week. She is committed to expediting a meeting to get stakeholders together. And I think we can do a lot of good work here. And, Dr. McDermott, I am looking to you to get on this bill.

And then finally, the H.R. 4853 is the SAFE Act. And in a nutshell, this legislation provides CMS with additional flexibility to permit approved private-sector accreditors to use their own updated standards and survey processes for hospital accreditation. So, in other words, we have got the private sector that is doing a fabulous job, we have got a statute that basically tethers us to an old system. So let's dump the loser stuff, pick up the things that work, and let's adopt it so that these hospitals can move forward on that basis, to allow accrediting bodies to use assessment methods that incorporated the latest, best practices in health care delivery to ensure hospitals adhere to high-quality standards and patient safety.

And Mr. Chairman, who doesn't love that? And I yield back.

Chairman TIBERI. Well done, Mr. Roskam, thank you very much.

Before I yield to Mr. Davis for five minutes, I just want to thank him for coming down to the floor yesterday and his kind words on the bill that originated in this Subcommittee, and thank all the Members for their input on a bill that passed the floor unanimously yesterday.

So with that, Mr. Davis, you are recognized for five minutes.

Mr. DAVIS. Thank you, Mr. Chairman. And I shall discuss H.R. 2124, the Resident Physician Shortage Reduction Act, introduced by Representatives Crowley and Boustany.

Mr. Chairman and Ranking Member, the Illinois 7th Congressional District, which I represent, contains the most hospital beds of any congressional district in the nation, and is also home to four major academic medical centers. Given our nation's growing and aging population, coupled with the coverage expansion contained in the Affordable Care Act, the demand for health care continues to increase, especially for those with complex health care needs, such as the fastest-growing population in the nation of those aged 75 and older.

Recent studies show that our nation will need as many as 90,000 new physicians over the next decade, and as many as 63,000 of which will need to be specialists.

Clearly, today more than ever, Congress should maintain and enhance our nation's investment in training tomorrow's physician workforce. Given that it takes anywhere from 5 to 10 years to train a physician, the question facing Congress is what are we doing to ensure that our nation is physician workforce ready to meet our nation's health care needs both today and in the future?

The teaching hospitals in my district are incurring the costs of these programs significantly greater than the direct and indirect graduate medical education payments they received. In fact, most of the major teaching hospitals in Chicago are training in excess

of 100 doctors over the residency cap, which costs tens of millions of dollars that will never be reimbursed to those institutions for training more physicians to address the growing shortages in primary care and acute surgical specialties.

Medical schools and teaching hospitals are also working to ensure that new doctors coming into the system are trained to serve in new delivery models that focus on care coordination and quality improvement. According to the latest physician workforce projections, roughly two-thirds of the shortage in coming years will be in specialty practice areas such as neurology, pediatrics, subspecialties, geriatrics, and oncology.

We need more doctors and allied health professionals to assist a health care system that for decades was not adequately addressed in health disparities among millions of racial and ethnic minority Americans. Many of our minorities are disproportionately more likely to suffer deleterious health just because they are low-income wage owners, poor in health, and suffer worse health outcomes, and are more likely to die prematurely and often from preventable causes compared to other members of the population.

This bill provides a greatly needed opportunity to train the physicians that we need throughout our country. I am delighted that Representative Crowley and Representative Boustany have collaborated to pass it. And I would urge all of my colleagues, certainly, to be in support of it.

And Mr. Chairman, I thank you and yield back the balance of my time.

Chairman TIBERI. Thank you, Mr. Davis.

Dr. Price, you are recognized for five minutes.

Mr. PRICE. Thank you, Mr. Chairman, and I appreciate the opportunity to discuss bills relating to a very important subject, and that is the issue of saving and strengthening and securing Medicare. The demographic challenges that we have in this country are huge, and Medicare is running out of resources, as you well know. That is according to their own trustees.

The challenge that we have right now is that CMS is saving money, according to them, by decreasing services and limiting access to care. And it is happening right now, it is not happening just in a fictitious way potentially in the future.

I want to talk about three pieces of legislation. The first is H.R. 5210, which deals with durable medical equipment, patient access to durable medical equipment. CMS instituted what is called a competitive bidding program for suppliers of durable medical equipment that is not either competitive and isn't bidding, and it isn't because it doesn't hold bidders accountable, it doesn't ensure that bidders are qualified to provide the products in the bid markets, and it produces bid rates that are financially unsustainable.

Mr. Chairman, this literally is harming lives, as we speak. Essential services, including oxygen, are being denied to patients because of difficulty gaining those services. In rural areas it is a huge, huge problem. Many areas, many rural areas of the country, the amount paid for these services doesn't even cover the costs. So you get decreased availability.

In Georgia, for example, 20 percent decrease in the number of DME suppliers in the last three years, and a nearly 40 percent re-

duction in medical equipment supply stores in our state, just in the last 3 years. Patients' lives are literally at risk.

The National Minority Quality Forum has data that demonstrates it is driving up costs by avoidable hospital bills and increasing out-of-pocket payments by patients. It has led to increased mortality—that means death and hospitalizations and a higher cost for Medicare beneficiaries. The OIG for Medicare itself said that CMS paid over $1 million to 63 suppliers for product categories they weren't even licensed to provide in their state, over $1 million.

So, H.R. 5210 would simply delay the onset of this competitive bidding program and expanding the onset of the program, and that is a bipartisan-supported bill.

Second is H.R. 4848, the Healthy Inpatient Procedures Act, called the HIP Act. As an orthopedic surgeon, I bear some familiarity with this area. This is talking about the comprehensive care joint replacement, or CJR, model. This is something that CMS put in place to try to decrease amount of resources spent on lower-extremity joint replacements. The problem is they have gotten it all wrong. It is what they call a demonstration product, but it is the first mandatory demonstration product.

So, how it could be a demonstration product and be mandatory is beyond me. Sixty percent of the hospitals, as estimated, will be penalized because of this. Decreasing resources available for patients to utilize for lower-extremity joint replacement. So what happens? Medicare CMS limits access, limits choice, increases consolidation of services, and therefore, increases prices.

What does this mean to patients? As a formerly practicing orthopedic surgeon, I would talk to patients about what kind of replacement they ought to have. And Medicare may or may not agree with that. The problem with this is that, if Medicare doesn't agree with it, then guess who doesn't get the joint replacement that they need? It is the patient.

So the H.R. 4848 would delay onset of this program until January 2018. Again, it is a bipartisan support, it would simply give docs time to get ready for it and give us an opportunity to modify this program.

And then, finally, H.R. 5001. Everybody has heard from their docs about the issue of electronic medical records. It is a disaster for physicians back home. The amount of time that they are having to spend on this to simply comply with regulations that don't increase the quality of care to patients is astounding.

What Medicare did this year is to change the meaningful use reporting period from a 90-day period, rolling 90-day period where docs would have to comply, to 365 days, which means the entire year, which means you can't have your server go down, you can't have any problem at all throughout the course of the year, or you get dinged by Medicare for not having what they believe is the appropriate electronic medical record. This bill would simply return it to the 90-day reporting period that we have had in the past. Again, common sense, bipartisan.

I appreciate the opportunity to present these, and look forward to them passing.

Chairman TIBERI. Thank you, Doc. With that, Representative Buchanan of Florida is recognized for five minutes.

Mr. BUCHANAN. Thank you, Mr. Chairman, for holding this important hearing. Before discussing my legislation I would like to mention the importance of examining medical competitive bidding also, as Dr. Price has clearly taken the lead on this, but has a huge impact on my region in Florida, especially Sarasota, but all through Florida. A lot of diabetics are very concerned about the impact it is going to have on them going forward.

So I appreciate, Dr. Price, your leadership. And hopefully this is something we can get done quickly.

Now, as for my legislation, along with my good friend, Congressman Pascrell, I introduced the Preserving Patient Act [sic] to Post-Acute Hospital Care, H.R. 4650.

Right now, tens of thousands of Medicare patients rely on access to highly specialized care facilities known as long-term acute care hospitals, or LTACs after they are released from intensive care units. These facilities are uniquely equipped to care for chronically ill patients over an extended period of time. And unless Congress acts, the allowable caseload for these facilities will be cut in half January 1, 2017.

So in six months it would be cut in half. This means people will either remain stuck in the hospital ICU longer than they want to, or be forced to move to another place, away from their homes and families, to find care that they need.

My bill prevents this cut from taking place, and Congress has approved similar measures several times over the last decade. We need to act soon. The cut takes effect at the end of the year, but these facilities need time to plan for their patients' care. If we fail to pass this bill, more than 100,000 seniors could be denied vital care at their local ATAC hospital.

With that, I yield back.

Chairman TIBERI. Thank you, Mr. Buchanan, and thank you for bringing up Dr. Price's bill. I too share that concern with respect to the durable medical goods issue, and have had constituents in my region of Ohio express concern. So I look forward to working with you on that, Dr. Price.

Ms. Jenkins, CPA Jenkins, you are recognized for five minutes.

Ms. JENKINS. Thank you, Mr. Chairman, and thank you for holding this important hearing and allowing me an opportunity to speak on bipartisan legislation that I am proud to advocate for that will allow more beneficiaries to access vital care in rural areas, save Medicare patients in the system money, and ensure its stability for generations to come.

H.R. 1202, the Medicare Patient Access to Hospice Act, which I introduced with Congressman Thompson, will allow physician assistants to receive reimbursement from Medicare as the attending physician in a hospice setting. Hospice care is incredibly important in my district because of the lack of hospitals and doctors' offices that urban districts have with large health systems.

Along with allowing physician assistants the ability to perform cost-saving medical care in hospice setting, H.R. 1784, the MEND Act, which I introduced with Congressman Tonka, will bring about an out-of-date CMS regulation in line with the accreditation body that allows hospital-based nursing programs to produce nurses and shore up critical shortage in the Medicare system.

A third bill, H.R. 2138, the Medicare Access To Rural Anesthesia Act, which I introduced with Congressman Cleaver, will pay anesthesiologists in certain rural hospitals under Medicare Part A for their services at the rate paid to a certified registered nurse anesthetist in those hospitals for the same services.

As I pointed out with H.R. 1202, Medicare beneficiaries in Kansas must use entire days sometimes to travel to certain hospitals to get care. Many of those hospitals can't afford a full-time anesthesiologist, so those folks are then forced to travel somewhere else to get care. H.R. 2138 will help eliminate that burden and allow more rural hospitals to hire and keep anesthesiologists on staff.

Similarly to that bill, H.R. 3355, which I introduced with Congressman Lewis, will allow physician assistants, nurse practitioners, and clinical nurse specialists to supervise cardiac intensive care and pulmonary rehabilitation programs. Again, this will allow critical access and rural hospitals to hire and keep these vital staff members and provide needed care to rural parts of Kansas and the United States. Americans living on farms and ranches and those rural areas have the same need for medical services as those living in urban areas. And this legislation will give them more adequate service and keep costs down for the patients and the whole system.

I will continue to work to give rural Medicare beneficiaries better access to care and save the entire Medicare system precious dollars so they can stay solvent and effective for generations to come. These four bills will make it much easier for Medicare beneficiaries to access and afford the care that they need, especially in rural parts of the states.

I strongly encourage my colleagues to support these pieces of legislation and help me bring them to the House floor.

I thank you, Mr. Chairman, and I will yield back.

Chairman TIBERI. Thank you, Ms. Jenkins. Representative Marchant is recognized for five minutes.

Mr. MARCHANT. Thank you, Mr. Chairman. Thanks for having this hearing and allowing us to put forward our ideas.

I introduced H.R. 3288 with my friend and colleague, Dr. Boustany, last year. This legislation amends Title XVIII of the Social Security Act to change the method of determining disproportionate share hospital payments under the Medicare program. As the members of this Committee are aware, DSH payments compensate hospitals for the above-average operating costs they incur in treating a large share of low-income patients.

Mr. Chairman, 19 states have decided not to adopt Medicaid expansion. DSH hospitals in each of these states such as Texas, Florida, Tennessee, Kansas, and Georgia, are financially disadvantaged by this. Though it is not our job to make state-level decisions, it is our job to ensure our hospitals have the resources necessary to care for our constituents.

My bill would help ease the burden these hospitals are facing. Patient care is not a partisan issue, and I urge all of my colleagues on this Committee to cosponsor this non-partisan, no-cost policy.

Mr. Chairman, once again I appreciate the effort being made here today and for the forum to speak on ideas to sustain Medicare, and look forward to continuing to work with you and the committee to advance the policy and strengthen the DSH program.

Thank you, and I yield back.

Chairman TIBERI. Thank you, Mr. Marchant.

Representative Paulsen from Minnesota, you are recognized for five minutes.

Mr. PAULSEN. Thank you, Mr. Chairman also for holding this hearing. I have two bills that I have introduced that I would like to touch on today that have bipartisan support and would benefit seniors on Medicare.

The first is H.R. 5075, the Accelerating Innovation in Medicine Act, also known as the AIM Act, which I introduced with Representative Ron Kind. Currently, patients and providers are having trouble accessing the newest, most innovative medical technologies and more and more barriers and coming from CMS, rather than from the FDA. And we, as a committee, need to take a serious look at the CMS coding, coverage, and reimbursement process to examine how the agency is functioning, its impact on the biomedical ecosystem, and its effect on ensuring that patients will have access to the next generations of advanced therapies.

Currently, the process of receiving a CMS code alone can take as long as three years. National coverage decisions are typically time consuming and cumbersome, and some new therapies must go through a process of convincing each local carrier to provide coverage before a patient or a senior can get access. This process delays patient access to ground-breaking treatments.

My bill, the AIM Act, would focus on the front end of this process by increasing patient access to the new—to new FDA-approved medical devices and procedures, and speeding up the collection of data needed for Medicare coverage decisions. The AIM Act does this by allowing a manufacturer to place FDA-approved devices and treatments on a list, where they are available for Medicare beneficiaries that self-pay.

By agreeing to not seek Medicare reimbursement for three years, the devices then will be available without government red tape, paperwork, and administrative costs. And during that three-year period the manufacturer could collect patient data that will help streamline a future Medicare coverage decision.

The current system is expensive, it is inefficient, and it gives providers, patients, and manufacturers uncertainty. And we need legislation like the AIM Act so that we can ensure the continued development of new treatments to improve Medicare outcomes, efficiencies, and lower costs.

And then, Mr. Chairman, the second bill is H.R. 2404, the Treat and Reduce Obesity Act that I have also introduced with Representative Ron Kind. Obesity is now an epidemic and a public health crisis that needs to be addressed. Over 40 percent of seniors are obese. This disease takes both a physical and an emotional toll on an individual, and often is the cause of many other chronic conditions like diabetes, heart disease, stroke, and others.

Nearly 20 percent of the increase in our health care spending over the last 2 decades was caused by obesity. And this disease directly costs Medicare more than $50 billion a year, and that number will continue to increase over the coming years. This is bad for our seniors and it is bad for Medicare.

Unfortunately, there are limitations in place preventing patients from accessing important treatments and providers that can help them combat obesity. The Treat and Reduce Obesity Act would remove these barriers by giving patients access to FDA-approved obesity drugs under Medicare Part D, and allowing additional qualified health care practitioners to provide intensive behavioral therapy services. Patients and clinicians require access to the full range of proven, safe, and effective therapies for the treatment of obesity.

We have the ability to save the health care system billions of dollars and, at the same time, make the lives of patients significantly better. And that is why this bill has nearly 150 bipartisan cosponsors. We can't solve this problem overnight. But by taking action now we will help us solve our obesity crisis over the long term.

And finally, Mr. Chairman, I just want to touch on another issue that I am working on. I recently held a roundtable in Minnesota with some hospitals, and they are concerned about the direction that Medicare is going in terms of too much regulation, too many requirements, and the reimbursement system being very unpredictable. Hospitals, providers, and patients all recognize that we need fundamental reforms to the system. Otherwise, the system will collapse and seniors will suffer.

Thankfully, there are providers, health plans, and states out there that are now trying to find ways to make our health care system more efficient and effective. They are not trying to tie the health care system up in knots with duplicative process measures that may or not yield the best results [sic]. But they are focusing on outcomes, high impact, clinically credible outcomes that we can focus providers around to achieve substantive and sustainable improvements for patients. And we can learn a lot from these state and local initiatives to strengthen Medicare.

I look forward to working with you, Mr. Chairman, and my colleagues on those efforts to do just that. Those are just several of the ideas that I have for reforming Medicare, and I look forward to working with the chairman in the future on these bipartisan ideas. I yield back.

Chairman TIBERI. Thank you, Mr. Paulsen. We are now to be joined by members of the full committee who have some ideas of their own on health care.

Welcome, everybody. How is it down there? Not bad?

Well, let's start with the gentleman to my far left, Mr. Dold.

You are recognized for five minutes to share your ideas with us.

STATEMENT OF THE HONORABLE ROBERT DOLD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. DOLD. Thank you, Mr. Chairman. I appreciate the comments from my colleagues down here—your comments.

[Laughter.]

Mr. DOLD. But anyway, Mr. Chairman, I thank you for the opportunity to testify before you today on two bills that I think will make some critically necessary reforms to Medicare.

The first I would like to speak about is H.R. 5122, a bill that I helped introduce alongside my colleagues, Dr. Bucshon, Dr. Boustany, Dr. Price, and Representative Shimkus. This legislation would prevent CMS from finalizing, implementing, or enforcing the

demonstration program they proposed on March 8th of 2016. The proposal will dramatically alter the way Medicare Part B reimburses physicians for medications they administer to seniors in outpatient settings. The resulting cuts could disrupt access to medications for our most vulnerable seniors, including those with cancer, arthritis, and other very serious diseases.

As you are all aware, this proposed demonstration was developed by the Center for Medicare and Medicaid Innovation with very little transparency and limited input from patients and physicians. Unlike previous CMMI demonstrations, all Part B providers are required to participate. As a direct result of the demonstration, by phase two, 75 percent of all providers will see drastic cuts to their reimbursements when providing Part B-covered medicines to patients.

It also appears that CMS has failed to fully model how this demonstration will interact with other programs, especially the implementation of macro-legislation passed to repeal the SGR.

Thanks to the ingenuity and perseverance of incredible researchers, our modern medical system has moved away from a one-size-fits-all treatment and has progressed into an era of precision medicine where treatments are highly personalized for each individual patient.

The proposed demo, or demonstration project, directly contradicts this progress by incentivizing doctors to provide older, less advanced treatments, rather than newer, more innovative options. By allowing this demonstration to proceed, we are putting physicians in a very difficult position that not only is unfair, but detrimental to patient care. This will be especially true for providers working in small clinics serving rural areas.

When the Federal Government created Medicare 50 years ago, Congress made a commitment to America's seniors, and the cuts embedded in this demonstration project are a betrayal of that commitment. We must stop this ill-conceived proposal, and uphold our commitment to protect health care for seniors.

I would also like to speak with you today about another bill that will ensure seniors receive the best care possible. It is H.R. 1178, the Ensuring Equal Access to Treatments Act, sponsored by my friends, Representative Reed and Representative Kind. It improves the way that CMS pays for certain diagnostic procedures that have a discretionary drug component by altering the current one-size-fits-all approach which does not allow seniors to receive the personalized care that best meets their needs.

In 2014 outpatient prospective payment system had a rule that CMS redefined in terms of packaged payments for certain drugs administered with corresponding procedure. Rather than reimbursing for the drugs and the procedure separately, CMS now uses one package payment, which includes the drugs and all other services and supplies associated with the procedure.

Unfortunately, since the package payment is the same whether or not the drug is used, the new payment structure has the effect of encouraging health care providers to choose treatments which may not result in the best long-term outcome for the patient. H.R. 1178 corrects the problem by requiring CMS to create two separate

payment codes, one for when the diagnostic procedure is performed with drugs, and another when it is performed without drugs.

We have already seen cases where 2014 packaged payments is negatively impacting vulnerable seniors. One example concerns the diagnostic of coronary heart disease. Providers have two options to raise a patient's heart rate to a specific target: a stress test on a treadmill or a stress test by an induced drug, which may be needed for those that are unable to get on a treadmill to raise their heart rate.

The current package payment system provides an incentive for providers to choose the free treadmill test over the drug, even if the drug may be more appropriate. I believe we have an obligation to correct this misaligned incentive, so that patients receive the most appropriate care necessary. We have seen a similar problem when physicians choose whether to diagnose bladder cancer with the new, innovative procedure known as a blue light cystostopy, or an older, less advanced white light test.

We made a commitment to provide America's seniors with high-quality health care through Medicare programs. I look forward to working with all of you on H.R. 5122 and H.R. 1178, and the other bills that have been presented here today, in order to ensure that we maintain our commitment to our seniors.

I thank you.

Chairman TIBERI. Thank you, Mr. Dold. Thank you for your leadership in trying to stop that Part B demonstration program being proposed. It is important for us to try to do that. Look forward to working with you in that attempt.

With that, Sheriff Reichert, you are recognized for five minutes.

STATEMENT OF THE HONORABLE DAVID G. REICHERT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. REICHERT. Thank you, Mr. Chairman. And I want to thank Chairman Tiberi and Ranking Member McDermott for being here today and holding this hearing and listening to our initiatives that we have been working on. I would like to talk about a couple of bills.

First I would like to talk about H.R. 2649. And this bill was introduced with Representative Mike Thompson, and it is assisting Medicare beneficiaries who have been injured on the job, filed a claim for workers compensation, and settled their claims. In these settlements an amount must be set aside to cover Medicare's share of future medical expenses related to the injury.

The problem is that there are no statutory or regulatory provisions defining how these set-aside amounts should be determined. And the current procedure used by CMS has been subject to change without reasonable notice to the parties involved. This broken process results in delays and hardships for injured workers.

My bill establishes a clear, predictable process. A few ways it accomplishes this is by setting up timeframes for CMS to review set-asides, providing an appeals process and also offering individuals the option to pay the total set-aside amount directly to CMS.

So I look forward to working with you on this bill in advance. It is one of the priorities that we have been discussing, both on the D and the R side.

The next bill is one that, Mr. Chairman, you and I have talked about. It is the Lymphedema Treatment Act. This is 1608. I introduced this bill with Mr. Blumenauer. Lymphedema causes painful swelling in parts of the body where the lymph nodes or vessels have been damaged. While there are many causes, damage from cancer treatment is probably the most common. While there is no known cure for lymphedema, it is treatable.

But sadly, Mr. Chairman, current Medicare law leaves patients without access to treatment items they need to manage the swelling and prevent further health complication. My bill will fix this by providing coverage of doctor-prescribed compression supplies. This will not only save lives, but improve patients' health. But it also will strengthen Medicare program by reducing costly hospital stays.

For example, Sarah from Ohio. When she was diagnosed with lymphedema she was on the verge of losing her mobility and suffered frequent episodes of cellulitis. Between 2002 and 2004 she was hospitalized more than 10 times. In 2005 she was prescribed her first pair of compression garments. And by wearing these garments on a daily basis, she was able to maintain the progress she has made through treatment, manage her lymphedema so well that she has not been to the hospital in over a decade. In over a decade.

Bob, from New York. In 2000 he was hospitalized twice with potentially fatal cellulitis infections. Later that year he was diagnosed with lymphedema. He received treatment and was prescribed the compression garments. In the 16 years since he has not had another cellulitis attack and has not been to the hospital.

Now, we can talk about whether or not this is expensive, because that is what, of course, the Administration's argument is, and Medicare's argument is. But we are saving a lot of money by providing these garments to these patients who have suffered through and survived cancer, saving money at the back end on other treatments and hospital stays. And not only that, it is the right thing to do for these patients.

So I want to thank Members here today who have already cosponsored this bill. I would like to recognize the patient advocates who have taken the time to meet with their Members and share their stories. Thanks to their tireless efforts, the bill now enjoys, Mr. Chairman, over 230 bipartisan cosponsors. And now we are working to even get more.

And I ask, Mr. Chairman, unanimous consent to enter into the record a statement from the lymphedema advocacy group.

Chairman TIBERI. Without objection.

Mr. REICHERT. The bottom line here is these are not defined by Medicare as medical devices because they don't fall within the definition of long-term, durable devices, which is three years, because in most cases the patients have to have new garments every six months. They are not disposable medical devices because they keep them six months and not a few weeks or a few days. This is ridiculous, a ridiculous rule, Mr. Chairman, and this bipartisan

piece of legislation changes this rule and helps these patients get the treatment they so desperately need.

Thank you, I yield back.

Chairman TIBERI. Thank you, Sheriff. Now, representing the entire South Dakota delegation in the House, Representative Kristi Noem.

Mrs. NOEM. That is a big job.

Chairman TIBERI. Thank you for being here.

STATEMENT OF THE HONORABLE KRISTI NOEM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF SOUTH DAKOTA

Mrs. NOEM. Thank you, Mr. Chairman. And thank you Ranking Member McDermott and Members of the Subcommittee, for holding this hearing and allowing me to talk about a Medicare bill that I am promoting.

I am here to discuss H.R. 4277, the Medicare Mental Health Access Act. I introduced this bipartisan bill with my Democratic representative, Jan Schakowsky, who has been a leader on mental health care policy. She is a member of the E&C committee. And I want to thank her and her staff for all of their hard work on this issue, as well.

As you know, millions of Americans lack adequate access to mental heath services. And it is especially true for thousands of seniors who age into Medicare every day. The Federal Government should be working to improve access for these individuals. But sadly, current law does exactly the opposite. In fact, it presents significant barriers to American seniors who seek mental health services.

The problem is that seniors have to go through a middle-man to get care, and that is because Medicare requires that many services provided by clinical psychologists must be prescribed and monitored by a medical doctor, a doctor who may or may not have any experience or training in mental health care. This supervision requirement is outdated and it stands in stark contrast to the private sector, in which clinical psychologists are largely allowed to provide treatment independently.

That requirement also fails to respect clinical psychologists' rigorous training and licensure requirements, which includes years of study in obtaining a Ph.D. This requirement is especially harmful for rural and under-served areas like South Dakota. When a physician is not available to oversee a clinical psychologists's treatment program, the services are simply not offered.

My bill, H.R. 4277, makes it easier for seniors to obtain mental health care services that they need, and it puts clinical psychologists on equal footing with other non-physician providers like chiropractors and optometrists. They are easily accessible by Medicare beneficiaries.

In short, the Medicare Mental Health Access Act amends Medicare's definition of "physician." It includes clinical psychologists. This would have the effect of removing the middle-man from the process of seeking mental health services and allowing seniors to go directly to clinical psychologists.

It is also important to note that, while this adds clinical psychologists to the physician definition, it would not allow clinical

psychologists to become medical doctors. Rather, it would simply allow them to practice in a more independent way by removing that physician supervision requirement.

I would like to thank Mr. Nunes, Mr. Kind, Mr. Blumenauer, the subcommittee members who have already cosponsored this important bill. I urge the rest of you to join them because the Medical Mental Health Access Act represents a huge opportunity for us. It will tear down barriers for mental health care access for our seniors where, in states like South Dakota, we see it being a real issue for them getting the kind of care that they need.

I sincerely hope the committee will take up this bill as soon as possible. And again, Mr. Chairman, I thank you for the opportunity to testify today.

Chairman TIBERI. Thank you for your leadership on these important issues.

Mr. Renacci, thank you for your leadership on the readmissions issue that became part of a bill that we passed unanimously on the floor last night. And we recognize you for five minutes.

STATEMENT OF THE HONORABLE JIM RENACCI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. RENACCI. Thank you, Mr. Chairman, for holding this hearing. I am grateful for the many bills that my colleagues have and will present today. Indeed, I am a proud cosponsor of many of them. I also think it is important we are here today presenting proposals, and continuing the conversation on how we can improve the delivery of services through Medicare and health care systems in general.

When it comes to seniors, for instance, too often they decide not to seek the care they need because of the price, the inconvenience, or the bureaucratic red tape which gets in the way. There are so many burdensome and confusing regulations which many times leave Medicare beneficiaries waiting for a level of care they need or potentially facing extremely large bills they thought Medicare was covering.

For example, under current Medicare payment policy, even if a physician knows the proper care setting for a beneficiary is a skilled nursing facility, beneficiary must be admitted to a hospital, stay at least three days as an inpatient, in order for Medicare to cover the cost of the beneficiary's stay in a skilled nursing facility. Many times the beneficiary's personal doctor is also on staff at that same hospital, and certainly knows the level of care needed before they are admitted.

Even more concerning is that often times patients are not actually admitted as an inpatient, and are only admitted under observation stay. Despite most not knowing their status, most beneficiaries actually see no difference in care while at the hospital, but are penalized for non-payment if later admitted to a skilled facility.

Unlike other post-acute care settings, Medicare requires a three-day inpatient hospital stay to qualify for skilled care, causing confusion for beneficiaries. According to an OIG report in 2012, beneficiaries had over 600,000 hospital stays that lasted 3 nights or more, but did not qualify them for skilled nursing facilities, meaning these individuals were either outpatient or observation status

during the hospital stay. Because they did not have the three days of inpatient care, as confusing as it sounds, they did not qualify for skilled nursing care, due to the inpatient requirement, and they are left incurring tens of thousands of dollars of costs that are not reimbursed by Medicare if they end up going to a skilled facility.

In order to protect access to rehabilitation services, I have introduced a bipartisan bill, H.R. 290, the Creating Access to Rehabilitation for Every Senior. It is called the CARES Act. It waives the three-day inpatient stay requirement for skilled nursing facilities that meet certain quality measures.

Here is an interesting fact. The average three-day inpatient hospital stay in many cases is equal to or sometimes more costly than the average 27-day stay in a skilled nursing facility. And we burden our Medicare system with both levels of cost. Even private insurance companies have already eliminated this unnecessary and duplicative expense, the three-day requirement.

Therefore, by eliminating the three-day inpatient requirement, Congress can save both the beneficiary and the Medicare system money by reducing unnecessary hospitalizations.

I understand this issue. I operated skilled nursing facilities for over 28 years. Just like many of the bills that passed the full House yesterday, I believe this is one more common-sense reform which will minimize hospital over-utilization, cut down on unnecessary red tape, eliminate unnecessary costs to Medicare program, and focus on what is best for the patient.

Why should a beneficiary have to go to a hospital, have a doctor diagnose the need for nursing home care, all while remaining in the hospital, costing the system thousands of dollars? The CARES Act fixes this one step, let's doctors decide the best care delivery system without burdening the cost of a three-day hospital stay, and helps protect the solvency of Medicare.

And I look forward to working with my colleagues on both sides of the aisle to try and move this legislation. Thank you, Mr. Chairman, and I yield back.

Chairman TIBERI. Thank you, Mr. Renacci.

Dr. Boustany, you are recognized for five minutes. Thanks for your leadership in health care.

STATEMENT OF THE HONORABLE CHARLES BOUSTANY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF LOUISIANA

Mr. BOUSTANY. Thank you, Mr. Chairman. I want to thank you and fellow members of the Ways and Means Committee, the Health Subcommittee, for holding this hearing and for hearing our priorities through a regular legislative order. I think this is really important, and especially with an emphasis now on strengthening the Medicare program, which is a vital program.

As you all know, the Medicare program was established in 1965 to provide reliable health coverage for America's seniors, and we all know there are significant challenges ahead to preserve and strengthen this program. And I am convinced that we cannot really truthfully and effectively solve the problems with Medicare unless we fully embrace innovation and the latest technology that comes

online to improve the health and the lifespan and the quality of life for our seniors.

I could tell you, as a long-time practicing cardio-vascular surgeon, I saw an explosion of new technology, just in the time I was in practice, that made major differences, huge differences in the lives of seniors, and that continues today.

I am proud to join my Ways and Means colleague, Richie Neal, as well as colleagues on the Energy and Commerce Committee, Gus Bilirakis and Tony Cardenas, to introduce H.R. 5009, called the Ensuring Patient Access to Critical Breakthrough Products Act. This legislation provides an accelerated route to FDA approval and subsequent limited coverage under Medicare in order to stimulate the development of important new diagnostics and treatments that address currently unmet medical needs.

For instance, following FDA approval it can take upwards of three years to receive a reimbursement code under Medicare, delaying patient access to groundbreaking technology. This is just unacceptable. We can do better. And while this legislation continues to allow CMS to remain the final arbiter for extending permanent coverage of this limited universal medical device technology, this legislation is a very important step to enhancing access on the front end to this cutting edge diagnostic and treatment technology for America's seniors.

Many examples exist. I have talked to a number of our companies, particularly the heart valve technology arena, where they move to advance technology now—for instance, instead of having to cut open the chest and spread the ribs and the sternum, they can do this through percutaneous technology to save lives and morbidity, and truly help people who might not have even been candidates for open heart surgery because of other existing comorbidities. That is just one example of the many advances.

But if we are caught whereby, after going through a lengthy FDA process CMS delays the implementation and the use of this technology because there is no reimbursement code, then, I mean, this technology sits there and it is not accessible for seniors.

This legislation is a modest approach to addressing this logjam and helping to move this technology forward, and so I look forward to working with the committee, and hope we can mark up this bill.

Thank you, Mr. Chairman, I yield back.

Chairman TIBERI. Thank you, Dr. Boustany, for your leadership. With that, the gentleman from New Jersey, my friend, Mr. Pascrell, a member of the subcommittee, is recognized for five minutes.

STATEMENT OF THE HONORABLE BILL PASCRELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PASCRELL. Thanks, Mr. Chairman, and thanks for putting this together. There are some things we disagree with, there are a lot of things we do have in common, though. So today I want to touch three subjects, if I may.

Huntington's Disease Parity Act, H.R. 842, the Huntington's Disease Parity Act, with my friend, Congressman Adam Kinzinger from Illinois. Today the bill has 253 bipartisan cosponsors, 15 from

our committee alone, and of itself, makes this bill, I think, worthy of consideration.

Huntington's Disease, or HD, is a genetic neuro-degenerative disease that causes total physical and mental deterioration over a 10 to 25-year period. Because it is a genetic disorder, HD profoundly affects the lives of entire families emotionally, socially, financially, like a lot of other diseases, too. This devastating disease has no treatment or cure, and slowly diminishes an individual's ability to walk, to talk, to reason.

Today I will focus on the one provision of the bill which would waive the two-year Medicare waiting period for individuals with HD. Under current law, once a person with HD is deemed eligible for disability benefits—which is a challenge in itself—they are then forced to wait two more years before they can receive Medicare benefits. This means that while people are in the grips of a terrible, all-consuming, degenerative disease they can often not access the range of health care services they desperately need. This is simply unacceptable, Mr. Chairman.

I thank all of my colleagues on the Ways and Means who joined with me on this legislation.

Second thing is Reserving Patient Access to Post-Acute Hospital Care Act. I would like to highlight H.R. 4650, the Preserving Patient Access to Close Acute Hospital Care Act, which I introduced with my friend, Congressman Vern Buchanan. As the co-founder and co-chair of the Congressional Brain Injury Task Force, I understand the important role that long-term care hospitals play in the recovery of many individuals who suffer moderate to severe traumatic brain injuries, or TBIs.

If there is one thing that I have learned about TBI in the 16 years I have been working on this issue, it is that recovery looks different for everyone. That is why we must preserve access to all post-acute care options, so patients can receive the individualized care that they need.

H.R. 4650 would provide an additional 2 years of relief from the full implementation of the 25 percent rule for long-term care hospitals. I would also note that the industry has offered to extend the current moratorium for a long-term care hospital to help offset the cost of the bill, which is something that I hope the committee would consider.

And my final point is this, Mr. Chairman, something you have heard me speak about too many times, probably, and that is the UDI and claims. More than a few times. I just want to touch briefly on it being included in the unique device identifiers, the UDIs, in health insurance claims.

This is an important patient safety measure that would improve post-market surveillance of medical devices to help identify problems with devices more quickly and help improve Medicare program integrity. I was very pleased last month when CMS Acting Administrator Andy Slavitt expressed support for the important policy.

I look forward to working with you, Mr. Chairman, Mr. Ranking Member, to get this done. And I thank you, and I yield back, Mr. Chairman. Thank you.

Chairman TIBERI. Thank you, Mr. Pascrell. We will go from Jersey to Philly.

Representative Meehan, you are recognized for five minutes.

Mr. MEEHAN. It is a great route, isn't it, Mr. Pascrell?

STATEMENT OF THE HONORABLE PATRICK MEEHAN, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MEEHAN. Thank you, Mr. Chairman and the full committee, for your participation and allowing us to take this opportunity. And I appreciate the opportunity to speak about H.R. 4212, which is the Community-Based Independence for Seniors Act of 2015, which I introduced with our colleague, Representative Linda Sánchez.

The bill would authorize community-based institutional special needs plan demonstration program to provide home and community-based long-term services and supports to low-income Medicare beneficiaries who need assistance with at least two activities of daily living.

Under current law, Medicare does not typically provide coverage for community-based, long-term care services and supports, which include medical and personal care, such as assistance with bathing or managing medications. And one study found that 13 percent of seniors spent down their savings in order to qualify for Medicaid.

The demonstration program is designed to eliminate the need for Medicare beneficiaries who receive a low-income subsidy to spend their savings and become dependent on Medicaid. Many seniors prefer to remain in their homes—in fact, they are more healthy as a result of it—to receive the care that they need. And home and community-based care holds the promise of keeping seniors healthy and avoiding costly care.

The demonstration offers up to five Medicare Advantage plans to provide coverage for long-term care services. The plans will receive a per-month payment not to exceed $400 for providing these services, and eligible Medicare beneficiaries with CBI in their area have the option to enroll in the plan.

HHS will evaluate whether providing home and community-based services to Medicare beneficiaries reduces state and Federal Government health care spending through delaying Medicaid eligibility for low-income seniors and reducing the need for acute care. The demand for long-term care services and supports continue to increase. The population of seniors 85 years and older is estimated to more than triple by 2050, and this group is 4 times more likely to use long-term services and supports compared to seniors age 65 to 84.

This program is one step towards reforming long-term service and supports that can generate savings while allowing seniors to remain healthy at home. A similar version of my legislation was reported out of the Senate Finance Committee last year, and I ask for the Chairman's support in advance of H.R. 4212.

I also want to highlight the arbitrary and capricious manner in which CMS is making decisions regarding eligibility to participate in Medicare programs as a hospital. CMS must not establish or change a substantive legal standard governing the eligibility of or-

ganizations to furnish services or benefits, unless the agency uses notice and comment rulemaking. However, CMS has done just that in a ruling that will make a determination that Wills Eye Hospital is not eligible to participate in Medicare as a hospital.

In contrast, the Pennsylvania Department of Health in the state of Pennsylvania, the survey agency determined that the hospital satisfied the Medicare conditions of participation and should be licensed under Pennsylvania laws an inpatient hospital. And I ask the chairman to work with me to ensure that CMS is using known standards in making determinations regarding hospital status for purposes of the Medicare reimbursement.

And lastly, I want to note that I am working with Ranking Member McDermott on the Beneficiary Enrollment Notification and Eligibility Simplification Act, also known as the BENES Act. And as many of you know, Medicare enrollment rules are complex, and seniors do not receive notice from CMS regarding their responsibility to enroll. And because of these confusing rules, seniors may find themselves subject to a late enrollment penalty.

The Part B late enrollment penalty permanently increases a beneficiary's premium by 10 percent for every 12-month period the beneficiary could have had Part B coverage but did not. Others are paying for private coverage that is a secondary coverage to Medicare. But without enrolling in Medicare, these seniors will find themselves responsible for significant out-of-pocket costs. Part of the solution is to require CMS, in cooperation with the Social Security Administration and the IRS, to issue notifications to individuals approaching eligibility about the enrollment rules and the coordination of Medicare coverage with other health insurance coverage.

I appreciate the consideration of my colleagues, and I thank you, Mr. Chairman.

Chairman TIBERI. Thank you, Mr. Meehan.

Welcome to the Ways and Means Committee room, Mr. Mooney from West Virginia. You are recognized for five minutes.

Turn on your—thank you.

STATEMENT OF THE HONORABLE ALEX MOONEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WEST VIRGINIA

Mr. MOONEY. All right. There you go. Thank you, Mr. Chairman. I do appreciate the opportunity to testify about my bipartisan bill, the Promoting Responsible Opioid Prescribing Act, or the PROP Act.

My home state of West Virginia has the highest rate of opioid overdose deaths in the country, more than double the national average. This drug abuse epidemic is a tragedy crying out for action. Addictions ravage our communities, rips families apart, stunts the development of our youth, and harms our economy.

The House has already taken some important steps to address this epidemic, but much more remains to be done. One solution is my bipartisan bill, the PROP Act, H.R. 4499. This bipartisan bill removes a harmful provision of the Affordable Care Act that places unnecessary pressure on doctors and hospitals to prescribe narcotic

pain medication, regardless of whether the patient actually needs it.

This problem was first brought to my attention by a group of doctors in Charleston, West Virginia, and I thank them for that. These doctors, many of whom serve Medicare patients, describe the dilemma they face when treating pain: either prescribe narcotic pain medicine to patients who do not need it, or risk receiving a low patient satisfaction score and a subsequent cut to the reimbursement rates. This dilemma is a result of a well-intentioned policy that is having unintended negative consequences.

In 2006 the Center for Medicare and Medicaid Services, CMS, and the Department of Health and Human Services, HHS, developed a survey called the "Hospital Consumer Survey of Health Care Providers and Systems." We know it as HCAPS. HCAPS is a standardized survey used to measure patient perspectives and satisfaction on the care they receive in hospital settings. At first hospitals used this survey on an optional basis. However, when the Affordable Care Act became law in 2010, it put in place "paid performance provisions" that use these survey results as a factor in calculating Medicare reimbursement rates for physicians and hospitals on "quality measures."

The survey includes three questions related to pain management, including one that asks whether patients feel that their caretakers did "everything they could to help" with pain. While these questions are clearly intended to help patients, doctors tell me that these questions pressure the doctors to over-use prescription pain narcotics when treating patients.

At a time when prescription pain abuse is rampant, this is deeply concerning. Doctors, not the Federal Government, know best how to treat patients. And that includes the question of how best to use narcotic pain medicine. The PROP Act would remove the three pain management questions from consideration only when CMS is conducting reimbursement analysis. However, the patient will still answer the pain management questions in the HCAPS survey, so hospitals can monitor how they are doing.

By severing the relationship between HCAPS question on the pain management and reimbursement, we can remove undue pressure on doctors to prescribe unnecessary opioid medications. This simple change will reduce access to narcotic pain medication for patients who do not need it, thereby reducing the risk of addiction.

According to the National Institute on Drug Abuse, people who abuse opioid pain killers are 19 times more likely to start using heroine than people who do not abuse those painkillers.

In addition, CMS is fully able to implement the PROP Act. The agency has already provided my staff and this Committee with technical assistance on the bill. If the bill passes, CMS will simply remove the questions from reimbursement calculations during the next rulemaking session. I would like to thank the staff from this Committee for their help with that.

The PROP Act is also broadly supported by groups active in this field, including the American Hospital Association, the American Medical Association, Physicians for Responsible Opioid Prescribing, Association of American Medical Colleges, and America's Essentials Hospitals. It has also been introduced in the Senate by Senators

Johnson, Manchin, Capito, Barrasso, Blumenthal, Markey, Toomey, Ayotte, and King.

Finally, I want to thank many members of the Ways and Means Committee who are already cosponsoring the PROP Act: Tom Price, Diane Black, Tom Rice, Pat Meehan, Earl Blumenauer, and Bill Pascrell.

Thank you, Mr. Chairman, for your consideration.

Chairman TIBERI. Thank you, Mr. Mooney, for your leadership on the PROP Act. It is one that I have heard about, too, back in my district in Ohio, as we have talked about. So I look forward to working with you.

Mr. MOONEY. Thank you.

Chairman TIBERI. Thanks for being here.

Mr. MOONEY. Sure.

Chairman TIBERI. Before I turn to Mr. Larson for five minutes, I wish to inform him that a member of this Subcommittee was going to object to you being here, but I don't see him right now. So be prepared if he comes back in the room.

Mr. CROWLEY. Mr. Chairman? Mr. Chairman?

Chairman TIBERI. Mr. Crowley?

Mr. CROWLEY. On behalf of Mr. Pascrell, I would like to object. [Laughter.]

Chairman TIBERI. Mr. Larson, you are recognized for five minutes. Can you turn on your microphone? Thank you.

Mr. LARSON. I thank the chairman for interceding on my behalf. We were just on one of Mr. Pascrell's shows.

Chairman TIBERI. I heard.

Mr. LARSON. He is perplexed after that show.

STATEMENT OF THE HONORABLE JOHN LARSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CONNECTICUT

Mr. LARSON. So, in keeping with the spirit of the meeting, let me first start by thanking Cathy McMorris Rodgers, as well as our colleagues, Tom Reed and Kurt Schrader, on introducing H.R. 3244, which is Providing Innovative Care for Complex Cases Demonstration Act of 2016.

Mr. Chairman, this bill would create a demonstration program in Medicare that would allow for contracts in several different parts of our country to be awarded with either a high-quality Medicare Advantage plan or physician organization ACO to provide an innovative care plan for the highest cost Medicare beneficiaries in this area.

As the chairman knows more keenly than most, that the hardest-to-serve population at the end of stages in their life is the most costly that we face, in terms of the Medicare programs that serve this nation so well. What this bill does, in short, is to provide more benefits, lower out-of-pocket costs, provide an integrated care model, and set high-quality standards.

What it does, in short, too, Mr. Chairman, is something I believe this Committee should always subscribe to, and that is combining the very best that public health and the government side of the ledger can bring to bear, along with the innovation and technology of the private sector and academic research organizations that we

have to lower the cost of health care in a way that is most efficient and productive.

It is no mistake that when we were looking at the Affordable Care Act that there is somewhere between 700 and $800 billion annually in fraud, abuse, and overlap of responsibilities that take place within the health care system. This can be eliminated.

We know this can happen, in large part, because of, well, innovators like the Aetna in my district, in Hartford, Connecticut, where we are fortunate to have an individual who is the CEO who is a visionary and way ahead of his time, a person who recognizes that what we want to do is make sure that we are able to keep people in their own homes, that they are able to stay there and provide for the needs. It is a place that they all want to be.

And in the process, if we can keep them out of the hospital, nobody wants their loved one to acquire a staff infection while in the hospital. Nobody wants to have to be readmitted after a hospital stay because of a lack of follow-up care. No one who has a loved one with a chronic health condition like heart disease or diabetes wants their health to be compromised because of a lack of coordination amongst health care providers.

What this bill will do is provide innovations. What it will provide is an opportunity for us to keep people in their homes in an integrated fashion by coordinating their care in a systemic manner that will allow us to impact the cost and also provide the patient with the best possible outcomes, Mr. Chairman.

I am proud to be a sponsor of this, and I think this is a prime example of how we can work together across the aisle by sharing the vitality of ideas in everything that technology and innovation and, frankly, that the public health system can bring to bear. And then, from a human standpoint, recognizing what the citizen and what the people want. In the final stages of life they want to be in their homes. And we ought to be able to come up with the innovation and way to do it.

Mark Bertolini, the CEO of the Aetna, recognizes this and is one of the leading thought thinkers with respect to innovative health care designed to reduce these costs so we get away from the near 20 percent of our gross domestic product that health care ends up costing.

So, Mr. Chairman, I again want to congratulate my cosponsors, especially Cathy McMorris Rodgers, our colleague, Tom Reed, and also Mr. Schrader for their support of this bill, and I thank you for the opportunity to testify before your committee, and hope it will be taken up during this brief session.

Chairman TIBERI. Thank you. I thank the gentleman from Connecticut. I have heard a little about that. Aetna has a large presence in Ohio. And I am kind of surprised that you promoted a gentleman with an Italian last name as being intelligent and thoughtworthy.

Mr. LARSON. Well, unlike Mr. Pascrell, he has a vowel at the end of his name.

[Laughter.]

Mr. LARSON. But thank you, Mr. Chairman.

Chairman TIBERI. I thank the gentleman. The gentleman from New York is recognized for five minutes.

STATEMENT OF THE HONORABLE JOSEPH CROWLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. CROWLEY. I believe Mr. Pascrell also objected to my testimony today, as well. So on his behalf I would like to object to my testimony. But thank you, Mr. Chairman and Mr. McDermott, for this opportunity to join you today as we hear proposals to strengthen the Medicare program.

I am glad to have the opportunity to talk about legislation I put forward to address what must be a priority within the Medicare program: training the doctors we need to meet the health care needs for tomorrow. And I thank Mr. Davis, who I believe spoke earlier about this particular bill.

This is not something we could take lightly. Estimates indicate that by 2025 we will have a shortage of up to 95,000 doctors, both primary care doctors and specialists in the United States. Our health care needs are only growing, with a greater importance on preventative care and comprehensive health in an aging population. Ten thousand Americans turn 65 every day, so it is clear we need to have doctors available to treat them and Americans of all ages.

Important steps have been taken. Medical schools have worked to increase their enrollment and their graduating classes. But what a lot of people don't realize is that once those students graduate, they need to complete another stage of training by doing a residency program at one of the nation's teaching hospitals. Without completing their residency, they cannot become licensed to practice medicine.

Unfortunately, growing numbers of smart, well-prepared medical school graduates are fighting for a stagnant number of residency slots. We are not just facing a physician shortage, we are facing a physician bottleneck.

But there is a clear path forward. For generations, training doctors has been a shared responsibility of the Federal Government and teaching hospitals, and that is because it is a shared benefit. The whole country benefits from more well-trained doctors. Congress has long recognized the value of investing in doctor training. And as a result, the Medicare program helps to support doctor training programs by funding residency slots around the country.

However, there was an arbitrary cap on the number of residency slots that Medicare will support. And this cap hasn't been raised in nearly two decades. Teaching hospitals have done their part in stretching their funds as far as they can go to help fund additional residency positions, even beyond that which Medicare covers. But they cannot do this alone. We must act and act soon to raise the Medicare cap on residency slots.

There is no way to create more doctors overnight, but we can make the changes now that will open up the doctor training pipeline. I have put forward bipartisan, common-sense legislation, the Resident Physician Shortage Reduction Act, to increase the number of Medicare-supported residency slots by 15,000 over 5 years. And I am pleased to have been joined in this effort by Dr. Charles Boustany, a member of this Committee, and someone who I think all

of us respect for his experience. After all, who better to stress the importance of medical training than a cardio-vascular surgeon?

Over 125 Members of the House, including many members of this Committee, have joined us as cosponsors of this bill. This bill would further address our doctor shortage issues by directing half of the new slots to go to specialists that are determined to be running a shortage. And it makes a decisive statement that we need to make a strong investment in our doctor training program. That is particularly important if we should seek continued proposals to cut or weaken the impact of graduate medical education funding.

Far from being a luxury, teaching hospitals depend on this funding to fulfill their mission. It is an investment, not just in dollars and cents of running a teaching hospital, but in the highly complex and costly patient care missions that teaching hospitals undertake. They run advanced trauma centers and burn units. They see more complex patient cases. They treat patients with rare and difficult disease, like Ebola. And that helps train future doctors in all those areas.

Graduate medical education payments were designed by Congress to reflect and encourage and reward all those efforts. And in a time of changing health care, teaching hospitals are doing more to train residents in community care settings and to give residents the skills for exactly the kind of coordinated care that our system is moving toward. So I urge all my colleagues on the committee to allow our teaching hospitals to continue to thrive in the mission of training the next generation of physicians. That means maintaining our investment in graduate medical education funding.

And in what I hope will be a priority for this Committee, it means lifting the outdated cap on residency slots, Mr. Chairman. It is not exaggerating to say the future of our health care system depends on just that.

And with that I yield back.

Chairman TIBERI. Thank you, Mr. Crowley. I appreciate your testimony today and bringing the matter to our attention.

We will stay in the State of New York and recognize and welcome to the committee room, the Ways and Means Committee room, Mr. Zeldin for five minutes.

STATEMENT OF THE HONORABLE LEE ZELDIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. ZELDIN. Thank you, Mr. Chairman. And thank you for the opportunity to present my bill, H.R. 3229, to provide for the non-application of Medicare competitive acquisition rates to complex rehabilitative wheelchairs and accessories, an important piece of legislation which would have a significant impact on individuals with severe disabilities.

Complex power and manual rehabilitative wheelchairs and related accessories are mostly utilized by a small percentage of individuals who suffer from significant disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, traumatic brain injury, and many more. Within the Medicare program these individuals represent less than 10 percent of all Medicare beneficiaries who use wheelchairs, making them an ex-

tremely vulnerable group of people suffering from significant disabilities.

The specialized equipment these individuals rely upon for daily life is provided through a clinical team model and requires evaluation, configuration, fitting, adjustment, or programming before it can be properly used. This small population of individuals has the highest level of disabilities and requires these individually-configured wheelchairs and critical related accessories to meet their medical needs and maximize their function in independence.

In 2008 Congress passed and the President signed into law the Medicare Improvements for Patients and Providers Act, MIPPA, which established a fixed price schedule for complex rehab technology, CRT, and related accessories. Under MIPPA, CRT devices would be excluded from CMS's competitive bidding program to ensure consistent and fair prices for consumers. Excluded devices include power wheelchairs and related accessories, which are the fundamental parts of the products that make them useful and beneficial to people with progressed disabilities such as recline tilt systems, specialty controls, and seatback cushions.

In November 2014, however, CMS issued a ruling contrary to MIPPA which stated that, beginning in January of 2016, accessories that are used on complex rehabilitative wheelchairs will no longer be a part of the fixed-fee schedule, but will now be subject to competitive bidding prices, which will decrease access to the individually-configured wheelchairs and accessories relied on by adults and children with disabilities.

While Congress acted to temporarily delay this measure until 2017, further action is needed to permanently address this issue. My legislation, H.R. 3229, seeks to codify the 2008 MIPPA regulations, and excludes power and manual wheelchairs and their related accessories from the competitive bidding process.

In addition to the significant support from groups such as the ALS Association, Muscular Dystrophy Association, National Multiple Sclerosis Society, Paralyzed Veterans of America, Vets First, the United Spinal Association, and the Christopher Reeve Foundation, just this past week the Government Accountability Office issued a report to Congress regarding the benefits of this legislation. This GAO report focused on utilization expenditures for Medicare wheelchairs and accessories, and how the 2016 competitive bidding program adjusted payment rates for accessories, and how those rates compared to the 2016 unadjusted fee schedule payment rates for the same items.

In addition to recognizing that CRT wheelchairs and accessories are required by individuals with high levels of disabilities, the report also details that these wheelchairs and accessories are not standard wheelchairs, and they are individually configured to each person utilizing this technology to meet their specific needs.

The report further states that the information CMS is relying upon to shift these wheelchairs and accessories from a fixed price schedule to the competitive bidding process is based on limited information from only 9 of 109 total bidding areas, which is clearly insufficient, in order to nationally shift policy. In fact, the report shows that this shift will bring about significant payment cuts,

ranging from 10 to 34 percent, which will only result in increased costs which are passed along to the consumer.

My legislation is a common-sense approach to addressing one of the significant issues currently affecting the Medicare system. This broadly bipartisan legislation is supported by well over 100 Members in the House and its companion bill, Senate Bill 2196, also enjoys significant bipartisan support in the Senate.

This legislation ensures that those who are in need of the most assistance are not unfairly impacted by this new policy shift.

Mr. Chairman, thank you again for the opportunity to testify on behalf of this essential piece of legislation. And I yield back the balance of my time.

Chairman TIBERI. Thank you, Representative Zeldin. Glad you have you here.

And last, but not least, welcome to the Ways and Means Committee Room—I think the dean of the New Jersey delegation—Representative Chris Smith.

STATEMENT OF THE HONORABLE CHRIS SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. SMITH of New Jersey. Mr. Chairman——

Chairman TIBERI. You are recognized for five minutes.

Mr. SMITH of New Jersey [continuing]. Thank you very much. Thank you, Ranking Member. As co-founder with Ed Markey some 16 years ago of the Congressional Alzheimer's Task Force, and as co-chair for the past 16 years, I am very grateful to you for providing me with the opportunity to speak about my bill, H.R. 1559, the Health Outcomes Planning and Education for Alzheimer's Act, which now has 286 cosponsors, including many members of this Subcommittee.

It is very appropriate that we are discussing hope today, as June is Alzheimer's and Brain Awareness Month. As I am sure you are aware, well over five million Americans suffer from Alzheimer's or related dementia. And as the Baby Boom population ages, that number is expected to skyrocket unless we find a cure or at least delay onset.

This disease is devastating. We all know people who have had it—and friends and family members—to both the patient and family, alike. Shockingly, many Alzheimer's patients do not receive an accurate diagnosis, especially in the early years. And, according to the Alzheimer's Association, fewer than half of individuals with Alzheimer's are even told of their diagnosis. The 200,000 Americans now affected with early onset Alzheimer's are especially likely to get an inaccurate diagnosis.

Alzheimer's is also the most expensive disease in America. It incurs catastrophic cost to Medicaid and to Medicare: approximately $236 billion in 2016, alone. On average, Medicare spends three times more on seniors with Alzheimer's than those without. That is to say about $22,000 for seniors with Alzheimer's per year. To ensure that optimum care to every Alzheimer's patient is provided, we need to find innovative ways to improve the quality of care. Occasionally, such initiatives will actually reduce—I say again, reduce—Medicare spending.

The HOPE Act would amend the Social Security Act to add an additional one-time benefit for care planning services for Medicare beneficiaries newly diagnosed with Alzheimer's disease and related dementia. This one-time comprehensive care planning session will arm patients and caregivers alike with the facts, prognosis, and options for the most efficacious treatment plan that they might pursue. Comprehensive care planning will mitigate huge, unnecessary costs associated with preventable trips to the hospital and the emergency rooms.

As far back as 10 years ago an article in the Journal of American Medical Association entitled, "Effectiveness of Collaborative Care for Older Adults with Alzheimer's Disease in Primary Care," Christopher Callahan wrote that there was a savings in a healthy aging brain center study that found a $3,500 net Medicare savings when it included such a care planning session. So if people know the facts, they are more likely to get the care they need earlier, rather than later, again averting hospital stays and also taking drugs that might have adverse impacts because of drug interaction.

I would just give you one example that many people are not aware of. Aricept, which is prescribed to treat symptoms of Alzheimer's, can be rendered ineffective when used with over-the-counter medicines such as Sudafed. Very often that is not known. And again, the drug is not having its positive impact that we would hope that it would have.

Chairman TIBERI. Without objection.

[The information follows: The Honorable Chris Smith]

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Effectiveness of Collaborative Care for Older Adults With Alzheimer Disease in Primary CareA Randomized Controlled Trial FREE

http://jama.jamanetwork.com/article.aspx?articleid=202837

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ABSTRACT

ABSTRACT | BOX. COMMON GUIDELINE RECOMMENDATIONS FOR DIAGNOSIS AND MANAGEMENT OF ALZHEIMER DISEASE AND RELATED DEMENTIAS* | METHODS | RESULTS | COMMENT | ARTICLE INFORMATION | REFERENCES

Context Most older adults with dementia will be cared for by primary care physicians, but the primary care practice environment presents important challenges to providing quality care.

Objective To test the effectiveness of a collaborative care model to improve the quality of care for patients with Alzheimer disease.

Design, Setting, and Patients Controlled clinical trial of 153 older adults with Alzheimer disease and their caregivers who were randomized by physician to receive collaborative care management (n = 84) or augmented usual care (n = 69) at primary care practices within 2 US university-affiliated health care systems from January 2002 through August 2004. Eligible patients (identified via screening or medical record) met diagnostic criteria for Alzheimer disease and had a self-identified caregiver.

Intervention Intervention patients received 1 year of care management by an interdisciplinary team led by an advanced practice nurse working with the patient's family caregiver and integrated within primary care. The team used standard protocols to initiate treatment and identify, monitor, and treat behavioral and psychological symptoms of dementia, stressing nonpharmacological management.

Main Outcome Measures Neuropsychiatric Inventory (NPI) administered at baseline and at 6, 12, and 18 months. Secondary outcomes included the Cornell Scale for Depression in Dementia (CSDD), cognition, activities of daily living, resource use, and caregiver's depression severity.

Results Initiated by caregivers' reports, 89% of intervention patients triggered at least 1 protocol for behavioral and psychological symptoms of dementia with a mean of 4 per patient from a total of 8 possible protocols. Intervention patients were more likely to receive cholinesterase inhibitors (79.8% vs 55.1%; $P = .002$) and antidepressants (45.2% vs 27.5%; $P = .03$). Intervention patients had significantly fewer behavioral and psychological symptoms of dementia as measured by the total NPI score at 12 months

(mean difference, −5.6; $P = .01$) and at 18 months (mean difference, −5.4; $P = .01$). Intervention caregivers also reported significant improvements in distress as measured by the caregiver NPI at 12 months; at 18 months, caregivers showed improvement in depression as measured by the Patient Health Questionnaire-9. No group differences were found on the CSDD, cognition, activities of daily living, or on rates of hospitalization, nursing home placement, or death.

Conclusions Collaborative care for the treatment of Alzheimer disease resulted in significant improvement in the quality of care and in behavioral and psychological symptoms of dementia among primary care patients and their caregivers. These improvements were achieved without significantly increasing the use of antipsychotics or sedative-hypnotics.

Trial Registration clinicaltrials.gov Identifier: *NCT00246896*

Most older adults, including those with dementia, receive their health care from generalist physicians.[1,2] Although primary care physicians prescribe the majority of the psychoactive medications to older adults,[3] the primary care setting appears to be poorly designed and underresourced to provide comprehensive management approaches for dementia.[2,4-6] Over the past decade, quality improvement efforts for geriatric syndromes in primary care have focused on decision support, care management, and other systems-level innovations to deliver guideline-level care.[7,8] Despite recent evidence that early recognition and treatment of cognitive impairment may improve patient outcomes,[9] there is continued controversy about the cost and utility of screening and early diagnosis, and continued debate about the effectiveness of cholinesterase inhibitors.[10-14] Current pharmacological treatment of behavioral symptoms such as aggression or psychosis is limited by modest efficacy and important adverse effects.[3,15] Nonpharmacological management of behavioral symptoms is recommended as an initial approach but caregivers and clinicians often do not have the resources to provide this care.

Indeed, behavioral and psychological symptoms of dementia represent a major challenge in the care of older adults with Alzheimer disease. These symptoms, which include a broad range of distressing behaviors and psychological reactions, affect the health and quality of life of both the patient and his/her caregiver. More than 90% of patients with dementia will experience behavioral and psychological symptoms of dementia at some point during the course of their illness.[16] Behavioral and psychological symptoms of dementia are not simply a manifestation of end-stage dementia. Older adults with mild cognitive impairment also experience clinically significant behavioral and psychological symptoms.[17] Leaving patients' behavioral and psychological symptoms of dementia untreated has been associated with caregiver burnout, nursing home placement, poor management of comorbid conditions, and excess health care costs.[18-20]

Several authoritative groups have published consensus guidelines for the care of patients with Alzheimer disease.[21-24] Ten factors (Box) are shared across these guidelines. The effectiveness of this comprehensive package of care has never been tested. Given the major system redesign needed to adopt these recommendations in primary care, such a field test is needed.[12] We previously reported findings describing the problems and prospects of a comprehensive dementia screening and diagnosis program in primary care.[6] The purpose of the current study was to conduct a randomized controlled trial to test the effectiveness of collaborative care management for older adults with Alzheimer disease compared with augmented usual care. Notably, the design of this trial assumes the perspective of the primary care physician and thus targeted the heterogeneous population of older adults with Alzheimer disease and multiple comorbid conditions that is typically found in primary care. For this reason, we hypothesized that the intervention's primary effect would be improvement in neuropsychiatric symptoms rather than cognitive function.

BOX. COMMON GUIDELINE RECOMMENDATIONS FOR DIAGNOSIS AND

MANAGEMENT OF ALZHEIMER DISEASE AND RELATED DEMENTIAS*

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- Active screening for cognitive impairment coupled with a second stage assessment to diagnose the specific type of dementia
- Evaluation for reversible causes of dementia
- Referral to patient and caregiver educational programs and/or community support agencies
- Consideration for specialty referral
- Active case finding and treatment for depression, psychoses, behavioral disturbances, and hazardous activities
- Active case finding and treatment for excess disability due to comorbid medical conditions
- Consideration for treatment with cholinesterase inhibitors
- Facilitated communication among the clinicians both within the health care system and the community
- Active surveillance and tracking of patient outcomes with feedback to the health care team
- Active monitoring and support of the caregiver's emotional and physical health

*Based on published guidelines.[21-24]

METHODS

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The study was approved by the institutional review board of Indiana University/Purdue University. All participants or their caregivers provided written informed consent for participation. Consent was obtained in 2 stages. Patients first consented to complete the diagnostic evaluation.[6] Among those eligible for the clinical trial following the diagnostic evaluation, additional informed consent was obtained from both the patient and the caregiver. The Figure describes the flow of individuals through the study.

Figure. Patient and Physician Participation in Study

View Large | Save Figure | Download Slide (.ppt)

Recruitment

Patients were recruited to the clinical trial from 2 large primary care practices from January 2002 through August 2004. The first practice includes 7 community-based health centers affiliated with Wishard Health Services, a university-affiliated urban health care system serving medically indigent patients in Indianapolis, Ind. This practice serves approximately 5000 older adults. The second site included 3 primary care practices at the Indianapolis Veterans Affairs Medical Center. This practice provides primary care to approximately 6000 veterans aged 65 years or older. Patients were recruited to the clinical trial by (1) physician referral following a written prompt from the research team that the patient screened positive on cognitive testing; or (2) physician referral following a written prompt from the research team that the patient may be eligible due to a medical record diagnosis consistent with dementia. All referred patients, regardless of clinic site or method of referral, completed the formal diagnostic evaluation described below. Exclusion criteria included residence in a nursing home, unable to understand English, no access to a telephone, or no caregiver willing to consent to participate in the study.

The diagnostic assessment has been previously described and was designed and implemented in collaboration with faculty at the Indiana Alzheimer Disease Center. The assessment included the neuropsychological battery from the Consortium to Establish a Registry for Alzheimer Disease,[25] a semistructured interview with the caregiver,[26] and a targeted neurological and cardiovascular physical examination. These data were reviewed by a consensus diagnosis panel, which included a psychologist, a neuropsychologist, a geriatrician, and a geriatric psychiatrist. Individuals were eligible for the clinical trial if they met criteria for possible or probable Alzheimer disease based on *Diagnostic and Statistical Manual of Mental Disorders, Third Edition*,[27] criteria.

All potential participants and their caregivers (both intervention and augmented usual care patients) were provided written materials and face-to-face counseling by a geriatric nurse practitioner, who had received specific training in communicating the diagnosis of Alzheimer disease to patients and families. This private meeting lasted between 40 and 90 minutes and was conducted at the primary care clinic. All participants also were provided with written materials describing local community resources, including access to the local chapter of the Alzheimer's Association. Primary care physicians provided permission for the meeting with the geriatric nurse practitioner and for approaching the patient for participation in the study. In addition, the primary care physicians for both augmented usual care and intervention participants received a written consultation note communicating the results of the diagnostic assessment. Because these interventions are not typical of usual care, we refer to the control group as "augmented usual care."

Randomization

To minimize the potential for contamination across groups, physicians were the unit of randomization. Thus, physician randomization status determined the patient's randomization status. Prior to initiating the study, we obtained a list of all primary care physicians at all participating clinics from the practice leadership. Physicians were randomized in blocks of 2 stratified by teaching status (faculty or resident) and the clinic site. A random number table was used to classify the first physician as usual care if the table generated an even number or intervention if the table yielded an odd number. The second physician was then assigned the opposite status and the process was repeated until all physicians were randomized. Physicians were not informed of their randomization status and control physicians did not have access to the intervention. Members of the diagnostic team, the geriatric nurse practitioner, and patients and caregivers were blinded to the physician's randomization status until the counseling session described above was completed and the patient consented to participate in the clinical trial and completed the baseline assessment.

Intervention

Primary care physicians of augmented usual care patients could pursue any evaluation or treatment they deemed appropriate. Intervention patients and their caregivers received collaborative care management for a maximum of 12 months by a team led by their primary care physician and a geriatric nurse practitioner who served as the care manager. All intervention patients were recommended for treatment with cholinesterase inhibitors (or memantine) unless contraindicated. The minimum intervention that all treatment group caregivers and patients received included education on communication skills; caregiver coping skills; legal and financial advice; patient exercise guidelines with a guidebook and videotape; and a caregiver guide provided by the local chapter of the Alzheimer's Association. All of the components of this minimum intervention as well as the behavioral interventions described below were provided by a geriatric nurse practitioner, who served as the care manager.

There were 2 care managers, each of whom was an advanced practice nurse, with 1 based at each of the 2 large primary care practices. Caregivers and patients were seen by the care manager in the primary care clinic bimonthly initially and then contacts were lengthened to monthly for a period of 1 year. At each contact with the care manager, caregivers completed the Memory and Behavior Problems Checklist[28] to assess current symptoms and stressors. Based on the caregiver's responses, individualized recommendations were made regarding how to manage a patient's behavioral symptoms. Items checked on a subscale of the Memory and Behavior Problems Checklist activated a specific behavioral intervention protocol that had been developed for this study. These 8 protocols included personal care, repetitive behavior, mobility, sleep disturbances, depression, agitation or aggression, delusions or hallucinations, and the caregiver's physical health. Each of these protocols focused first on nonpharmacological interventions. A description of these nonpharmacological interventions has been previously published[29] and the protocols are available at *http://iucar.iu.edu/research/behavioralprotocols.html*. If the nonpharmacological approach failed, the care manager then collaborated with the primary care physician to institute drug therapy for depression, agitation, sleep disturbance, or delusions.

The primary care physician and the care manager were supported through 2 additional mechanisms. First, the care manager had weekly meetings with a support team comprised of a geriatrician, geriatric psychiatrist, and a psychologist who reviewed the care of new and active patients and monitored adherence to the standard protocols. Second, the care manager was supported by a Web-based longitudinal tracking system that managed the schedule for patient contacts, tracked the patient's progress and current treatments, and provided an instrument for communicating the patient's and caregiver's current clinical status to the entire care team. All intervention patients and their caregivers also were invited to participate in voluntary group sessions. During these sessions, caregivers were taken to a support session led by a social psychologist that focused on caregiver stress. Patients were taken to a nearby room for a group chair-based exercise class led by a health psychologist and the care manager.[30] The study protocol did not mandate additional visits to the primary care physician.

Outcome Measures

The caregivers of patients in both treatment groups completed a baseline assessment by telephone with interviewers who were blinded to the patient's randomization status. This telephone interview was repeated at 6, 12, and 18 months. The interview included 3 standardized instruments developed by the Alzheimer's Disease Cooperative Study investigators[31]: the Neuropsychiatric Inventory (NPI),[32,33] activities of daily living,[34] and health care resource use.[31] Caregivers also provided the data to complete the Cornell Scale for Depression in Dementia[35,36] for the patient. Caregivers completed the caregiver portion of the NPI and the Patient Health Questionnaire-9 to assess the caregiver's mood.[37] Patients completed the Telephone Interview for Cognitive Status, a telephone version of the Mini-Mental State Examination (MMSE).[38] Using each patient's list of prescribed medications, we calculated a chronic disease score as a measure of medical comorbidity.[39,40] The patient's race was identified by the caregiver and race was considered an important patient characteristic to measure because prior work in this patient population demonstrated that race was associated with the prevalence of cognitive impairment.[4] Caregiver's satisfaction with the patient's care was assessed with the question: "Over the last 3 months, how would you rate the quality of care [the patient] has received overall from the primary care clinic?"

Process of care measures included the frequency of initiation for any of the 8 protocols for caregiver education and nonpharmacological management of behavioral symptoms. We report these educational processes of care measures only for the intervention group for 3 reasons. First, the protocols were only available through the study for intervention patients and were not otherwise available in the primary care clinics. Second, primary care physicians infrequently record the provision or content of counseling in the medical record even when it occurs. Third, telephone interviewers were not allowed to query respondents about these interventions because this would have provided a mechanism for the telephone interviewer to learn the patient's randomization status. Process of care measures for pharmacotherapy were collected for both treatment groups using the pharmacy database from each study site.

At each follow-up interview, caregivers completed the Alzheimer's Disease Cooperative Study health resource use questionnaire.[31] Specific questions included "In the last 6 months, how many times was [the patient] examined by a doctor or nurse? In the last 6 months, how many times was she [or he] admitted to the hospital and how many nights for each hospital stay?" The caregiver also provided information on whether the patient had been placed in a nursing home for long-term care.

Statistical Analysis

The primary hypothesis was that older adults in the intervention group would have lower total NPI scores compared with augmented usual care patients at 12 months. We specifically hypothesized that the intervention would not result in significant differences in cognition between groups because we anticipated frequent ambient use of cholinesterase inhibitors among the augmented usual care group. In addition, we suspected lower effectiveness of cholinesterase inhibitors among primary care patients with a high burden of medical and social comorbidity. These patients are underrepresented in efficacy studies of pharmacotherapy. We chose the NPI as the outcome measure most likely to be sensitive to change in this heterogeneous patient population. We did not exclude patients without behavioral and psychological symptoms of dementia at baseline because most patients with Alzheimer disease will develop behavioral and psychological symptoms of dementia and because the process of care changes we hoped to facilitate are broader than behavioral and psychological symptoms of dementia interventions alone. Consistent with the current geriatric health services literature, cognition, activities of daily living, and resource use are included as secondary outcome measures because it is possible to improve behavioral and psychological symptoms of dementia at the expense of overall functioning.

Nursing home placement or death was considered an end point for the study. Patients or their caregivers were not contacted further after these end points were reached. In our original power calculations, we determined that a sample size of 225 participants would result in 80% power to detect a difference of 4.2 points on total NPI scores between groups using a 2-tailed α level of .05. We did not reach this sample size because we exhausted the available pool of potential participants across all participating clinics after nearly 3 years of recruitment. Although we did not reach targeted enrollment, the effect size of the intervention on the NPI exceeded the posited difference of 4.2 thus eliminating concern for type I error on the primary

outcome measure. The sample size does limit the power to detect smaller differences in cognition, activities of daily living, or nursing home placement.

Two-sample *t* tests and χ^2 tests were used to compare the demographic and clinical characteristics of intervention and augmented usual care patients at baseline. For each dependent variable, mixed-effects regression models were used including 6-, 12-, and 18-month follow-up data in an intention-to-treat analyses using last observation carried forward for patients who were lost to follow-up before reaching a study end point. Baseline values were adjusted for in the model. Because NPI scores are highly skewed, we analyzed the log (total NPI + 1). In the mixed-effects models, time was treated as a categorical variable, with time, intervention status, and their interaction being included as fixed effects. A random effect for physician and patient nested within physician was included to account for within-patient and within-physician correlation. If the time × intervention interaction was significant, the difference at each time point was tested to determine when the intervention took effect. For time to death and nursing home placement, Kaplan-Meier estimation was used to obtain the survival curves. The Wilcoxon test was used to test for differences between the intervention and augmented usual care groups. We used SAS software version 9.1 (SAS Institute Inc, Cary, NC). All tests were considered significant at $P<.05$.

RESULTS

ABSTRACT | BOX. COMMON GUIDELINE RECOMMENDATIONS FOR DIAGNOSIS AND MANAGEMENT OF ALZHEIMER DISEASE AND RELATED DEMENTIAS* | METHODS | RESULTS | COMMENT | ARTICLE INFORMATION | REFERENCES

Sample Characteristics

Baseline characteristics of the 153 individuals randomized to intervention or augmented usual care appear in Table 1. These patients were cared for by 74 different primary care physicians (37 in each treatment group). The mean number of enrolled patients per augmented usual care physician was 1.9 (range, 1-6 patients) and per intervention physician was 2.3 (range, 1-8 patients). Approximately 80% of usual care patients were seen by faculty physicians while 71% of intervention patients were seen by faculty ($P = .26$). Half of the study patients were black and most patients had multiple comorbid chronic conditions and were socioeconomically disadvantaged. Augmented usual care patients were significantly more likely to be black and have a female caregiver. Approximately 1 in 5 of the caregivers was neither a spouse nor a child of the patient. Patients had moderate dementia as demonstrated by the group mean MMSE score of 18. The mean MMSE score of our sample is comparable with the weighted mean MMSE score of 17.9 among studies of cholinesterase inhibitors, which was identified in a recent systematic review.[15]

Table 1. Baseline Comparison of Demographic Characteristics*

	Augmented Usual Care (n = 88)	Intervention (n = 86)	*P* Value
Patient Characteristics			
Female	27 (30.7)	39 (45.4)	.41
Black	40 (54.3)	35 (41.7)	.06
Married	33 (47.8)	41 (48.8)	>.99
Medicaid recipient	48 (70.6)	57 (76.0)	.56
Age, mean (SD), y	77.7 (6.7)	77.4 (5.9)	.79
Annual income, mean (SD), $	14 113 (12 160)	15 750 (14 215)	.48
Education, mean (SD), y	8.4 (3.8)	9.6 (4.5)	.15
Mini-Mental State Examination score, mean (SD)	17.5 (5.2)	18.0 (5.8)	.24
No. of medications being, mean (SD)	5.8 (2.8)	5.8 (3.3)	.98
Chronic disease score, mean (SD)	6.3 (3.8)	7.6 (4.3)	.63
Caregiver Characteristics			
Age, mean (SD), y	61.7 (14.4)	60.3 (15.9)	.56
Female	66 (85.7)	70 (83.3)	.02
Live with patient	50 (72.5)	55 (65.7)	.45
Relationship of caregiver to patient			
Spouse	32 (46.4)	36 (42.9)	.81
Child	25 (36.2)	30 (35.7)	
Other	12 (17.4)	18 (21.4)	

*Values are expressed as number (percentage) unless otherwise indicated.

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Process of Care

The mean (SD) number of contacts with the care manager was 14.4 (8.9) and the median was 13 (range, 0-51) over 12 months. Approximately half of these contacts (mean [SD], 7.7 [5.8]; median, 7 [range, 0-28]) were face-to-face and half were telephone contacts (mean [SD], 6.7 [5.8]; median, 5 [range, 0-35]). During these visits, the care manager initiated treatment protocols based on responses to the Memory and Behavior Problems Checklist. Table 2 shows the frequency of use of these protocols. Demonstrating the level of symptoms and distress among this population, 89% of intervention patients triggered at least 1 protocol for behavioral and psychological symptoms of dementia with a mean of 4 per patient from a total of 8 possible protocols. Although support group counseling was offered only as an option, 56% of patients and their caregivers attended at least 1 session. Intervention group patients were more likely to be treated with cholinesterase inhibitors and antidepressants (Table 3). However, 55% of the augmented usual care group also received cholinesterase inhibitors, underscoring the fact that the control group in this study is not a placebo control. In addition, the intervention did not result in an increased use of antipsychotics or sedative-hypnotics compared with augmented usual care. At 12 months, 82.8% of intervention caregivers rated the patient's primary care as very good or excellent compared with 55.9% of those in augmented usual care ($P = .002$). At 18 months (6 months after the intervention ended), only 70% of intervention caregivers rated the patient's primary care as very good or excellent compared with 62% of those in augmented usual care ($P = .27$).

Table 2. Intervention Patients Receiving Nonpharmacological Protocols

Table 2. Intervention Patients Receiving Nonpharmacological Protocols

	No. (%) of Intervention Patients Receiving Nonpharmacological Protocol (n = 84)
Offered to all intervention patients	
Stress/coping	76 (90.5)
Exercise	76 (90.5)
Communication	74 (88.1)
Legal and financial	72 (85.7)
Offered based on reported symptoms	
Caregiver's physical health	75 (89.3)
Depression	69 (82.1)
Repetitive behavior	62 (73.8)
Aggression	60 (71.4)
Mobility	52 (61.9)
Personal care	35 (41.7)
Sleep disturbances	31 (36.9)
Delusions	26 (31.0)
Optional participation	
Support group attendance	47 (56.0)

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Table 3. Group Comparison of Pharmacological Management

Table 3. Group Comparison of Pharmacological Management

	Augmented Usual Care (n = 69)	Intervention (n = 84)	*P* Value
Prescribed medication			
Cholinesterase inhibitors	38 (55.1)	67 (79.8)	.002
Memantine*	6 (8.7)	7 (8.3)	>.99
Antidepressants	19 (27.5)	38 (45.2)	.03
Antipsychotics	5 (7.2)	11 (13.1)	.29
Sedative-hypnotics	7 (10.1)	8 (9.5)	>.99
No prescribed medications	1 (1.5)	1 (1.2)	>.99

*N = 13 patients prescribed memantine also received a cholinesterase inhibitor.

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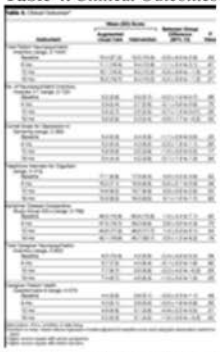
Overall attrition for any reason was relatively low for this frail patient population (17% at 12 months and 25% at 18 months). Attrition due to death (7 augmented usual care patients vs 8 intervention patients; $P > .99$), nursing home placement (5 vs 7 patients; $P > .99$), or dropping out of the study or unable to contact (8 vs 4 patients; $P = .14$) were not significantly different between the 2 groups at 18 months. Time to death and time to nursing home placement also did not differ between groups. In comparing those lost to follow-up for any reason between intervention and augmented usual care patients, there were no group differences in baseline total NPI score, MMSE score, or chronic disease score.

Main Outcomes

The patient and caregiver outcomes at all time points for both groups appear in Table 4. Intervention patients experienced significant improvements in total NPI scores compared with patients who received augmented usual care. Lower NPI scores reflect fewer behavioral symptoms. Although the intervention was discontinued at 12 months, significant improvements in NPI scores continued at the 18-month assessment. The intervention had no significant impact on patient depression scores as measured by the Cornell Scale for Depression in Dementia, cognition as measured by the Telephone Interview for Cognitive Status, or function as measured by the Alzheimer's Disease Cooperative Study's activities of daily living compared with augmented usual care. Caregivers experienced significant improvements in caregiver stress at 12 months but not at 18 months as measured by the caregiver NPI. Lower scores on the caregiver NPI reflect fewer symptoms of stress related to the patient's behavioral and psychological symptoms of dementia. These improvements in caregiver stress were reflected in improved caregivers' Patient Health Questionnaire-9 scores at the 18-month assessment.

Table 4. Clinical Outcomes*



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Health Care Use

Augmented usual care patients reported fewer cumulative physician or nurse visits (mean [SD], 5.6 [5.1]; median, 4 [range, 0-27]) than intervention patients (mean [SD], 9.3 [13.4]; median, 5 [range, 0-67]) over the 12 months of the intervention ($P = .03$) and these differences persisted at 18 months (7.5 [median, 5.5; range, 0-36] vs 12.9 [median, 9.0; range, 0-127]; $P = .02$). There was no difference in cumulative hospitalization rates between augmented usual care and intervention patients at 12 months (18.8% vs 22.6%, respectively; $P = .69$) or at 18 months (24.6% vs 29.8%; $P = .59$) or in mean hospital days at 12 months (1.0 vs 1.7; $P = .34$) or at 18 months (1.5 vs 2.6; $P = .28$). Rates of nursing home placement did not differ significantly between augmented usual care and intervention patients at 12 months (1.5% vs 6.0%; $P = .22$) or at 18 months (2.9% vs 8.3%; $P = .19$).

COMMENT

ABSTRACT | BOX. COMMON GUIDELINE RECOMMENDATIONS FOR DIAGNOSIS AND MANAGEMENT OF ALZHEIMER DISEASE AND RELATED DEMENTIAS* | METHODS | RESULTS | COMMENT | ARTICLE INFORMATION | REFERENCES

To our knowledge, this is the first randomized clinical trial testing the effectiveness of treatment guidelines for Alzheimer disease as delivered through a collaborative care model. We believe this is the first trial in this area that integrates these recommendations within primary care. This setting is important because it represents the care site in which most older adults receive their medical care, including those with

dementia, and primary care physicians frequently prescribe psychoactive medications to these older adults. This setting is also important because it represents the logical target for any initiatives to improve the early identification and treatment of dementia or precursor conditions. The primary care practices targeted in the current study serve a medically-indigent, mixed-race population with multiple comorbid conditions. These patient groups have been understudied in previous treatment trials[15] of Alzheimer disease and these patients have fewer personal resources, including family caregivers. The enrolled patients were, however, similar to previous clinical trials in terms of severity of dementia and severity of neuropsychiatric symptoms.

Unlike previous trials[41, 43] that have focused on medications alone or psychosocial interventions alone, the current study adopted a comprehensive set of guidelines and integrated these guidelines within the context of primary care. We have demonstrated that this comprehensive approach results in clinically significant improvements in behavioral and psychological symptoms of dementia. These improvements are accompanied by a reduction in caregiver stress. The control patients in this study received augmented usual care, which included counseling for the patient and his/her caregiver about the diagnosis of Alzheimer disease, written educational materials, and referral to community resources. Control physicians received notification of the patient's diagnosis and could choose to treat Alzheimer disease or the behavioral and psychological symptoms of dementia. Thus, our findings may underestimate the impact of the intervention compared with true usual care.

We found no evidence that the intervention improves or worsens cognition, activities of daily living, or rates of nursing home placement. Prior studies[44-46] of similar size have shown a decline in the rate of deterioration in cognition among older adults treated with cholinesterase inhibitors compared with adults treated with placebo. There are several reasons why we may not have found such differences. First, 55% of the patients in our augmented usual care group were treated with cholinesterase inhibitors. Second, unlike most efficacy studies, our patient population included a more heterogeneous group of older adults who had multiple competing morbidities; these comorbidities may limit the tolerability and effectiveness of these medications. Third, our assessment of cognition by telephone interview may be less sensitive to change over time than longer instruments administered in person.

Demonstrating differences in nursing home placement may require either a larger sample size or a longer follow-up period. Rates of nursing home placement were low for both groups during the observation period. In a study of support and counseling for spouse-caregivers of patients with Alzheimer disease that was specifically designed to forestall nursing home placement, Mittelman et al[41] reported a mean time of 2.7 and 4 years to nursing home placement among controls and intervention patients, respectively. The current study is limited to 18-month outcomes. In addition to the shorter follow-up period, the scope and complexity of the intervention studied in the current trial requires a substantial amount of time to implement, especially among this patient population. For many patients, the full implementation of the protocol required 3 to 6 months.

The clinical impact of the intervention tested in the current study, as measured by differences on the NPI, exceeds that of most previous studies reporting changes on the NPI. Looking at mean differences at 12 months, we found a group difference in NPI scores of 7.4 without adjusting for baseline differences and a group difference of 5.6 with this adjustment. In a recent comprehensive review of the impact of cholinesterase inhibitors on neuropsychiatric symptoms, Trinh et al[47] reported a mean NPI improvement of 1.72 (95% confidence interval, 0.87-2.57). In a similar review of pharmacological treatment of neuropsychiatric symptoms, Sink et al[15] reported that "pharmacologic therapies are not particularly effective for management of neuropsychiatric symptoms of dementia." These authors found only 1 clinical trial that reported group differences in total NPI scores as high as 8 points. In that study, 206 nursing home patients with severe Alzheimer disease (mean MMSE score of 6.9) were followed up for only 6 weeks.[48] In a randomized trial testing the combination of donepezil and memantine compared with donepezil alone among 404 patients with Alzheimer disease, Tariot et al[43] reported a 3.8-point difference in total NPI score between groups at 6 months. The group difference in NPI score in the current study of 5.6 points over 12 months was associated with a reduction in caregiver stress. Notably, these improvements were achieved without significantly increasing the use of antipsychotics or sedative-hypnotics. In addition, 6 months after

the care management ended, the intervention group still had a 5.4-point difference in NPI scores compared with the augmented usual care group.

We were unable to identify any prior intervention studies that specifically targeted patients with Alzheimer disease cared for in primary care practices. Most previous studies enrolled patients from specialty clinics, Alzheimer disease centers, or nursing homes while others used volunteer samples from the community.[41,42] For example, Teri et al[42] enrolled 153 community-dwelling patients with Alzheimer disease and demonstrated significant improvement in function and depression scores among patients receiving an exercise plus behavioral management intervention. Mittelman et al[49] enrolled a volunteer sample of 206 spouse-caregivers for Alzheimer disease patients in a study testing the effectiveness of individual, family, and support group counseling. Mittelman et al demonstrated significant delays in nursing home placement among the intervention group after more than 3 years of follow-up. Global neuropsychiatric scores were not reported in these 2 studies and neither study was integrated with the primary care management of the patient's comorbid conditions.

Our study was specifically designed to apply the shared elements of current treatment guidelines for patients with Alzheimer disease. The study design does not allow us to identify subcomponents of the intervention that might represent the most important active ingredients. Consistent with chronic disease management models, the strength of the intervention is believed to be due to its comprehensive and integrated approach. Unfortunately, application of these treatment guidelines is beyond the resources of most primary care practices as currently structured. This is true both in terms of the practice design requirements and the costs.

Our study was not designed to complete a formal cost-effectiveness analysis. However, we can provide an estimate of the cost of the intervention. We estimate per patient annual costs of the care manager to be approximately $1000 per patient based on a case load of 75 patients per year. Establishing the computer-based tracking system, organizing access to consultants, and arranging for group sessions would represent additional costs per patient. The intervention group also reported more physician or nurse visits than the augmented usual care group. Medication costs for cholinesterase inhibitors are estimated at $1200 per year but these medication costs are not unique to this care management program. Costs of antipsychotic, antidepressant, and sedative-hypnotics used in the management of behavioral and psychological symptoms of dementia represent other current costly expenditures for patients with Alzheimer disease in primary care. Murman and Colenda[50] have estimated that a 1-point deterioration on the NPI is associated with an additional $250 to $400 per year in direct health care costs. Thus, future studies should address the potential for cost savings with this intervention.

Our study has important limitations. The sample size may not have provided sufficient power to detect smaller changes in cognition or nursing home placement and there were baseline differences in race of the patients and the sex of the caregivers between the 2 treatment groups. We repeated the mixed-effect regression models adjusting for these differences and these analyses and our results remained unchanged. Studies of Alzheimer disease among nonvolunteer samples present formidable recruitment challenges. These challenges include patient reluctance to be labeled with a diagnosis of dementia, the need for a consenting caregiver, regulatory requirements for study participants, the costs of standardized screening and diagnosis, resource limitations within primary care practices, barriers to tracking patients and caregivers over time, and the competing morbidity and mortality from the spectrum of chronic illnesses found among vulnerable older adults. Although the study design supports a high level of internal validity, the generalizability of the findings is limited to those patient-caregiver dyads that were willing to pursue both an evaluation of cognitive impairment and enroll in a clinical trial. The study design also may have biased against demonstrating a larger impact of the intervention because we did not document the caregiver's adherence to the nonpharmacological protocols and reductions in adherence would be expected to reduce the effectiveness of the intervention. In addition, the control patients in this study received a substantive intervention as part of the study protocol and some control patients received substantive additional treatments by their primary care physicians.

In summary, application of the current treatment guidelines for the care of older primary care patients with Alzheimer disease resulted in significant improvements in behavioral and psychological symptoms of dementia and significant improvement in caregiver stress. These improvements exceed those previously reported in studies focusing on pharmacological therapy alone. Achieving a guideline-level dose and duration of the intervention required a care manager who supported the patient's caregiver and physician and adhered to recommended treatment protocols. The intervention demonstrates that care for patients with Alzheimer disease can be improved in the primary care setting but not without substantial changes in the system of care.

Mr. SMITH of New Jersey. SPIREN, a Washington, D.C.-based health care consulting firm, conducted a cost estimate for HOPE. They did it at the behest of the Alzheimer's Association. And they found that a result of this legislation net federal health spending would decrease by $692 million over a 10-year period. And again, most of those savings to Medicare would be the result of reduced hospitalizations and emergency room visits, as well as better medication management and better management of comorbidity, which of course is a major problem with people suffering with Alzheimer's.

I do hope the committee will consider the bill. It already has a huge majority of the House supporting it. And I yield back the balance of my time, and I thank you.

Chairman TIBERI. Thank you, Congressman Smith, for your leadership not only on this bill, but for your leadership on the issue over the years, over the last 16 years.

Mr. SMITH of New Jersey. Thank you, Mr. Chairman.

Chairman TIBERI. There is hope out there.

So, what a great day, Dr. McDermott. Some great ideas, some fascinating testimony. And I would like to get back to you on that. I would like to thank all the colleagues who came before us today, both from the committee and outside the committee.

I appreciate all the time and work that they have done, that their staffs have done, that our staffs have done, as we have started this robust conversation about how we can modernize our health care system, including reforms to improve and to strengthen our Medicare system.

And I am happy we have had the time, once again, to pursue regular order and make the public record—make a public record of the efforts that can help us achieve that goal.

So please be advised that Members will have two weeks to submit written questions that can be answered later in writing. These questions and answers will be made part of the formal record.

With that, the subcommittee stands adjourned.

[Whereupon, at 3:55 p.m., the subcommittee was adjourned.]

[Submissions for the record follow:]

The Honorable Diane Black, Statement

Rep. Diane Black
Statement for the Record
W&M Medicare Member Day Hearing
6/8/2016

- Thank you Chairman Tiberi and Ranking Member McDermott for allowing me the opportunity to submit statements for the record on three different bills that I believe will have a significant impact on the quality and solvency of the Medicare program.

- Health care is what I know and my years as a nurse taught me that if Medicare is to provide real benefit to seniors while ensuring real efficiency for taxpayers, it must embrace the advances in technology and innovation that are already taking place across the health care sector.

- My first bill, **HR 4442- the CONNECT for Health Act**, brings Medicare up to speed with every other populations' use of telehealth in bringing quality care and cost savings to our nations' seniors. Telehealth and remote patient monitoring allow providers to be virtually present 24/7 patients and quickly intervene should promise arise. When you can stop unnecessary visits to the ER and prevent escalating health issues, telehealth quickly pays for itself while allowing patients to spend more time in the comfort of their homes.
    - In fact, an independent analysis of the three major provisions of my bill showed $1.8 billion in savings over 10 years.
    - HR 4442 is endorsed by over 100 organizations from all across the health care spectrum- including the AMA, AHIP, and the National Association of Rural Health Clinics.

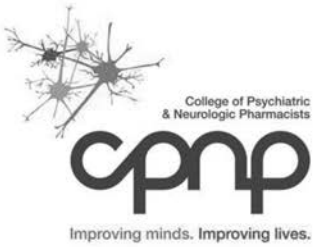
- The second bill I would like to speak on today is **HR 4059- the Medicare Choices Empowerment and Protection Act**, which would provide a one-time financial incentive for Medicare beneficiaries to voluntarily create a digital advance medical directive, which can be modified or cancelled at any time. While CMS recently took the first step by covering advance care planning as a separate and billable service, I believe that seniors need to be educated so that they can have better, more productive discussions with their family members and health care providers.
    - HR 4059 ***empowers Americans*** by protecting patients' health care choices and reducing confusion and anxiety for their family members.
    - I'm proud to say this legislation has been supported by the American Nurses Association, National Hospice and Palliative Care Organization, and the National Right to Life Committee- which I worked closely with on

the drafting of the text.

- Lastly, I would like to bring the Committee's attention back to the issue of Medicare's Area Wage Index- which is determined by the relative hospital wage level in a particular geographic area compared to the national average. This calculation helps to determine hospital payments for Medicare inpatient and outpatient services for hospitals across the country and has resulted in severe and disproportionate disadvantages for hundreds of communities—particularly those in rural areas. My bipartisan, cost-neutral bill, **H.R. 4428- the Fair Medicare Hospital Payments Act of 2016**, would ensure that all hospital geographic regions are reimbursed, at minimum, on a 0.874 Area Wage Index.
    - While the Area Wage Index is designed to average a 1.0- 20 states do not contain a single area with a 1.0 or greater.
    - For example, the nonurban areas of my district receive payments based on a 0.735, while hospitals in Santa Cruz, California receive payments based on a 1.705.
    - Providing this small relief will allow the most economically disadvantaged regions in the U.S. to recruit and maintain a skilled workforce and provide quality care.

- Colleagues, every single one of these bills is bipartisan, bicameral, common sense and would help ensure the Medicare program is equitable, solvent, and innovative. I urge you to take a look and contact my office if you have any questions, or would like to cosponsor.

The American College of Clinical Pharmacy, and the College of Psychiatric and Neurologic Pharmacists, Statement



Comments of the American College of Clinical Pharmacy and the College of Psychiatric and Neurologic Pharmacists

Submitted to the United States House of Representatives Ways and Means Health Subcommittee Hearing

"Legislation to Improve and Sustain the Medicare Program"

June 6, 2016

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On behalf of the American College of Clinical Pharmacy and the College of Psychiatric and Neurologic Pharmacists, we applaud Chairman Tiberi and the Ways and Means Subcommittee on Health for holding this important hearing on "Legislation to Improve and Sustain the Medicare Program." We would like to submit these comments for the hearing record.

Our organizations are dedicated to advancing a quality-focused, patient-centered, and team-based approach to health care delivery that enhances the quality and safety of medication use by patients and ensures that medication-related outcomes are aligned with patients' overall care plans and goals of therapy. Since a vast majority of Medicare beneficiaries rely on the medications that their physicians prescribe to treat their illnesses and improve their health, it is imperative that any Medicare reforms made by Congress ensure that these medicines are being effectively used to fully achieve clinical goals. Unfortunately, as it stands today, this occurs too infrequently, with unnecessary suffering and costs as a result.

Clinical pharmacists, working collaboratively with physicians and other members of the patient's health care team, utilize a consistent process of direct patient care that enhances the safety and quality of medication use, improves clinical outcomes and lowers overall health care costs. Any Medicare reforms that Congress contemplates should ensure that clinical pharmacists are fully recognized and utilized as partners in the medication management team. Otherwise, opportunities to improve care and reduce costs associated with medication use will be lost.

Accordingly, we have endorsed H.R. 4878, The Better Care, Lower Cost Act, by Representatives Erik Paulsen and Peter Welch. This bipartisan legislation would create a successful framework within Medicare to enable the appropriate health care providers – including clinical pharmacists -- to be fully integrated into collaborative health care teams. This legislation reflects the authors' commitment to preserve and strengthen Medicare for chronically ill beneficiaries in particular.

Members of our organizations practice "comprehensive medication management" (CMM) in a collaborative process that helps ensure that seniors' medication use is effectively coordinated, achieves clinical goals of therapy and, in doing so, enhances seniors' health care outcomes. This in turn contributes directly to the goals of enhanced quality and affordability. In short, CMM helps to **"get the medications right"** as part of an overall effort to improve the quality and affordability of the services provided to Medicare beneficiaries.

CMM practice is fully supported by the Patient-Centered Primary Care Collaborative, (PCPCC), in which ACCP as well as the four major primary care medical organizations are actively involved. It is a rapidly emerging standard of care within integrated health care delivery systems.

However, despite coverage for drug products under the Part D drug benefit, CMM is not currently a covered Medicare benefit for the vast majority of Medicare beneficiaries. Therefore, we believe it is imperative that CMM be included as a Medicare benefit, even as we support other reforms to increase provider collaboration and care coordination.

This is particularly critical for seniors because of the central role that medications play in their care and treatment:

- the typical Medicare beneficiary sees two primary care providers and five medical specialists in any given year. Four of every five medical encounters result in a prescription order (new or refill);
- 66% of Medicare beneficiaries have two or more chronic diseases; 40% have four or more;
- 60% of seniors are taking 3 or more discrete prescription or non-prescription medications at any point in time.

In focusing directly on a practice that "gets the medications right," CMM also contributes to enhanced productivity for the entire health care team, allowing other team members to be more efficient in their own patient care responsibilities. Team members are freed up to practice at the highest level of their own scopes of practice by fully utilizing the qualified clinical pharmacist's skills and training to coordinate the medication use process as a full team member.

In summary, as part of the process of improving Medicare, we encourage the Subcommittee to enact reforms to the Medicare Part B program that provide for coverage of CMM services provided by qualified clinical pharmacists as members of the patient's health care team. While we support H.R. 4878, and other legislation to increase collaboration among health providers, we believe that Medicare would be enhanced by the incorporation of CMM services as part of its core benefit structure and delivery system design expectations. We would welcome the opportunity to provide the Subcommittee with further information about this service in the context of Medicare payment and delivery system reforms.

We appreciate the Health Subcommittee's consideration of our views and its members' commitment to improving the quality of care available to Medicare beneficiaries. If you have any questions, please do not hesitate to contact either of our organizations.

Lymphedema Advocacy Group, Statement

- Statement for the Record -

Ways and Means Health Subcommittee

Hearing on "Legislation to Improve and Sustain the Medicare Program"

June 8, 2016

The Lymphedema Advocacy Group applauds the Ways and Means Health Subcommittee for calling the hearing, "Legislation to Improve and Sustain the Medicare Program." We look forward to working with you on policy changes aimed at better serving beneficiaries suffering from lymphedema, a chronic medical condition.

Currently, Medicare beneficiaries diagnosed with lymphedema contend with a set of fragmented rules and regulations. In a 2001 Centers for Medicare and Medicaid Services (CMS) memo related to lymphedema pumps (CAG-00016N),[1] the agency states: "The keystones of lymphedema treatment are elevation, compression and exercise. Encourage patients to use compression garments between pump sessions to prevent re-accumulation of fluid." One year later, the agency also issued a National Coverage Determination notice recognizing the importance of compression garment therapy in conjunction with pneumatic pumps.[2] Yet, despite the announcement and repeated inquiries by Congress to the Secretary of Health and Human Services, compression supplies remain uncovered under the Medicare Durable Medical Equipment program or another benefit category.

Lymphedema is an umbrella term for dozens of lymphatic system diseases. It is the end result of any significant impairment to all or part of the lymphatic organ system, and can result from numerous conditions.

Lymphedema afflicts millions of Americans including men, women, and children who can be born with a primary form. The majority of cases, however, are secondary, caused most often by cancer treatments that damage the body's lymph transport and immune functions. Other causes include trauma / injury, chronic venous insufficiency, lymphatic infection, congenital malformations and obesity.[3]The end result is an accumulation of protein-rich lymph fluid in parts of the body where lymph nodes or lymphatic vessels are damaged or inadequate.

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[1] http://www.cms.gov/medicare-coverage-database/%28S%283iepps3hnwcrz5es0ppyu045%29%29/details/nca-decision-memo.aspx?NCAId=50&ver=6&NcaName=Lymphedema+Pumps&NCDId=190&ncdver=2&IsPopup=y&bc=AAAAAAAEAAA&

[2]CMS Decision Memo: National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6); January 14, 2002. Link: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&NCAId=63&IsPopup=y&bc=AAAAAAAAAgAAAA%3D%3D&

[3] McMaster University Evidence-based Practice Center. "Diagnosis and Treatment of Secondary Lymphedema, Technology Assessment Report". Prepared for Agency For Healthcare Research and Quality (AHRQ). May 28, 2010. http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id66aTA.pdf

A 2010 peer-reviewed study in the American Cancer Society's *Cancer* journal, states that "lymphedema is a common post-treatment condition [and] has been described as one of the most significant survivorship issues." The study found an overall cancer-related lymphedema incidence rate of 15.5 percent, with specific rates as follows: sarcoma 30 percent, breast 20 percent, gynecological 20 percent, melanoma 16 percent, genital-urinary 10 percent, and head and neck 4 percent. Risk increased by 22 percent after pelvic lymph node removal and 31 percent after radiation therapy.

The only exception in coverage is for those beneficiaries diagnosed with breast cancer-related lymphedema post mastectomy and reconstruction surgery. This was included under the Women's Health and Cancer Rights Act of 1998, which requires group health plans, insurance companies, and health maintenance organizations to cover comprehensive lymphedema treatment regimens. This coverage does not extend to Medicare beneficiaries with breast cancer-related lymphedema.

Regardless of cause, both primary and secondary lymphedema is treated the same way, with compression therapy being the cornerstone of the standard of care for lymphedema. Left untreated or under-treated, lymphedema is progressive and puts patients at greater risk for serious infections or other costly complications.

Given the rising number of Medicare beneficiaries living with lymphedema – approximately 1.5 million with projections as high as 3 million – legislation has been introduced providing coverage of compression garment therapy when prescribed by a physician. Representatives Reichert, Blumenauer, Lance and Schakowsky introduced H.R. 1608, the *Lymphedema Treatment Act*, which as of press time boasts 231 bipartisan cosponsors. Senators Maria Cantwell, Chuck Grassley, Chuck Schumer and Mark Kirk have introduced a companion bill, S. 2373, which includes 18 cosponsors as of press time.

As seniors live longer and cancer survivorship increases, compression therapy will become an even more essential component to managing this chronic disease. Many lymphedema patients cannot maintain their condition and experience an unnecessary loss of health and of function in the activities of daily living.

We encourage you to include coverage of compression therapy as a cost-effective solution to treating lymphedema patients. As the Subcommittee seeks comments, the Lymphedema Advocacy Group respectfully submits our statement in an effort to close the Medicare coverage gap. Also, enclosed please find additional clinical evidence demonstrating the effectiveness and reduced hospitalization attributed to compression therapy.

If you have any questions or need additional information, please feel free to contact Heather Ferguson, Executive Director, at Heather@LymphedemaTreatmentAct.org or visit our website at www.LymphedemaTreatmentAct.org.

Enclosures: Compilation of Medical Literature and Chronic Care Management

Compression in the Treatment of Lymphedema: Evidence for Effectiveness and Reduced Healthcare Expenditure

Compression is an integral component of the standard of care for the treatment of lymphedema known as **Complete Decongestive Therapy (CDT)**. The first six documents outlined below summarize several position papers, reviews, and consensus documents, all of which recognize the necessity of compression for patients with lymphedema. The remaining documents reveal the fact that lymphedema, especially in *preventable* advanced stages, is costly, and that compression therapy reduces disease progression, complications, and the associated cost of care.

1. International Lymphedema Framework (2010): *Compression Hosiery (Garments) in Lymphedema*[1]

The authors reviewed the published evidence for efficacy of compression garments and concluded the following:

- Studies with follow-up periods of six months to five years indicate that compression garments are effective in reducing and/or maintaining lymphedema of the arm and leg both in primary and secondary lymphedema.
- Compression hosiery (garments and arm sleeves) are an integral part of lymphedema management with strong evidence to support their use.
- Outcomes are less optimal in lymphedema management when compression therapy is not used.

2. MEDCAC Meeting on Lymphedema Treatment Protocols (2009)[2]

A Medicare Evidence Development Coverage Advisory Committee (MEDCAC) meeting was held on November 18, 2009. The committee reviewed the Agency for Healthcare Research and Quality's (AHRQ) technology assessment of the efficacies of lymphedema diagnosis and treatment protocols. They also heard scheduled testimony of 15 leading experts on lymphedema as well as a number of unscheduled stakeholders and experts.

- The committee reports that the greatest confidence, for the best outcome, was in Complete Decongestive Therapy[7], of which compression is an integral component (page 14 of meeting transcript)[8].

- When isolating individual modalities of treatment, the committee reports the highest level of confidence was found in compression (page 5 of meeting tables)[7].

3. International Lymphedema Framework (2012): *Compression Management, A Position Document on Compression Bandaging* [3]

The authors note the following regarding compression bandaging and garments:

- Lymphedema requires constant compression, if discontinued edema will recur rapidly.
- Compression removes edema by a reduction in capillary filtration, an increase in lymphatic drainage, a shift of fluid to non-compressed areas, and via a breakdown of fibrosclerotic tissue.
- Patient understanding and adherence are critical to sustained outcomes.
- Once swelling is maximally reduced, long term compression garments are required.

4. National Lymphedema Network Position Statement on The Diagnosis and Treatment of Lymphedema[4]

- The gold standard for the treatment of lymphedema is known as Complete Decongestive Therapy.
- Compression Bandaging is always a requisite part of Complete Decongestive Therapy.
- Following achievement of maximal volume reduction with Complete Decongestive Therapy, patients should be fitted with a compression garment.

5. Cochrane Review of the Effectiveness of Various Lymphedema Therapies[5] **(2008)**

The review concluded that the use of compression bandaging *and* garments was more effective than garments alone. Additionally, they noted that when comparing no treatment to the use of compression garments alone, the garments were deemed beneficial.

6. CMS Decision Memo on Pneumatic Pumps[6]

The decision memo notes the following:

- Standard management of lymphedema typically includes positioning (elevation), manual lymphatic drainage, exercise, and compression garments or wraps.
- A pump may be an appropriate therapy for certain patients that have not been able to reduce limb swelling by conservative treatment. Such conservative treatment must include the use of a compression garment.

- Patients should use compression garments between pump sessions to prevent re-accumulation of fluid.

7. Journal of The American Physical Therapy Association ~ *Breast Cancer Related Lymphedema: Comparing Direct Costs of a Prospective Surveillance Model and a Traditional Care Model (2012)*[9]

- Modeled the direct costs of caring for patients identified in the early stages of lymphedema (using primarily compression garments) through a prospective surveillance program vs. caring for them in the later stages of the disease.
- Determined that the annual direct cost to manage early stage lymphedema with compression garments and minimal therapy was $636.19 vs. $3,124.92 in the more advanced stages requiring intensive therapy and compression.
- Thus, early identification and initiation of compression was calculated to significantly reduce healthcare costs.

8. Journal of Clinical Oncology ~ *Incidence, Treatment Costs, and Complications of Lymphedema After Breast Cancer Among Women of Working Age: A 2-Year Follow-Up Study*[10]

- This study evaluated the economic burden of managing breast cancer related lymphedema via analysis of insurance claims data on a total population of 550,000 insured, nearly 2000 of which had been diagnosed with breast cancer and 180 with breast cancer related lymphedema.
- The two year medical cost differential between breast cancer survivors with and without lymphedema was $22,153 more spent on patients with lymphedema.
- Only 3.4% of the added cost was spent on therapy or compression supplies which are known to prevent disease progression. The remaining 96.6% was spent on the cost of evaluating and treating complications.
- The authors noted:
    - "Breast cancer related lymphedema patients are likely to incur high medical costs as a result of frequent visits to physicians and/or physical therapists to seek symptom control."
    - "Poorly managed lymphedema may lead to complications needing medical attention, which increases the costs of care."

9. Rehabilitation Oncology Journal ~ *Effect of Complete Decongestive Therapy on the Incidence Rate of Hospitalization for the Management of Recurrent Cellulitis in Adults with Lymphedema*[11] (and The American Journal of Infection Control ~ *Outcomes and management costs in patients hospitalized for skin and skin-structure infections)*[12]

- Lymphedema was recognized as one of the most potent risk factors for the development of recurrent cellulitis, which frequently requires hospitalization.
- The authors remarked that the study removed a significant barrier to idealized treatment by covering the cost of bandages and garments (not covered by Medicare) through the study's funding. The item costs ranged from $120–$1000 and items were replaced every 6 months per standard of care.
- The study revealed that 18 months of treatment, primarily consisting of compression including bandaging and custom garments, reduced the cumulative average annual number of hospitalizations among the study participants from 8.5/year down to 0.67/year.
- In 2011, the American Journal of Infection Control published an evaluation of multihospital insurance data which reviewed the cost of over 5,000 admissions between 2002 and 2006 for complicated cellulitis[12]. This population included patients with an underlying condition, such as lymphedema, which complicates the response to treatment. The study found that the length of stay per episode was 9.5–17.2 days and cost ranged from $40,046–$80,093 per hospital stay. Costs are expected to have risen modestly since that time.
- Thus, even at the lower end of cost, 8.5 hospitalizations per year would be expected to cost at least $340,391 whereas, after receiving compression therapy, 0.67 hospitalizations per year would be expected to cost well over **12 fold less** at $26,830.

References:
1.http://www.lympho.org/mod_turbolead/upload/file/Lympho/Template_for_Practice_-_Compression_hosiery.pdf
2.http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=51&fromdb=true
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CAId=50&ver=6&NcaName=Lymphedema+Pumps&NCDId=190&ncdver=2&IsPopup=y&bc=AAAAAAAAEAAA&
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Medicare Rights, Statement

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June 8, 2016

The Honorable Pat Tiberi
Chairman, Health Subcommittee
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

The Honorable Jim McDermott
Ranking Member, Health Subcommittee
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Re: "Member Day Hearing on Legislation to Improve and Sustain the Medicare Program"

Dear Chairman Tiberi and Ranking Member McDermott:

On behalf of the Medicare Rights Center (Medicare Rights), I am writing to submit a statement for the hearing record identifying 50 opportunities to strengthen Medicare for today's beneficiaries and for future generations. 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. Our organization serves more than two million Medicare beneficiaries, family caregivers, and professionals annually.

For more than 50 years, Medicare has provided guaranteed health benefits to millions of older adults and people with disabilities. Today, 55 million Americans and their families rely on Medicare for basic health and economic security—making Medicare an undeniable success story. Still, we greatly appreciate efforts by the Health Subcommittee to explore how to further improve the Medicare program.

In 2015, Medicare Rights commemorated the 50th anniversary of this landmark program by identifying 50 wishes for Medicare's future. We believe it is critically important for lawmakers to advance global changes to modernize benefits in both Original Medicare and private Medicare health plans and to press forward on seemingly small fixes to improve how beneficiaries navigate their coverage day-to-day. Among our 50 wishes, Medicare Rights' top recommendations include:

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- Add comprehensive dental, vision, and hearing benefits to Original Medicare;
- Modernize Part B enrollment through enhanced notice, enrollment periods, and relief processes;
- Make Medicare more affordable by expanding access to Medicare Savings Programs;
- Streamline and update Medicare Advantage and Part D appeals processes;
- Increase funding for counseling via State Health Insurance Assistance Programs (SHIPs); and
- Rein in rising prescription drug costs through tools like Medicare rebates and price negotiations.

We encourage the Health Subcommittee to pursue these and other advancements to improve the Medicare program. Medicare Rights' 50 wishes for Medicare's future are available at: http://www.medicarerights.org/50wishes. For more information, please contact Stacy Sanders, Federal Policy Director, at ssanders@medicarerights.org or 202-637-0961. Thank you.

Sincerely,

Joe Baker
President
Medicare Rights Center

Property Casualty Insurers Association of America, Statement

Property Casualty Insurers
Association of America
Advocacy. Leadership. Results.

NATHANIEL F. WIENECKE
SENIOR VICE PRESIDENT
FEDERAL GOVERNMENT RELATIONS

June 22, 2016

The Honorable Pat Tiberi
Chairman
Subcommittee on Health
House Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Tiberi:

On behalf of the member companies of the Property Casualty Insurers Association of America (PCI) which write approximately 35 percent of the private workers compensation market in the United States, I write to strongly encourage you to consider including the language of H.R. 2649 in Medicare in an appropriate legislative vehicle before the end of the 114th Congress. This legislation, sponsored by Reps. David Reichert and Mike Thompson, is urgently needed to improve the handling of Medicare Secondary Payment issues arising from workers' compensation claims filed by individuals who have been injured in workplace accidents or who have suffered work-related illnesses. PCI also thanks you for your co-sponsorship of this bill.

The current procedures required by the Center for Medicare/Medicaid Services (CMS) related to the handling of these claims often result in additional costs and complications for employers and their insurance carriers and, more importantly, for injured workers and their representatives who assist them in adjudicating their claims. It is vital that these improvements be enacted if we are to better serve these affected parties.

Passage of this legislation would vastly improve the current process by:

- Creating certainty in the calculation of the amount required to compensate the Medicare Trust Fund for expenses relating to the care of injured workers;
- Establishing clear criteria for optional "qualified" set asides relating to these injuries/illnesses, to assure that Medicare's interests are appropriately compensated;
- Establishing fair guidelines to govern set aside compromise settlement cases;
- Establishing a reasonable time period during which CMS may review these cases;
- Establishing an appeals process to review CMS' determination of these cases; and
- Establishing an optional method to permit direct payment of set aside amounts to CMS.

Although the Congressional Budget Office (CBO) has not yet scored H.R. 2649, it has been estimated that passage of this legislation would result in significant savings to the worker's compensation Medicare Secondary Payment process, and better protect Medicare's financial interests arising from these settlements.

Inclusion of the provisions of H.R. 2649 in Medicare legislation this year would simplify and streamline the complicated and costly current system of protecting Medicare's interests in adjudicating these claims which often involve working middle class Americans who lack the sophistication required to navigate the

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complex Medicare Secondary Payment process. I urge you to seriously consider these significant improvements, and I appreciate your consideration of the views and interests of the nation's worker's compensation beneficiaries, businesses and the companies which insure them.

Sincerely,

Nathaniel Wienecke

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